Evaluation of Behaviour and Anxiety in Children During Local Anesthesia Administration Using Conventional Syringe Vs Custom Made Economic Sleeve Syringe: A Clinical Study

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Abstract:

Aim: The aim of this study was to compare the behaviour and anxiety in 6-11 years old children during local anesthesia administration using conventional syringe vs. custom made economic sleeve syringe, a clinical study. Subjects and method: This study included 98 Children aged between 6 to 11 years. Children’s were distributed equally into two groups, Group 1 consisted of 49 children age group of 6-11 years old in which conventional syringe was used and Group 2 consisted of 49 children age group of 6-11 years old in which custom made economical sleeve syringe was used for anesthesia. Result: Result showed in group 1, conventional syringe FLACC scale scores was 6.7±1.76 and in group 2, custom made economic sleeve FLACC scale was 0.49±0.58.while In group 1, conventional syringe frankel’s behaviour rating scale scores was 3.47±0.5 and in group 2, it was 3.57±0.5, so frankel’s behaviour rating scale was higher in experimental group with a t value of -1.006 and is statistically non-significant with a p value of 0.317. Conclusion: The custom made economical sleeve syringe in children during local anesthesia administration can be used to reduce the fear and anxiety as compared to the conventional syringe. Keywords: Anesthesia, Behaviour Management, Fear and Anxiety

INTRODUCTION

The local anesthesia administration is difficult procedure in pediatric dental treatment. It is used during the dental treatment to reduce the pain.¹ According to American dental association, dental fear is common in children and teenagers as it is related to pain, discomfort and anxiety. However patients often express more fear of the injection of local anesthetics than of the dental treatment itself, which is the major obstacle for seeking dental care.²,³

Children find it difficult to cope with the stimuli and behavioural demands associated with dental experience. This could be due to fear of the needle, bodily harm or a general fear of the unknown. In Successful treatment of pediatric patients, in terms of reduce their anxiety and discomfort during restorative and surgical procedures, is facilitated by profound local anesthesia⁴,⁵.

There are some basic technique of behaviour management that are used in daily dental practice to reduce the anxiety during local anesthesia administration are Tell-Show-Do, positive reinforcement, nonverbal communication, voice control and distraction⁶,⁷,⁸,⁹,¹⁰. In this, distraction is common technique used for the reduction of dental fear. As before local anesthesia administration several method have been used to reduce pain during injection, such as the application of topical anesthesia, the use of small diameter needles or the application of laser in the injection area.¹¹,¹² Less pain occurs in
patient with the less anxiety and fear than the patient with more anxiety and more fear.\textsuperscript{13}

The custom made economic sleeve syringe of local anesthesia creating a new image which divert the mind and focus on new stimulus leading to less pain and anxiety. The conventional syringe of local anesthesia creating a visually and psychologically threatening in children. Now a days camouflaging syringe used in pediatric dentistry to reduce the anxiety in children during local anesthesia administration.\textsuperscript{14, 15}

No existing literature has been reported regarding custom made economical sleeve syringe. However there are studies related to commercially available camouflaged syringes in 6-11 years of old children during local anesthesia administration.

SUBJECTS AND METHODS
This single blind, randomized, clinical study was conducted in the Department of Paediatric and Preventive Dentistry, Collage of Dental Science and Hospital, Amargadh, Bhavnagar, Gujarat. After obtaining approval from institutional ethical committee (REF No: CODS/IEC/102/20211) and CTRI registration (CTRI/2022/01/039273), the written informed consent obtaining from parents of children involved in this study. This study included the 98 Children aged of 6 to 11 years old. Children’s were distributed equally into two groups according inclusion and exclusion criteria.

Inclusion criteria:
1. Children aged of 6-11 years old who required local anesthesia during any dental procedure.
2. Those children are having positive and definitely positive frankel’s behaviour rating scale.

Exclusion criteria:
1. Medically compromised children’s.
2. Parents who refused written consent.

Armamentarium used for this study given in [Figure 1]

Sample size calculation was done with 95% confidence Interval with the power - 80% turned out to be 49 per group, so the total sample size was 98.

Study Design
According to the sample size calculation the total 98 sample were randomly allocated in to group according to even and odd number method by the investigator.
1. Group 1 (49): conventional syringe use. (Control group)
2. Group 2(49): custom made economical sleeve syringe. (Experimental group)

Method
This study included only those patients who required infiltration anesthesia in any dental procedure in upper and lower arch and who had never experienced dental injection.

Before starting any treatment in which local anesthesia injection was required, 15% topical anesthetic spray (Lidocaine Topical Aerosol USP nummit) (\textit{Indian pharmaceutical combine association limited}) applied at the injection Site and baseline pulse rate were noted using a finger pulse oximeter (CLEAN+ MEDATM , Generic Fashion, India). In group 1: local anesthesia was given by using conventional syringe and in group 2: local anesthesia was given by using custom made economical syringe during this procedure the co-investigator record the pulse rate by pulse oximeter (CLEAN+ MEDATM, Generic Fashion, India). During the local anesthesia administration (2% Lignocaine hydrochloride & Adrenaline bitartrate) (\textit{(Indian pharmaceutical combine association limited)}), co-investigator records video in Redmi 8A mobile with Resolution 1030p at 30fps. To grade the child’s behaviour was used Faces, Legs, Arms, Crying, Consolability (FLACC) behaviour pain scale.

Statistical Analysis
The data collected was tabulated and subjected to statistical analysis. Statistical data were analysed by the Independent t test and paired \textit{t} test was applied within each group to find significant difference between two groups, result were obtained using the SPSS statistical
software package version 20.0. \( P \) value of <0.001 was considered statistically significant.

RESULT

This study was conducted as an in-vivo experimental study with total sample size of 98. Statistically difference found was noted in two groups. In **Figure 2 and Table 1** showed that mean FLACC in custom made economical syringe group was lower than the conventional syringe group. In group 1 (conventional syringe) FLACC scale scores was 6.71±1.76 and group 2 (custom made economic sleeve syringe) FLACC scale scores was 0.49±0.58. While comparing between two groups FLACC scale was higher in Control group with a t value of 23.555 and is statistically significant with a p value of <0.001.

**Table 1 and Figure 3** shows in conventional syringe group 1, frankel’s behaviour rating scale scores was 3.47±0.5 and in group 2 it was 3.57±0.5 that showed frankel’s behaviour rating scale is higher in experimental group with a t value of -1.006 and is statistically non-significant with a p value of 0.317.

**Figure 4** shows pre and post injection anxiety in groups conventional and custom made economic sleeve syringe groups. In this figure pulse rate before treatment in group 1, (conventional syringe) and in group 2, (custom made sleeve syringe) was 91.6327 and 94.5918 respectively. This showed that there was average increase in pulse rate was less in both the groups while using custom made syringe that indicate lower anxiety levels. While comparing the pulse rate between the two groups custom made sleeve syringe and conventional syringe it was found 96.8776 and 104.8163 respectively that showed after treatment pulse rate was higher in conventional syringe group compared with custom made sleeve syringe group.

**Table 2** shows the higher pulse rate in custom made sleeve syringe group compare to the conventional syringe group. In conventional syringe group with a t value of -1.04 and is statistically non-significant with a p value of 0.301. Conventional syringe group with a t value of 2.69 and is statistically significant with a p value of 0.008.

**Figure 4 and Table 2** shows the comparison of the difference in pulse rate between the two groups. Pulse rate was recorded in group 1 and in group 2 was 13.1837 and 2.2857 respectively, that showed pulse rate was higher in group 1 with a t value of 12.357 and is statistically significant with a p value of <0.001. Paired t test used for the comparison of pulse rate in two group separately.

**Figure 1:** armamentiums 1) conventional disposable 2-ml syringe with long needle (27 gauge). 2) custom made economical sleeve syringe 3) local anesthesia solution, (lignocaine with 2% adrenaline) 4) topical aerosol – lidocaine
Figure 2: mean faces, legs, activity, cry, consolability (flacc) scores in group 1 and group 2 with the use of custom made economic and conventional syringes.

Table 1: Comparison between flacc and frankel’s behavior rating scale in flacc

<table>
<thead>
<tr>
<th>Behaviour rating scales</th>
<th>Group -1 (n=49)</th>
<th>Group -2(n=49)</th>
<th>T</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flacc scale</td>
<td>6.71±1.76</td>
<td>0.49±0.58</td>
<td>23.555</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Frankel's behaviour scale</td>
<td>3.47±0.5</td>
<td>3.57±0.5</td>
<td>-1.006</td>
<td>0.317</td>
</tr>
</tbody>
</table>

Figure 3: Mean comparison of frankel’s behaviour rating scale in group 1 and group 2 with used of custom made economic sleeve and conventional syringe.
Figure 4: Mean change in pulse rate in groups 1 and 2 with the use of custom made and conventional syringes before and after treatment.

Table 2: Comparison of pulse rate in two group control and experiment before treatment and after treatment.

<table>
<thead>
<tr>
<th></th>
<th>Group - 1(n=49)</th>
<th>Group - 2 (n=49)</th>
<th>T</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before treatment</td>
<td>91.63±13.29</td>
<td>94.59±14.82</td>
<td>-1.04</td>
<td>0.301</td>
</tr>
<tr>
<td>After treatment</td>
<td>104.82±14.53</td>
<td>96.88±14.69</td>
<td>2.69</td>
<td><strong>0.008</strong></td>
</tr>
<tr>
<td>Difference in pulse rate</td>
<td>13.18±5.42</td>
<td>2.29±2.95</td>
<td>12.357</td>
<td><strong>&lt;0.001</strong></td>
</tr>
</tbody>
</table>

Figure 5: mean comparison of pulse rate in conventional syringe and custom made syringe group separately before and after treatment.
Table 3: Comparison between mean values of pulse rate before and after treatment

<table>
<thead>
<tr>
<th>Group-</th>
<th>Pair 1</th>
<th>Before treatment</th>
<th>49</th>
<th>91.63±13.29</th>
<th>-</th>
<th>-</th>
<th>&lt;0.001</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>After treatment</td>
<td>49</td>
<td>104.82±14.53</td>
<td>13.18±5.42</td>
<td>17.02</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group-</th>
<th>Pair 1</th>
<th>Before treatment</th>
<th>49</th>
<th>94.59±14.82</th>
<th>-2.29±2.95</th>
<th>-5.42</th>
<th>&lt;0.001</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>After treatment</td>
<td>49</td>
<td>96.88±14.69</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 5 and Table 3** shows in conventional syringe group mean values of pulse rate before treatment and after treatment are 91.63±13.29 and 104.82±14.53 respectively. Mean Values of pulse rate found higher in conventional syringe group after local anesthesia administration as compared to the custom made sleeve syringe with a difference of 13.18±5.42 is statistically significant with a p value of 0.001.

In custom made sleeve syringe group comparison of the mean values of pulse rate before treatment and after treatment are 94.59±14.82 and 96.88±14.69 respectively. After administration local anesthesia mean values of pulse rate is equal or slight higher in custom made sleeve syringe group with a difference of 2.29±2.95 is statistically significant with a p value of <0.001.

**DISCUSSION**

In children fear and anxiety age group of 6–11 years seen is higher regarding to dental procedure.16

Pulse oximeter was used as an objective measure of anxiety in number of studies done recently.17,18 In present study, a small custom made sleeve syringes was used, that showed lower anxiety levels.

The FLACC Behavioural Scale comprises of descriptors and behavioural categories in children, adult and patient with cognitive impairment are related with pain.19 In our study, FLACC scores was noted lower in custom made sleeve syringe group during the local anesthesia injection administration.

No existing literature has been reported regarding custom made economical sleeve syringe. However there are studies present that during local anesthesia administration commercially available camouflaged syringes are used in 6-11 years old children and results showed use of these custom made sleeve syringe helpful in reducing the dental fear and prevent anxiety.

Present study included children age between 6 to 11 years this was to fact that children at this age exhibit with more negative behaviours during dental procedure. In our study most of children were easily distracted by the custom made sleeve syringe compared as the conventional syringe. In younger children, custom made economic sleeve syringe is good alternative possibly as it’s toy-like appearance can easily distract children’s mind.

**Anjana M Melwani (2018)20** evaluated the behaviour and anxiety in 6–11-years-old children during local anesthesia administration by using conventional and camouflaged syringes and it was seen that camouflaged syringe was more effective during local anesthesia administration in terms of improving the children behaviour and reducing their anxiety as compared to conventional syringes.

**Barreiros D (2018)21** had done systematic review and concluded that Audiovisual distraction.
(AD) helps in reducing the anxiety in children during dental treatment.

Result of our study showed that before and after local anesthesia administration in group 1 (conventional syringe) pulse rate was noted higher as compared to group 2 (custom made sleeve syringe) and FLACC score was low in custom made sleeve syringe compared to the conventional syringe during administration of local anesthesia.

S. Singh and A. Garg (2013) compared the pain levels of computer controlled and conventional anesthesia techniques in supraperiosteal injections and it was seen that while giving computerized anesthesia subject’s perception of pain was significantly lower for supraperiosteal injections as compared to that of conventional disposable syringes.

Our study showed that advantage of using custom made sleeve syringe is it acted as a good method of distraction of children mind as it was play full. Other advantages of these syringes are these are autoclavable and easily available in the toy Shoppe and for these reasons custom made economic sleeve syringes are more acceptable as compared with conventional syringes for local anesthesia administration during the dental procedure. We included 6 to 11 years of subjects in our study as it is difficult to distract older children or adults with toy-like appearance of custom made sleeve syringe. CONCLUSION:

From the result of our study we concluded that in 6 to 11 years of age children custom made economic sleeve syringes are helpful in reducing the dental anxiety and fear during local anesthesia administration, So it can be considered as better alternative to the conventional syringes.

Conflict of Interest:

The authors declare no conflict of interest.

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References


