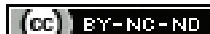


Assessment and Comparison of Sense of Coherence in Young Individuals Participating in the Treatment of their Cleft Lip and Palate Anomalies: A Prospective Interventional Study

DHWANI SUCHAK¹, RANJIT KAMBLE², SUNITA SHRIVASTAV³, JENI MATHEW⁴, NANDLAL GIRIJALAL TOSHWAL⁵



ABSTRACT

Introduction: Cleft lip and/or Cleft of Palate (CL/P) is amongst the most common congenital oral and maxillofacial deformities. CL/P is not thought to be harmful to one's health. However, even if a cleft is treated early in a child's development, there are genuine consequences, including the possibility of long-term negative health impacts such as functional and psychological issues. Antonovsky A developed a questionnaire to measure the Sense Of Coherence (SOC). It consists of three elements: comprehensibility, manageability, and meaningfulness. In patients having any kind of deviancy, SOC provides positive experiences such as increased sense of purpose, expectations, spiritual practices, respect and understanding, self-improvement and confidence, and connections have all improved.

Need of the study: Undergoing orthodontic treatment along with psychological counselling can improve the mental, emotional and social well-being of cleft lip and palate patients.

Aim: To assess changes in SOC of young patients undergoing treatment for cleft lip and palate anomalies.

Materials and Methods: The present prospective interventional study will be conducted in the Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, Maharashtra, India, and to be conducted on 20 patients of 14 years and below, with cleft lip and palate. Data will be gathered via questionnaires which will be distributed to patients having CL/P undergoing orthodontic treatment. The questionnaires will be collected within half an hour and will be checked, if completed. Patients will be given the same questionnaires at different points of time, i.e., at the start of the treatment, two months, six months and one year after the start of treatment. Statistical Package for the Social Sciences (SPSS) statistical software (27.0) and Graph Pad Prism will be used to analyse the data (version 7.0).

Keywords: Oral and maxillofacial deformities, Orthodontic treatment, Psychological issues

INTRODUCTION

Cleft lip and palate presents with a wide array of problems and subjects the patients to a multitude of problems [1]. Children with orofacial clefts may endure numerous surgical and non surgical treatments from birth until adulthood, which psychologically affects both the children and their family members [2]. The CL/P is a multifaceted problem which requires a carefully planned team work to rehabilitate the patient. The disorder is presumed to be multifactorial and polygenic in its origin. Cleft lip and palate affects approximately 0.033% of the Indian population. Male population had a prevalence rate of 33.37 per 100,000 and the female population had a rate of 31.01, and all genders had a rate of 32.18. The overall number of untreated clefts in India is estimated to be 79,430, or 18.76% of the entire population [3]. The presence of CL/P also affects the emotional, psychological and social well-being of the patients [4].

The concept of SOC was put forward by Antonovsky A in 1987 wherein he tried to explain why some people fall sick under stressful conditions while others cope up well. It is made up of three elements: comprehensibility, manageability, and meaningfulness [5]. In patients having any kind of deviancy, SOC provides positive experiences such as increased sense of purpose, expectations, spiritual practices, respect and understanding, self-improvement and confidence, and connections have all improved. It is important to pay attention to what a patient feels and provide them with a sense of purpose of their life [6].

Young persons with CL/P frequently express decreased appearance and speech satisfaction compared to non cleft control groups, despite other research finding no difference in appearance satisfaction between cleft and non cleft groups, or even better appearance satisfaction in the former group. Self-esteem, mental health, and quality of life are just a few of the primary psychosocial functioning areas that can be affected by dissatisfaction with one's appearance and speech. It is crucial for research to determine which groups within the CL/P community experience the lowest appearance and speech satisfaction because many psychosocial disorders mentioned in cleft research appear to be connected to worries about appearance and speech [4].

There is a paucity of studies conducted on the changes of SOC of patients undergoing orthodontic treatment for cleft lip and palate anomalies. The rationale of this study is to assess the SOC and its changes observed over time in a group of patients having cleft lip and palate and help them by providing assistance required during their orthodontic treatment along with evaluation of their psychological state of mind.

A similar study has been conducted by Kamble R et al., on the parents of patients undergoing treatment for cleft lip and palate [3]. This is a continuation of the previous study to assess the effects of the treatment on the social well-being, communication skills and the acceptance in the society of the patients undergoing orthodontic treatment for cleft lip and palate.

Study Objective

- To evaluate the SOC at the time of reporting after two months, six months and one year of treatment.
- To compare results of SOC at various intervals of time.
- To evaluate the psychological changes in patients after their counselling.

REVIEW OF LITERATURE

A study was conducted by Noar JH to evaluate the self-perceived problems of patients undergoing treatment for complete unilateral cleft lip and palate and their parents [7]. The findings imply that the patients were happy with the treatment they had received. They stated that the efforts of the cleft palate teams had been successful, and they were generally pleased with their overall facial look and speech. However, some were unhappy with certain features of their appearance, such as their nose, lip, profile, speech, and teeth. The parents were pleased with all elements of their child's treatment, as well as his or her appearance and speech. The parents believed that their children's cleft had an emotional and social impact on them, as well as a negative effect on the academic performance.

Antonovsky A developed a questionnaire to measure the SOC. The SOC scale, is a 29-item semantic differential questionnaire based on Guttman's facet theory, helps us to understand this concept. The current paper's goal was to provide existing data from research done in 20 countries for estimating, if the scale was feasible, reliable, and valid, as well as normative data. The Cronbach alpha measure of internal consistency in 26 studies, using SOC-29 ranged from 0.82 to 0.95. The alphas of 16 SOC-13 studies range from 0.74 to 0.91. A high level of content, face, and consensual validity is indicated by the systematic procedure utilised in scale construction and the inspection of the final output by several colleagues. The limited evidence available indicates a high level of construct validity. Criterion validity is assessed by demonstrating a similarity between the SOC and assessments in four domains: a global orientation to oneself and one's environment; stresses; health, disease, and well-being; attitudes and behaviour. Correlations were statistically significant in the great majority of cases. The known groups technique is used to present all available published normative data on SOC-29 and SOC-13 [5].

Ramstad T et al., conducted a study on 233 Norwegian adults ageing between 20-35 years, who had completed their treatment for CL/P; of which 45 had cleft on the right, 126 had cleft on the left and 62 had cleft bilaterally [8]. The Oslo cleft palate team provided standardised care to all subjects. The questionnaire-based survey reflected a nationwide study of socio-economic lifestyles in the Norwegian population. Adult patients with complete clefts were studied in comparison to a large age-matched control group. The goal of the present study was to describe the occurrence of common psychological problems in CL/P patients.

A study was conducted on people with cleft lip or cleft lip and palate to assess their judgment patterns and coping methods to find its impact on the psychological well-being and social anxiety with the help of a questionnaire by Cochrane VM and Slade P (1999) [9]. The effects of the cleft were investigated on the basis of perceptions of consequences on individual and interpersonal aspects, as well as measurements of SOC, psychological well-being, levels of happiness, and how they coped in tough situations. The results were varied and there were a small number of individuals with remarkably extreme responses. A 75% of the individuals reported problems they believed to be due to their cleft. Positive responses were linked to happiness. Coping strategy patterns were linked to emotional adjustment thus concluding that individual assessments of patients with CL/P and facial appearance may be more important in determining emotional well-being of the patients.

Kamble R et al., carried out a study to evaluate the SOC in parents of the patients, undergoing treatment of CL/P [3]. A questionnaire

was distributed at time intervals of T0, T1, and T2 on 50 parents of children with CL/P. Most of the parameters were found to be statistically significant (p -value < 0.05). From T0 to T1, the subjective outcomes were determined to be non significant. It was concluded that orthodontic treatment had a good impact on the parents of patients with CL/P too. It was discovered that the parents' psychological, financial, emotional, and social well-being was affected positively.

According to Rajan AM and John R, parental resilience is receiving more attention, as a strategy for addressing their innate abilities to endure the possible pressure, that comes with raising a kid with an intellectual handicap [6]. Applications for fostering their resilience can be found in understanding its basic causes. The current study investigated the relationship between parents' resilience and the effects of children disability. A total of 121 parents in all, were evaluated using the Connor Davidson Resilience Scale and Disability Impact Scale of the National Institute for the Mentally Handicapped. The findings of his study showed that, they encountered both good and bad experiences while parenting a child with an intellectual handicap. Their assessments of the child's health had a big impact, on how resilient they were.

According to Sousa AD et al., rehabilitation and development of patients with cleft lip and cleft palate are impacted by social and vocational concerns [10]. However, psychological issues like low self-esteem and trouble interacting with others have also been observed in them.

MATERIALS AND METHODS

This prospective intervention study will be conducted in the Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, Maharashtra, India. The duration of the study will be two years. The study has been approved by the Institutional Ethics Committee (IEC) of Datta Meghe Institute of Medical Sciences, Deemed to be University with reference number DMIMS(DU)/IEC/2022/743.

Inclusion criteria:

- Patients having cleft lip and palate.
- Patients of over 14 years of age coming to the Outpatient Department (OPD).

Exclusion criteria:

- Patients below 14 years of age.
- Patients with syndromes affecting their Intelligence Quotient (IQ)
- Patients who have undergone revision surgeries.
- Daily wage workers, since they earn on a daily basis and the time invested during the study may have an impact on their day to day lives and their economical conditions.

Sample size calculation: The calculated sample size of 20 patients having cleft lip and palate undergoing orthodontic treatment will be selected for the study. Daniel formula for sample size estimation [11]:

$$n = \frac{Z_{\alpha}^2 \cdot P \cdot (1 - P)}{d^2}$$

where,

$Z_{\alpha/2}$ is the level of significance at 5% i.e., 95%

Confidence interval=1.96

P=Prevalence of cleft lip and palate=1.11%=0.011 [3]

d=desired error of margin=5%=0.05

$$n = \frac{1.96^2 \times 0.011 \times (1 - 0.011)}{0.05^2}$$

=16.86

n=20 patients needed in the study.

Study Procedure

Data will be gathered via questionnaires which will be distributed to patients. The questionnaires will be collected within 30 minutes and will be checked, if completed. Same questionnaires will be distributed to the patients at different points of time during the course of their treatment.

The SOC questionnaire was modified [3] according to the sample selected in English and modified into the regional language i.e., Marathi and Hindi. The questionnaire consisted of six parts. First part consists of demographic details the second part is subjective questionnaire. The third part is assessment of SOC using short version of SOC-13 (Antonovsky A, 1993) [5]. Negatively worded items will be reverse scored, so a high score indicated a strong SOC. The fourth part is patient's subjective experience with family. The fifth part will be family impact questions. The sixth part is regarding receipt of support from hospital staff during treatment. The validity and reliability scores of the questionnaire will be calculated after a pilot study [Annexure-1].

The questionnaire is a modified version of the questionnaire devised by Antonovsky A [12]. A similar questionnaire was used in the previous study by Kamble R et al., [3]. With the reference of the article published by Antonovsky A (1993) [5], the time intervals selected were:

- T0- At the time of reporting
- T1- After two months of treatment
- T2- After six months of treatment
- T3- After one year of treatment

The patients will be referred to the Department of Psychology for monthly counselling sessions and the psychological changes will then be assessed by the same questionnaires, which will be collected at different points of time. The questions will be scored and the total scores will be assessed.

Primary outcome: Undergoing orthodontic treatment along with psychologic counselling might have a positive impact on the patients undergoing treatment for cleft lip and palate.

STATISTICAL ANALYSIS

The SPSS statistical software (27.0) and Graph Pad Prism will be used to analyse the data (version 7.0). All descriptive and inferential data will be subjected to statistical analysis using the Chi-square test.

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PARTICULARS OF CONTRIBUTORS:

1. Postgraduate, Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India.
2. Head, Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India.
3. Professor, Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India.
4. Postgraduate, Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India.
5. Head, Department of Orthodontics and Dentofacial Orthopaedics, Rural Dental College, Pravara Institute of Medical Sciences, Loni, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dhwani Suchak,
102, Department of Orthodontics and Dentofacial Orthopaedics, Sharad Pawar Dental College, Sawangi (M), Wardha, Maharashtra, India.
E-mail: dj.suchak25@gmail.com

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