Effects of audiovisual distraction in children with Down syndrome during dental restorations: a randomised clinical trial

Abstract

Aim To evaluate the effect of audiovisual distraction on the dental chairside behaviour of children with Down syndrome (DS) during dental restorations and its influence on the operator stress and the duration of the appointment.

Materials and Methods Study design: This randomised controlled trial included 48 children with DS requiring dental restorations. The study group was treated while wearing video eyeglasses, the control group with conventional behaviour management techniques. The child behaviour was evaluated using the revised Face, Leg, Activity, Cry, Consolability scale (r-FLACC) and the Frankl scale. The operator stress was evaluated using a VAS scale and the duration of the appointment was recorded.

Results In the study group 64% of the children refused to wear the video eyeglasses during the whole duration of the dental treatment, the median r-FLACC score was significantly higher (p = 0.01552; Mann Whitney U test) and significantly more children showed a negative behaviour (68% vs 30%; p = 0.011; Chi-square test).

Conclusion Audiovisual distraction using video eyeglasses is not useful in managing the dental chairside behaviour of children with DS.

KEYWORDS Down Syndrome, Distraction, Behaviour.

Introduction

Down syndrome (DS) is the most common chromosomal abnormality and the most common cause of intellectual disability. The incidence ranges from 1 in 650 to 1 in 1,000 live-births [Sherman et al., 2007]. DS is characterised by typical facial features and by a mild-moderate physical and intellectual developmental delay [Weijerman and De Winter, 2010]; congenital heart defects are diagnosed in 50% of individuals [AAP, 2001]. Oral health is an important component of the general health; furthermore, in children with congenital heart disease at risk of infective endocarditis, oral diseases can pose a threat to life [AAPD, 2012; Descamps and Marks, 2015].

The behavioural management of patients with DS can be challenging due to a delay in cognitive development with specific deficits in speech, language production and auditory short-term memory and due to impairments in adaptive behaviour [Will et al., 2018]. Because of a lack of understanding, children with intellectual disability may exhibit resistant behaviours that interfere with the safe delivery of the dental treatment. When the parent/caregiver’s assistance is not feasible or effective, sedation or general anaesthesia is the behavioural management modality of choice [AAPD, 2012]. In the recent years the use of audiovisual distraction has become very popular in paediatric dentistry: many studies demonstrated the efficacy of video eyeglasses in managing distress and reducing dental fear and dental anxiety in children [Asl Aminabadi et al., 2012; El-Sharkawi et al., 2012; Hoge et al., 2012; Al-Namankany et al., 2014; Mitrakul et al., 2015; Nuvvula et al., 2015; Al-Khotani et al., 2016; Al-Namankany, 2019]. Based on this scientific background, a previous study was conducted to test the efficacy of this behavioural management technique in children with special healthcare needs during dental treatments [Bagattoni et al., 2018]. The use of video eyeglasses significantly reduced the operator stress, but there was no improvement in children pain-related behaviour, self-reported pain and mean duration of the appointment. To achieve a homogeneous sample, children with intellectual disability were excluded, considering that a factor which might have affected the results.

The aim of this study was to evaluate the effect of audiovisual distraction on dental chairside behaviours in children with intellectual disability affected by Down syndrome and its influence on the operator stress and duration of the appointment.

Materials and methods

Participants

This randomised case-control study was conducted on outpatients attending the Unit of Special Needs Dentistry and Paediatric Dentistry, Department of Biomedical and Neuromotor Sciences, University of Bologna, Italy, referred from the Paediatric Unit of St. Orsola-Malpighi Polyclinic, Department of Medical and Surgical Sciences, University of Bologna, Italy. A written informed consent for participation and publication was obtained from the parents/legal guardians of each patient in full accordance with the ethical principles of the Helsinki Declaration. The investigators were three dentists trained in special needs dentistry and involved in a previous research protocol to test the applicability of the audiovisual distraction in children with special healthcare needs without intellectual disability [Bagattoni et al., 2018]. The research protocol of this study was part of a project approved by the local Ethics Committee of the Bologna University Hospital Authority St.
TABLE 1

<table>
<thead>
<tr>
<th>Categories</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F Face</td>
<td>0</td>
<td>No particular expression or smile</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Occasional grimace or frown, withdrawn or disinterested; appears sad or worried</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Consistent grimace or frown; frequent/constant quivering chin; clenched jaw; distressed-looking face; expression of fright or panic</td>
</tr>
<tr>
<td>L Legs</td>
<td>0</td>
<td>Normal position or relaxed; usual tone and motion to limbs</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Uneasy, restless, tense; occasional tremors</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Kicking, or legs drawn up, marked increase in spasticity, constant tremors or jerking</td>
</tr>
<tr>
<td>A Activity</td>
<td>0</td>
<td>Lying quietly, normal position, moves easily; regular &amp; rhythmic respirations</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Squirming, shifting back and forth, tense; mildly agitated, shallow, splintering respirations intermittent sighs</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Arched, rigid, or jerking, severe agitation, head banging, shivering, breath-holding, gasping or sharp intake of breath, severe splintering</td>
</tr>
<tr>
<td>C Cry</td>
<td>0</td>
<td>No cry/verbalization</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Moans or whimpers, occasional complaint, occasional verbal outburst or grunt</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Crying steadily, screams or sobs, frequent complaints, repeated outbursts, constant grunting</td>
</tr>
<tr>
<td>C Consolability</td>
<td>0</td>
<td>Content or relaxed</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Reassured by occasional touching, or being talked to, distractible</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Difficult to console or comfort; pushing away caregiver, resisting care or comfort measures</td>
</tr>
</tbody>
</table>

Orsola-Malpighi Polyclinic (PG. N 0019293). The inclusion criteria were:
- 5 to 12 year-old Italian-speaking child with a documented diagnosis of Down syndrome;
- at least one carious molar (primary or permanent) requiring a Black class I or II composite restoration with local anaesthesia.

The exclusion criteria were:
- History of seizures or convulsion disorders, nystagmus, vertigo, visual or hearing impairments;
- severe or profound intellectual disability according to the International Classification of Diseases-10 [WHO, 1992];
- need for pulp therapy;
- pain or swelling in the oral cavity.

Considering the primary outcome “child pain-related behaviour” using the revised Face, Legs, Activity, Cry and Consolability scale (r-FLACC) (Table 1) [Merkel et al., 1997], assuming a standard deviation of 1.7 from a previous study [Bagattoni et al., 2018], the inclusion of 20 patients for each group would be sufficient to detect a clinically significant difference of 1.5 in child pain-related behaviour between the groups (significance level: 5%; power: 80%). To compensate for dropouts, additional subjects were recruited. During the data collection period (January 2017– June 2018), 63 children for dropouts, additional subjects were recruited. During the data collection period (January 2017– June 2018), 63 children were included in the study group. The other 24 children were included in the control group. The random allocation sequence was generated by the biostatistics involved in the study. The allocation was concealed to the dentists through the use of sequentially numbered sealed envelopes.

The study group received the distraction intervention using video eyeglasses; the control group received conventional behaviour management techniques as voice control, nonverbal communication, tell-show-do and positive reinforcement.

Dental procedure

Parents were present in the operating area. An album of coloured pictures of popular cartoon movies was presented to the children of the study group to choose the favourite movie before the dental treatment. The volume was adjusted to allow instructions from the operator.

The restorative dental treatment followed four steps. Topical anaesthesia with 15% lidocaine spray (Septodont, France) applied with a cotton roll for 1 min on the dried mucosa; slow injection of 2% mepivacaine with 1:100,000 epinephrine (Septodont, France). Rubber dam application. Caries tissue removal (in case of deep cavities, partial one-step caries excavation) and cavity preparation using rotary instruments and manual excavation. Light-cured composite restoration.

Outcomes: child pain-related behaviour

During the first 2 minutes of each step of the dental procedure, the trained examiners, seated in the room and not actively involved in the dental procedure, objectively assessed the behaviour of each child using the r-FLACC scale. This scale has been identified as a recommended measurement tool to assess pain in children with cognitive impairments [Merkel et al., 1997]. Each of the r-FLACC’s categories is scored from 0 to 2, which results in a total score between 0 and 10: 0 = Relaxed & comfortable; 1–3 = Mild discomfort; 4–6 = Moderate pain; 7–10 = Severe pain or discomfort or both.

Frankl scale

At the end of the dental treatment the behaviour of each
child was reassessed using the Frankl scale [Frankl et al., 1962]. The most negative score observed during the four different steps of the dental treatment was considered. In case of refusal of the child to wear the eyeglasses, the behaviour was scored as “definitely negative”.

**Duration of appointment**

Duration of the appointment was recorded using as start point the topical anaesthesia application and as end point the occlusal adjustment.

**Operator stress and child satisfaction**

The operator stress was assessed using the Visual Analog Scale (VAS) [Lesage et al., 2012]. The VAS consists of a small, unmarked 100 mm ruler with endpoints labelled “none” and “as bad as it could be” with the instruction “Indicate how stressed you feel on the small ruler”. The scale yielded a single subjective stress between 0 and 100.

**Training and calibration**

The investigators were trained and calibrated in the application of the r-FLACC scale during a previous study [Mahiya et al., 2006]. During dental injection they observed the patients simultaneously and scored the child pain-related behaviour independently. Using Cohen’s kappa statistics, the agreement was excellent among examiners for each category of the r-FLACC, as well as for the total r-FLACC score (κ=0.85), supporting the inter-examiner reliability of the tool.

**Statistical analysis**

Descriptive statistical analyses were first performed. Continuous variables were tested for distribution using the Kolmogorov-Smirnov test. Between-groups comparisons would be performed with two-sample t-test if data were normally distributed and with Mann-Whitney U test if data was not normally distributed. For analysis purposes, the behaviour of each child was dichotomised as positive (“definitely positive” and “positive” categories of the Frankl scale) and negative (“definitely negative” and “negative” categories of the Frankl scale). Chi-square test was used for categorical variables. The level of significance was set at p <0.05. SPSS for Windows (23.0, SPSS Inc, Chicago, IL, USA) was used.

**Results**

**Participants**

Of the 54 recruited children, 6 children were excluded due to low cooperation during V2 and 3 children did not complete the study (absent during V3).

The study group consisted of 22 patients with a mean age of 8.0 ± 1.8 years, 12 males (55%) and 10 females (45%). The control group consisted of 23 patients with a mean age of 7.9 ± 1.8 years, 15 males (65%) and 8 females (35%). No significant differences according to age (p= 0.436) were found between the groups (Chi-square test). Twenty-eight restorations were performed in the study group (8 Black class I and 20 Black class II) and 31 in the control group (15 Black class I and 16 Black class II). No significant difference was found between the groups (0.298; t-test).

**Child pain-related behaviour**

Four patients (18%) of the study group and 3 patients (13%) of the control group did not complete the restorative sessions due to a lack of cooperation. Fourteen patients (64%) of the study group removed their video eyeglasses and refused to wear them during the subsequent treatment steps. The median r-FLACC score was 7 (range: 2.5-8.5) in the study group and 4.5 (range: 2.8-8.5) in the control group. The difference between the two groups during the overall treatment was significant (p= 0.015; Mann-Whitney U test). During anaesthesia (p= 0.075) and rubber dam application (p= 0.303) there were no significant differences between the groups (Mann-Whitney U test) (Table 2).

**Frankl scale**

In the study group 68% of the children showed a negative behaviour and 30% in the control group. The difference between the groups was statistically significant (p =0.011; Chi-square test).

**Time of appointment**

The patients who did not complete the clinical session were excluded. The mean duration of the appointment was 33.4±4.7 min in the study group and 32.3±4.0 min in the control group, with no significant differences between the groups (p=0.221; t-test).

**Operator stress**

The mean stress VAS score was 46.8±15.5 in the study group and 41.3±13.2 in the control group, with no significant differences between the groups (p=0.103; t-test).

**Discussion**

Previous studies showed that audiovisual distraction is useful in relieving anxiety and pain in healthy children during dental treatment [Asl Aminabadi et al., 2012; El-Sharkawi et al., 2012; Hoge et al., 2012; Al-Namankany et al., 2014]. The use of audiovisual distraction reduced the FLACC scores in pre-operation and during the use of high-speed handpiece during restorative treatments in a crossover trial involving healthy children [Mitruk et al., 2015]. Al-Khotani et al. [2016] showed that healthy children wearing video eyeglasses during restorative treatments reported an improved behaviour after the injection with local anaesthesia and less distress than those without video eyeglasses. Garrocho-Rangel et al. [2018] found no significant difference in the FLACC scores during restorative treatment’s between audiovisual distraction and conventional behaviour management techniques. A recent review with meta-analysis found some low-quality evidence suggesting that the use of audiovisual distraction may relieve children’s dental anxiety [Liu et al., 2019]. The authors did not observe any statistically significant differences in the Faces Pain Scale between audiovisual distraction and control groups and found no consistent results of the audiovisual distraction effect on behaviour.

A recent crossover study was conducted to evaluate the effect of video eyeglasses on behaviour and perceived pain in children with special healthcare needs without intellectual disability during dental restorations [Bagattoni et al., 2018]. The mean r-FLACC score was 2.7 ± 1.9 in the study group and
Future studies should assess whether a specific preparation may change the response to this source of distraction and increase the cooperation of the child. However, the clinician should evaluate the cost-benefit ratio by spending time promoting video eyeglasses acceptance rather than using conventional behaviour management techniques during the dental treatment. The major limitation of the present study may be considered the choice of a case-control study design: a crossover design would have eliminated the variability among participants. It was not adopted because the range of DS would have made it difficult to recruit the sample with the same inclusion/exclusion criteria. However, the groups were similar for age, gender, and medical and dental history. Another limitation was the absence of blinded condition of the examiners because the application of the r-FLACC scale requires a direct observation of the child. The sample size calculation was performed based on the primary outcome “child pain-related behaviour”, but the results of the secondary outcome did not have the same statistical authority as the primary endpoint.

### Table 2: Child pain behaviour measures on r-FLACC scale.

<table>
<thead>
<tr>
<th>Treatment step</th>
<th>r-FLACC score</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study group median (range)</td>
<td>Control group median (range)</td>
<td></td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>3 (1-5)</td>
<td>1 (1-6)</td>
</tr>
<tr>
<td>Rubber dam application</td>
<td>5 (2-10)</td>
<td>4 (2-10)</td>
</tr>
<tr>
<td>Caries tissue removal</td>
<td>10 (4-10)</td>
<td>5 (3-10)</td>
</tr>
<tr>
<td>Composite restorative</td>
<td>10 (2-10)</td>
<td>5 (2-10)</td>
</tr>
<tr>
<td>Overall treatment</td>
<td>7 (2.5-8.5)</td>
<td>4.5 (2.8-8.5)</td>
</tr>
</tbody>
</table>

*Significant difference (Mann-Whitney U test).