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Madouh, M and Tahmassebi, JF (2016) Utilising a paediatric version of the Indicator of Sedation Need for children's dental care: A pilot study. European Archives of Paediatric Dentistry, 17 (4). pp. 265-270. ISSN: 1818-6300

https://doi.org/10.1007/s40368-016-0238-8

Abstract

Aim: To assess the treatment outcomes of using inhalation sedation for comprehensive dental care in children by utilising a modified version of the Indicator of Sedation Need tool.

Methods: Investigating the outcomes of dental treatment of patients referred to the sedation unit at the Leeds Dental Institute when the paediatric version of the indicator of sedation need (p-IOSN) was utilised.

Results: Forty patients of mean age 9.99 (SD=3.14) years were followed up to ascertain treatment outcomes when the p-IOSN was used. Of the total of 40 children included, 20 scored 6 on p-IOSN. Treatment completion rate was 72.5%. Although major differences existed between age and treatment outcomes, they failed to achieve statistical significance. No significant association was found between gender and p-IOSN of any score with any treatment outcome.

Conclusions: p-IOSN may be a useful tool that can be utilised to predict child patients who would benefit from sedation for their dental treatment. However, the p-IOSN is still in the investigational stages and further research is required prior to its use on clinical grounds.

INTRODUCTION

It is well-known now that dental fear and anxiety could represent a barrier for seeking dental care. It has been reported that 23 million people with dental fear would be more willing to visit a dentist if a form of sedation was offered (Alexopoulos et al. 2007). Many studies have been conducted to assess the need for sedation with such studies utilising either a paper questionnaire posted to dental health care providers/general population or via telephone contact. The results of these studies revealed that clinicians felt that sedation for dental treatment should be available to all children (Crawford 1990; Shaw et al. 1996; Hosey 2002). In addition, respondents from the general population showed preference to receive sedation as a way of anxiety relief and were more willing to go to the dentist more often when such services were available (Girdler and Hill 1998). It can be argued that there are some dentally anxious patients who are not being offered conscious sedation to facilitate their treatment and at the same time sedation services may be demand rather than needs-led. For that reason Coulthard and co-workers (2011) developed the Indicator of Sedation Need (IOSN). The IOSN is a tool – as its name indicates – to be used to assess the need for sedation. The IOSN can be used as a referral tool to help clinicians to make a decision about referring adult patients to have sedation for their dental treatment, and also as a health needs assessment tool for commissioners. This tool investigates the need for sedation by ranking a combination of information on patient anxiety, medical history and the complexity of the clinical treatment. It was introduced in September 2011 to be utilised for referral of adult patients who may require sedation to help with accepting dental treatment. It is composed of three components; one of which is the anxiety component which uses the Modified Dental Anxiety Scale (MDAS) and is completed by the patient. This anxiety scale is specifically designed for

adults. The second component of IOSN is medical status which is based on the patient's ASA class. The last component is the treatment complexity and again, the indicative list of treatment provided is based on treatment offered to adults. The latter two components are completed by the clinician. Each of these components is given a score and the sum of all the three components will provide the IOSN score, based on which a need for sedation can then be assessed (Pretty et al. 2011). A recent study by Yuan et al (2015) investigated the use of IOSN in a convenience sample of patients who were referred to the public dental service practitioners for dental anxiety management. The result of this study revealed that "IOSN discriminated between patients who were assessed as requiring more complex sedation modalities and had a greater normative treatment need". The authors concluded that the IOSN is a useful and valid assessment of sedation need and predicted sedation modality for patients referred with high dental anxiety states and secondly that component parts of the IOSN add explanatory value in practitioners' choice of planned sedation modality.

Currently, child patients are referred to sedation services for their dental treatment based on the opinion of their dentist. This means that the decision of referral is subjective as there is no available tool such as IOSN that can be utilised to assess the need for dental sedation in children. Therefore, the aim of this pilot study was to assess the treatment outcomes of using inhalation sedation (IHS) for comprehensive dental care within the hospital dental service by utilising a modified (paediatric) version of the Indicator of Sedation Need (IOSN) assessment tool.

MATERIALS AND METHODS

The outcomes of treatment under IHS were obtained on a prospective basis as well as the p-IOSN score. Therefore, a parent's/carer's information sheet explaining the current study was

posted to all paediatric patients attending the sedation unit at the Leeds Dental Institute (LDI) for assessment along with their appointment letter. These patients were referred to the sedation unit at the LDI as an outcome of their initial "new patient consultant clinic" visit; hence, they were referred to the sedation unit following the opinion of consultant/specialist in paediatric dentistry. On the day of the appointment, potential participants and their parents were introduced to the study by the chief investigator in the sedation unit. The study included all the patients who were assessed for dental treatment under inhalation sedation at the LDI during the period of January to June 2013 who were 5-16 years of age and agreed to participate. Only those patients for whom a decision was made to treat utilising means other than IHS on their initial assessment visit at the sedation unit were excluded.

Upon their willingness to participate, the parent or legal guardian was asked to sign a consent form. Similarly, the child patient was assented to participate. Following this, each child participant was asked to complete an anxiety questionnaire. There were two anxiety questionnaires; the Facial Image Scale (FIS) (Buchanan and Niven 2002) was used for children under 10 years of age and the faces version of the Modified Child Dental Anxiety Scale ($MCDAS_f$) for older children (Howard and Freeman 2007). According to the score the patients achieved on the anxiety scale, the chief investigator calculated an "anxiety score" for each child and transferred this to the data collection sheet. The data which were transferred to the data collection sheet were age, gender and p-IOSN. The p-IOSN is the sum of anxiety score treatment complexity score and medical status score.

On completion of the course of the treatment in the sedation unit which the treatment was always carried out by postgraduate students in paediatric dentistry under supervision of a consultant/specialist in paediatric dentistry, the chief investigator reviewed the participants' clinical records to note the treatment outcome which was then entered into the data collection sheet. Table 1 shows the 5 categories for the treatment outcome.

The treatment outcome was recorded as "completed as planned" if the record showed that the treatment which the child patient had received was in accordance with the proposed treatment plan that was documented in the patient's file (outcome 1). In cases where the patient received a modified treatment than that originally planned, then the outcome was recorded as "modified treatment received". For example, if the initial treatment plan was to perform the full course of treatment under inhalation sedation (IHS) but due to lack of cooperation with treatment only the restorations were carried out under IHS, following this the child was referred to have extractions under GA, this was considered a modified treatment (outcome 2). If there was an alteration to the treatment plan (e.g. an extraction was carried out instead of a restoration) but still the treatment was completely performed under sedation, it would not fall in this category and counted as "treated as planned – outcome 1". In cases were the child patient did not received any treatment at the sedation unit and was referred to have his/her full course of dental treatment under general anaesthesia, this was recorded as "treatment abandoned and child referred on to be treated under general anaesthesia – outcome 3". On the other hand, there were patients for whom the treatment did not require IHS and were referred to complete their treatment under local anaesthesia; in which case, the outcome was recorded as "treatment abandoned in sedation unit and child referred to be treated under local anaesthesia.

Calculation of p-IOSN Score

p-IOSN is the paediatric version of the IOSN which the investigators of the current study have modified from the IOSN which was introduced by Coulthard and co-workers (2011). The modification of the IOSN was carried out such that it could be used in paediatric dentistry. Therefore the components of IOSN (and then symbolised as p-IOSN to emphasise the modifications to fit paediatric dentistry) were modified by the investigators as follows:

Anxiety

Due to the wide age range of the study group, the investigators decided to use two anxiety scales; the FIS was used for children less than 10 years of age because of its ease of use and briefness; with the minimum FIS score being 1 and maximum 5. The patients who had minimal anxiety (FIS 1) were scored 1 on the anxiety domain of the p-IOSN. Those who had moderate anxiety (FIS 2-3) were scored 2 on the anxiety domain; highly anxious patients (FIS 4-5), were scored 3. For older patients the $MCDAS_f$ was used to evaluate their anxiety levels. $MCDAS_f$ can yield a minimum score of 8 and a maximum of 40. Consequently, patients who scored 8-17 on $MCDAS_f$ were considered as having minimal anxiety and scored 1 on the anxiety domain of the p-IOSN. Those who had moderate anxiety ($MCDAS_f$ 18-28) were scored 2 on the anxiety domain of the p-IOSN. Patients were given a score of 3 on p-IOSN for the anxiety domain if they scored 29 to 40 on $MCDAS_f$. It is worth mentioning here that the cut-off points for categorising the level of anxiety were determined arbitrarily by the investigators.

Treatment Complexity

The treatment complexity ranking score proposed by the IOSN authors could not be used in paediatric dentistry. Hence, the investigators modified the treatment complexity rank score to the one used in the p-IOSN as described in Table 2, such that it could be applied to procedures often carried out in paediatric dentistry. The score of treatment complexity of p-IOSN ranges from 1-4.

Medical Status

The medical status scoring was adopted from the same ranking score of the IOSN and ranged from 1-4. It was based on the ASA class. Patients who were ASA I had a score of 1 on p-

IOSN. Those who were ASA II and/or have a strong gag reflex were given a score of 2 or 3 depending on the severity of the case. Finally those who were ASA III had a score of 4. A summary of calculating p-IOSN is presented in Table 3.

Sample Size Determination

Statistical advice was sought and as there were no previous studies to investigate the p-IOSN for children then no sample size calculation was undertaken. It was recommended though to have as many participants as possible to reflect the population.

Analysis of Data

The collected data were compiled into Excel sheets (Microsoft Excel 2010) and then statistical analysis was carried out using the SPSS statistical package for windows version 19 (SPSS Inc. Illinois). A significance level of $\alpha < 0.05$ was adopted.

Ethical Approval

The present study received ethical approval from the Dental Research Ethics Committee (DREC) at the Leeds Dental Institute (LDI), the National Research Ethics Service (NRES) and the Leeds Research and Development Directorate (R&D) in order for it to be performed at the Leeds Teaching Hospital Trust (LTHT) (REC reference: 12/NW/0770, IRAS reference: 103361).

RESULTS

During the period of January to June 2013, 42 patients agreed to participate in the study. All the assessments and treatments under IHS in the sedation unit were carried out by postgraduate students in paediatric dentistry under supervision of a senior paediatric staff. Two patients were excluded, of which one patient was excluded because they were 19 years

of age; the other was excluded due to deciding to carry out their dental treatment under GA following their sedation assessment. The sample consisted of 40 patients; 16 males and 24 females. The mean age was 9.99 years (SD= 3.14).

Statistical analysis was carried out in order to determine whether a significant association existed between patient age and treatment outcome. The result indicated no significant mean differences in patient age on the basis of treatment outcome. Table 4 summarises the descriptive statistics conducted focusing upon patient age on the basis of treatment outcome.

There was no significant association between patient gender and treatment outcome. No significant difference was also found in median p-IOSN scores on the basis of treatment outcome. Figure 1 shows the distribution of p-IOSN scores according to treatment outcomes.

The results revealed that there was no significant difference in patient anxiety level existed on the basis of treatment outcome. Moreover, it showed that there was no significant difference in treatment complexity level existed on the basis of treatment outcome. There was also no significant association between medical status and treatment outcome. Out of the 40 participants in the current study, 29 have completed the treatment as planned (72.5%); 20 patients of whom – which also represent 50% of the total number of participants – have p-IOSN score of 6 (Table 5).

DISCUSSION

The IOSN was modified by the investigators of the current study so that it could be used in paediatric dentistry. In the present study, using the IOSN as a referral tool was assessed. The modified version is abbreviated as p-IOSN in order to differentiate it from the IOSN and to refer to the paediatric-dentistry-based modification.

In the current study 72.5% of the participants completed their dental treatment as planned under inhalation sedation. These figures were lower than what have been reported previously in the literature where it ranged from 83% to 86% (Crawford, 1990; Bryan, 2002).

In the present study, 12.5% of patients abandoned treatment in the sedation unit and were referred to have treatment performed under general anaesthesia. This was in accordance with the studies by Crawford (1990) and Shaw et al (1996). However, these figures were higher than the work performed by Bryan (2002) where IHS was abandoned in 7.5% of the total study population.

There was a statistically significant relation between patient age and outcome 3 where the treatment being abandoned in the sedation unit and child being referred to have treatment under GA. When that significant association was further explored, it was found that the patients who were younger than 10 years were more likely to require general anaesthesia for their dental treatment. This is in agreement with previous studies which reported that children with mean age ranging from about 3 years to slightly above 7 years were referred to have their dental treatment under general anaesthesia (Shaw et al. 1996; Alexopoulos. et al 2007; Wilson et al. 2007).

Girls represented the majority of the sample included in the current study. This compares favourably with the findings of Soldani and co-workers (2010) whilst there were more males in the cohorts studied by other researchers (Bryan 2002; Ashley et al. 2010; Soldani et al. 2010).

The literature is equivocal regarding the association between gender and dental anxiety. Some studies have found no gender differences in children's and adolescent's dental fear (Locker et al. 2001; Majstorovi et al. 2003; Foley 2005). However, several studies reported

that girls were more dentally anxious than boys (Majstorovi and Veerkamp 2004; Muris et al. 2005).

It is interesting to note that in the present study, there was no significant association between gender and any particular treatment outcome. This contrasts with the results of Foley's study on the perception of IHS where male participants less than 10 years of age were found to cope better with IHS than female patients of the same age (Foley 2005). Many studies in the literature however lacked the investigation of gender differences on the basis of treatment outcome. For example, the study by Bryan has commented on the percentage of males and females included in the study population which was 51.2% and 48.8% respectively, but failed to relate any gender differences to treatment outcomes (Bryan 2002). Similarily, the female to male ratio was 3:2 in Soldani and co-workers study, but there was no mention about gender differences based on treatment outcomes (Soldani et al. 2010) .

Similar to the IOSN, the p-IOSN tool is composed of three components: anxiety score, medical status and treatment complexity. Statistical analysis was performed to investigate whether or not there was an association between the score of any component and any particular treatment outcome. The analysis resulted in that neither anxiety score, medical status nor treatment complexity score singly was associated with any specific outcome; which indicates that all of these components are equally important in assessing the need for sedation. This is expected as these three components embrace the indications for dental sedation in general. According to the European Academy of Paediatric Dentistry (EAPD) guidelines on sedation in paediatric dentistry, sedation is indicated for the dental treatment of the children who have low coping ability, dental anxiety, or disruptive behaviour as well as those who require extensive dental treatment (Hallonsten et al. 2003). Moreover, it is reported in the literature that inhalation sedation with nitrous oxide/oxygen is indicated for dentally

anxious patients, some medical conditions (especially for which GA is contra-indicated) and for extensive or unpleasant dental procedures (Klingberg and Broberg, 2007).

In the current study, the FIS and $MCDAS_f$ were used to assess the level of dental anxiety of participating children and then determine the score of the anxiety component of the p-IOSN. The FIS was used to assess the anxiety level in 5-9 year old children enrolled in the present study, while the $MCDAS_f$ was used for children who were 10-16 years. Statistical analysis revealed that differences between treatment outcomes yielded by the two age groups failed to achieve statistical significance. This would imply that both FIS and $MCDAS_f$ were equally effective in measuring the anxiety of children in the respective age groups. This is expected as both scales have been previously validated.

Although both FIS and $MCDAS_f$ have been validated by previous research (Buchanan and Niven 2002; Hosey 2002), a recent paper by Guinot and colleagues have argued that because children's anxiety is of a multi-dimensional nature, more studies are needed to determine the reliability and validity of the measures used to assess dental anxiety in children. The authors further explained that the low level of correlation among the different methods of assessing anxiety in children seems logical given the physiological, cognitive and motor responses that manifest in different ways in each individual (Guinot et al. 2011).

There is anecdotal evidence to suggest that some sedation services may be demand rather than needs-led and some children who are anxious about dental treatment are not being offered conscious sedation to help with their treatment. There is a need to support clinicians in their decision making. The p-IOSN is a new tool that is still in the investigational stages. Hence, further research is needed prior to adopting its use in the clinical field. The results yielded by the current study could form the basis of future research.

Conflict of interest

The authors declare no conflict of interest. The authors alone are responsible for the content and writing of the manuscript.

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