A comparative study of the clinical efficiency of chemomechanical caries removal using Carie-Care gel for permanent teeth of children of age group of 12–15 years with that of conventional drilling method: A randomized controlled trial

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ABSTRACT

Background: Dental caries is considered as one of the most serious dental diseases that results in localized dissolution and destruction of the calcified tooth tissues. As possible alternatives to conventional techniques of caries removal, chemomechanical caries removal systems have emerged. This study aims to clinically observe the advantages of chemomechanical method of caries removal over conventional technique.

Materials and Methods: In this randomized controlled trial a total of 60 children with Class I open carious lesions were selected for the study. They were divided into two equal groups according to a method of caries removal (30 chemomechanical and 30 conventional on permanent molars). In Group A, caries was removed using the Carie-Care system and in Group B with the conventional drill and were restored equally with glass ionomer cement. The visual analogy face scale was used to determine the level of anxiety in children at baseline, during treatment and after treatment.

Results: The results were subjected to statistical analysis using Student’s unpaired t-test. It showed that though chemomechanical technique took a marginal increase in time compared to the conventional technique, it was found to be more comfortable for all the children.

Conclusion: Chemomechanical technique though time-consuming is definitely superior compared to the conventional technique provided we use a less technique sensitive restorative material which retains in the oral cavity for longer period. It is definitely a better treatment protocol in school-based dental treatment and atraumatic restorative dentistry compared to the conventional technique.

Key Words: Caries, dental care for children, permanent dentition

INTRODUCTION

In children, caries removal by means of conventional rotary instruments is often associated with discomfort.
The main disadvantages of the traditional rotary drills are perception of patients is unpleasant, requirement of local anesthesia, damaging thermal effects, resulting in excessive loss of sound tooth tissue, and drilling can cause pressure effects on the pulp which causes aversion in many patients, especially in children. \cite{1,2} It is of great importance for the dental health professional to identify dentally anxious children as early as possible. Instilling a positive behavior toward dental care has become increasingly significant.

Chemomechanical caries removal (CMCR) agents are an alternative method to conventional drill. It involves chemical softening of carious dentin followed by gentle excavation to eliminate the outermost portion (infected dentin) leaving behind the affected demineralized dentin that can be remineralized and repaired.

The concept of conserving healthy tooth structures and atraumatic restorative treatment during cavity preparation is minimal invasive dentistry giving comfort, solace, and instilling a positive attitude toward dental treatment, which justifies the specialty of public health dentistry. \cite{3}

In chemomechanical method, partially degraded collagen in carious dentine will be chlorinated by CMCR solutions. This chlorination affects the secondary and/or quaternary structure of collagen, by disrupting hydrogen bonding. Cariogenic material removal was thus facilitated. The main advantage of this method is that it does not require complete patient cooperation.

Carie-Care, a gel based on papain and containing chloramines, similar to Papacárie is less costly than carisolv and has similar use, indication, and CMCR efficiency. Carie-Care has been locally introduced as its main active ingredient from papaya extract an endoprotein, chloramines, and dye. Papain, a papaya extract has antibacterial and anti-inflammatory properties \cite{4,5,6} and also acts as a debris-removing agent. It does not harm healthy tissues and promotes tissue healing and acts only on carious tissue, which lacks plasmatic protease inhibitor alpha-1-antitrypsin; its proteolytic action is inhibited on healthy tissue because healthy tissue contains this substance. \cite{1}

Chloramines help in the healing process and shorten tissue repair time and have the potential of dissolving carious dentin by means of chlorination of partially degraded collagen. This helps in disruption of collagen structure, dissolves hydrogen bonds, and helps in tissue removal. \cite{5} Clove oil has an analgesic and antiseptic action. Sodium methylparaben is used as a preservative. \cite{7} In addition to clove oil and sodium methyl paraben, \cite{8} the preparation also contains specific percentages of essential oils from plant sources, which again has anti-inflammatory and mild anesthetic effect. The preparation also contains explicit gelling agent in accurate percentage to give exact consistency to the gel so that when applied there is no spill over. The main agents in all these existing gels used in chemomechanical caries removal consist of a mixture of sodium hypochlorite and three amino acids (lysine, leucine, and glutamic acid) in a gel preparation. It softens the carious dentine which is then hand excavated and claims that it will not affect the underneath healthy affected dentine. Carie-Care not only softens-infected dentine but also gives the additional advantage of anti-inflammatory activity and aroma.

Carie-Care is applied directly onto the tooth having caries by means of a disposable applicator tip; soon gel changes the color in the affected area. After 1 min, the gel along with dissolved caries is removed by means of a sharp spoon excavator. \cite{8,9,10}

Currently, research in dentistry has concentrated its efforts on the quality of treatment given to patients, those who present some deviation from the normal standards, and those who require attention and approaches for oral health care. \cite{11}

Hence, the objective of this study is to evaluate a new CMCR method using Carie-Care for permanent teeth of children comparing it with traditional caries removal using a traditional drill.

The aim of the study was to compare the clinical efficiency of CMCR using Carie-Care gel with that of conventional drilling method (CDM) in permanent molars of children aged 12–15 years.

**MATERIALS AND METHODS**

Ethical approval was obtained from the Ethical Committee of Jaipur Dental College. Informed consent was obtained from both individuals and their parents before the commencement of the procedure. The this randomized controlled trial study was carried out in the Department of Public Health Dentistry, Jaipur Dental College. A pilot study was designed and carried out to check the feasibility of the study among
five patients in the age group of 12–15 years and for the estimation of sample size for the main research in the same institute. The study population comprised of 60 children which were divided into two Group A and Group B. Each group consisted of 30 students. A total of 78 individuals in the age group ranging between 12 and 15 years were screened from the institute, and those fulfilling the inclusion criteria were selected for the study. Thus, a sample of sixty individuals was obtained who fulfilled all the inclusion criteria of the study.

Inclusion criteria
1. Single open carious lesions with dentin involvement, but not involving the pulp
2. The access of the carious lesion has to be large enough to allow the penetration of the excavator
3. Asymptomatic vital teeth, without clinical evidence of pulp, furcation, or periapical pathology.

Exclusion criteria
1. Children with systemic diseases
2. Presence of intraoral/extraoral swellings
3. Deep dental caries involving pulp

Methodology
The examination was carried out in outpatient department (OPD) of Public Health Dentistry, Jaipur Dental College and the treatment was done in PG Clinic of the department. The examination was carried out by making the individual sit on a chair, and examiner stood on the right side of the individual during the examination and also sat on the right side during the procedure. The person recording the data were positioned on the left side of the subject so that the data recorder was able to hear the examiner’s instructions and codes, and the examiner was able to see the data being entered correctly.

Clinical procedure
Guardians and also the children were asked about the preference of treatment among chemomechanical method or conventional method, and according to that, the treatment was given.: so for sampling convenience patients were distributed equally in both groups.

Patient were distributed equally in both groups to justify sampling. Initially, the sample size was 80. Out of 80, there were 20 dropouts who was having systemic diseases, who was indicated for pulp therapy and teeth with abscess or sinuses were excluded since pulpal pain can be overlooked as pain due to the dental procedure. Children with adequate cognition and communication skills were included in this study. Finally, the study included totally 60 children of age group 12–15 years which are then randomly divided into 2 groups one chemomechanical method treatment group (CMCR) and other CDM. For CMCR, Carie-Care was used, and number 2 round diamond bur was used for caries removal in CDM. One half assigned to Carie-Care gel excavation group is Group A, other half assigned to CDM group is Group B. Further, the cavity inspection will be performed by a coinvestigator who will be blinded to the methods of caries removal. Restoration with glass ionomer cement type 02 will be the end of the procedure. During the treatment procedure of each patient, visual analogy of faces scale was applied. Visual analogy faces scale was presented at each phase at baseline, during treatment, and after treatment. Scores of visual analogy scale of faces were recorded in all these three phases and were subjected to statistical analysis for assessment of patient acceptance. Treatment duration was also measured in all groups [Table 1]. The armamentarium used for the clinical procedure and the Carie-Care gel used is shown in Figure 1. And also the application of gel on tooth is shown in Figure 2.

Analysis
Data thus collected were summarized as mean and standard deviation. Intra- and inter-comparison were
done among both groups using the Student’s \( t \)-test. For all test, a \( P \leq 0.05 \) was used for statistical significance. Obtained data were compiled systematically and were entered into Statistical Package for the Social Sciences (SPSS) software 19 version. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.: SPSS.

**RESULTS**

The individuals were divided into experimental CMCR and control group (traditional way). Diagnosis in permanent teeth: A total of 60 children (60 teeth, 30 in each group) in the age group of 12–15 years were included in the study after obtaining informed consent from their parents orally when they visited the OPD of Jaipur Dental College. Large carious lesions to medium carious were assessed. Structure was of complaints in CMCR and traditional treatment groups.

Pain Experienced Between Group A And Group B is shown in [Table 2]. CDM group showed a significant increase in the discomfort level in form of pain compared with the CMCR group [Table 3]. Also the comparison of pain regarding gender in both group A and group B is shown in [Table 4]. There were no significant differences between the two groups considering the preference of treatment type, the overall acceptance and the presence of bad smell/taste. The mean time taken by the dentist for complete caries removal is shown in [Table 1]. CMCR showed a statistical significant reduction \( (P < 0.0001) \) in the time needed for caries removal. Anxiety Level At Baseline, During And After Treatment Within Both Group A and Group B in mean is shown in [Table 5].

**DISCUSSION**

In studies involving Carie-Care gel, did not cause any pain yet in few cases, there was a small degree of pain involved. Fear and anxiety are mentioned as barriers to oral care among children. Hence, CMCR is an efficient therapeutic alternative to prevent fear and anxiety. Another point that merits the use of Carie-Care gel is that there is no need to invest in dental equipment as the method is simple and easy to apply. Thus, this product can be used outside the dental office such as schools and other places in which dental equipment is not available. The material of choice for this study was the conventional glass ionomer since it presents advantages such as gradual

### Table 1: Comparison of cleaning duration among both the Group A and Group B

<table>
<thead>
<tr>
<th>Time</th>
<th>Minimum of cleaning duration (min)</th>
<th>Maximum of cleaning duration (min)</th>
<th>Mean±SD</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>15</td>
<td>27</td>
<td>18.9±3.78</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Group B</td>
<td>08</td>
<td>18</td>
<td>11.5±2.83</td>
<td></td>
</tr>
</tbody>
</table>

SD: Standard deviation

### Table 2: Comparison of pain severity among two groups

<table>
<thead>
<tr>
<th>Pain assessment</th>
<th>Group A, n (%)</th>
<th>Group B, n (%)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>11 (74)</td>
<td>13 (86)</td>
<td>0.86</td>
</tr>
<tr>
<td>No</td>
<td>2 (13)</td>
<td>1 (7)</td>
<td>0.26</td>
</tr>
</tbody>
</table>

### Table 3: Comparison of complaints amongst both the Group A and Group B

<table>
<thead>
<tr>
<th>Valid</th>
<th>Group A, n (%)</th>
<th>Group B, n (%)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>6 (20)</td>
<td>12 (40)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Unpleasant taste</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Unpleasant smell</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>No complaints</td>
<td>21 (70)</td>
<td>5 (16.6)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>3 (10)</td>
<td>13 (43.33)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>30 (100)</td>
<td>30 (100)</td>
<td></td>
</tr>
</tbody>
</table>

### Table 4: Comparison of pain regarding gender in both Group A and Group B

<table>
<thead>
<tr>
<th>Pain</th>
<th>Male, n (%)</th>
<th>Female, n (%)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>2 (14.2)</td>
<td>4 (25)</td>
<td>0.16</td>
</tr>
<tr>
<td>Group B</td>
<td>5 (33.3)</td>
<td>7 (46.6)</td>
<td></td>
</tr>
</tbody>
</table>

### Table 5: Anxiety level at baseline, during, and after treatment within both Groups A and Group B

<table>
<thead>
<tr>
<th>Anxiety level</th>
<th>Mean±SD</th>
<th>Group A</th>
<th>Group B</th>
<th>( t )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.66±0.8022</td>
<td>1.1±0.4806</td>
<td>2.5385</td>
<td></td>
</tr>
<tr>
<td>During</td>
<td>1.83±1.0531</td>
<td>1.63±1.1885</td>
<td>0.6899</td>
<td></td>
</tr>
<tr>
<td>Final</td>
<td>0.23±0.6260</td>
<td>0.36±0.4901</td>
<td>0.9183</td>
<td></td>
</tr>
</tbody>
</table>

SD: Standard deviation

### Table 6: Comparison of dental drill over carie-care

<table>
<thead>
<tr>
<th>Dental drill</th>
<th>Carie-care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invasive</td>
<td>Selective</td>
</tr>
<tr>
<td>Low precision</td>
<td>Precise</td>
</tr>
<tr>
<td>Noise</td>
<td>No noise</td>
</tr>
<tr>
<td>Patient uncooperative</td>
<td>Patient cooperative</td>
</tr>
</tbody>
</table>

flouride release in the oral cavity, good adhesiveness, possibility of repair, and ease of use. Piva et al. 2008\(^{[9]}\) concluded that papacarie negatively affected the microtensile bond strength of self-etching adhesive
system. This study limits the usage of self-etching adhesives and promotes the usage of glass ionomer cements. Glass ionomer has low resistance to wear and presents low durability. Kavvadia et al. in 2004[11] reported the no significant difference between the two groups, regarding the taste and smell during the two procedures. Although CMCR was more time consuming, some children preferred it, probably because of fear toward drilling, sound, and pain. Some children preferred CDM since it was less time consuming and they could spend more time in the play area. Similar results are reported in present study with Carie-Care gel. Attari et al. in 2001[12] Maragakis et al. in 2001[5] and Kavvadia et al. in 2004[11] reported that the time taken by the pediatric dentist for complete caries removal using CMCR method was significantly higher than the CDM method and this was in accordance with the present study.

Kochhar et al. in 2011[13] evaluated pain threshold experienced by children during various caries removal methods such as hand instruments, airotor, carisolv, and papacarie gel using Ericson et al. scale and visual analogy scale. It was concluded that pain threshold experienced by children was very less when treated with papacarie and carisolv which is in accordance with the present study [Table 6].

CONCLUSION

Carie-Care may represent a new option for caries removal. Carie-Care is more economical when compared to other chemo-mechanical agents. The product is readily available in Indian market. The chemomechanical caries using Carie-Care seem to be more practical clinically than other minimally invasive techniques such as (I) atraumatic resin restoration where caries cannot be completely removed by manual instrumentation alone, (II) air abrasion-due to specialized instruments and the need of power supply, and (III) lasers-because of the large unit with a very sensitive delivery system and is not cost-effective further clinical studies with large samples, long-term follow-up, and comparison with other agents are required.

Financial support and sponsorship
Nil.

Conflicts of interest
The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

REFERENCES