IMPACT OF EARLY CHILDHOOD CARIES ON ORAL HEALTH RELATED QUALITY OF LIFE ON YOUNG CHILDREN– A LONGITUDINAL STUDY

15. Chapter-7 Conclusion.docx

Dissertation

Submitted to

BABU BANARASI DAS UNIVERSITY

LUCKNOW, UTTAR PRADESH.

In the partial fulfilment of therequirements for the degree

Of

MASTER OF DENTAL SURGERY

In

PEDODONTICS AND PREVENTIVE DENTISTRY

By

Dr.NehaDubey

Under the guidance of

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Professor & Head

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

(Faculty of BabuBanarasi Das University)

BATCH: 2015-2018

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Background: The purpose of this study was to investigate effects of early childhood caries(ECC) on children's oral health-related quality of life (QOL) before and 4 weeks after its treatment, as assessed by the children themselves and by their parents/guardians.

Methods: This study included 200 children, 100 with ECC, 100 caries free and their parents/guardians responded to face-to-face surveys before dental treatment was started. 44 children with ECC completed dental rehabilitation. Four weeks after treatment, these 44 children and their parents/guardians responded to a second survey (follow-up assessment).The data was analyzed and evaluated using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical software and Chi square test.

Results: Children with ECC have significantly lower oral health related QOL than children without ECC as assessed by the children and the parents/ guardians at baseline. Children with ECC who received dental treatment had significantly improved oral health-related QOL at the follow-up assessment when compared with their baseline measurement as measured both with the children's self-ratings of oral health-related QOL and parents'/guardians' perception of their child's oral health related QOL.

The following Statistical formulas were used:

1. Mean, Standard Deviation,**Median**,**Chi square test,Student's' test**,**Mann-Whitney U test**.**Paired "t" test**, **The Wilcoxon signed rank statistic, Level of significance**:

Conclusions: ECC and its treatment affects children's oral health-related QOL significantly. Oral health-related QOL can be assessed reliably both in self-reports from pre-school and school going children and by asking parents/guardians about their perceptions of their child's oral health-related QOL.

Dental caries have an impact on a child's oral and general well-being throughout their lives. Dental caries is the single most common chronic childhood disease and children in many communities around the world are affected by it. Early childhood caries (ECC) is a particularly severe dental condition affecting many young children around the world. [1]

Pediatric patients differ from most adult patients in at least two significant ways. First, they do not necessarily self-regulate their behavior concerning health promotion and health care. It is the primary caregiver's responsibility to take care of these needs. The second major difference between children and adults is the qualitative difference between the perceptions and assumptions of children and adults about the world and their experiences.

Oral health means more than just healthy teeth. Oral health is a state of being free from mouth and facial pain, oral and throat cancer, oral infection and sores, periodontal diseases, tooth decay, tooth loss, and other diseases and disorders that limit an individuals capacity in biting, chewing, smiling, speaking, and psychosocial well-being.[2]

Oral Health Related Quality of Life is an integral part of general health and well – being and is recognized by the WHO as an important segment of the Global Oral Health Program. Despite its relatively recent emergence over the past few decades, oral health-related quality of life (OHRQoL) has important implications for the clinical practice of dentistry and dental research. With increasing focus of health policy to address health promotion and disease prevention, OHRQoL have incorporated both positive and negative perceptions of oral and general health outcomes. Oral disease and disorders during childhood can have a negative impact on the life of preschool children and their parents. The negative impact of ECC on children's life includes chewing difficulties, decreased appetite, weight loss, sleeping difficulties, change in behavior like irritability and low self-esteem and decrease in school performance.[3]

Early Childhood Caries (ECC) is considered as a serious public health problem as it is a complex disease of primary dentition which relays serious socio-behavioral issues that affect mainly the infants and toddlers.[4]

The American academy of pediatric dentistry defined early childhood caries as the presence of one or more decayed (non-cavitatedand cavitated),missing(due to caries),or filled tooth surfaces in any primary tooth in a child upto 71 months of age or younger.[5]

ECC is quite a debilitating disease which has social, behavioral, medical, psychological, economical and dental consequences that affects overall quality of life.ECC can begin early in life, progresses rapidly in those who are at high risk and often goes untreated. ECC can be particularly a virulent form of caries, beginning soon after dental eruption, developing on smooth surfaces, progressing rapidly and having long lasting detrimental impact on the dentition.

Children's quality of life can be seriously affected by severe caries because of pain and discomfort which could lead to disfigurement, acute and chronic infections, and altered eating and sleeping habits, as well as risk of hospitalization, high treatment costs, and loss of school days with the consequent diminished ability to learn. In most small children, ECC is associated with reduced growth and reduced weight gain due to insufficient food consumption to meet the metabolic and growth needs of children.

This interventional study was done with an aim to assess the effects of ECC on oral health-related QOL as reported by the children themselves as well as by their parents/guardians, to explore how the treatment of ECC affects the child patient's oral health-related QOL after they return to their "normal" life, and to develop multidimensional and differentiated scales for measuring children's self-reported oral health-related QOL as well as their parent's/guardian's proxy reports of their child's oral health-related QOL.

AIM

To evaluate the impact of early childhood caries on oral health related quality of life of pre-school and school going children .

OBJECTIVES

1. To assess the children's self-reported oral health related quality of life as affected by ECC.
2. To assess the parental perception of their child's oral health related quality of life.
3. To establish correlation, if any, between ECC and quality of life in children.

Despite of its relatively recent emergence over the past few decades, oral healthrelatedquality of life (OHRQoL) has important implications for the clinicalpractice of dentistry and dental research. OHRQoL is an integral part of generalhealth and well-being and is recognized by the WHO as an important segment ofthe Global Oral Health Program (WHO, 2003). [3]

OHRQoL is important for both theoretical and practical reasons. The Surgeon General'sreport and conference, *The Face of the Child*, highlighted the importance of children's oral health to their overall health , well-being and their profound impact thatoral health can have on children's Quality of Life (McGrath, *et al*.,2007).[6]OHRQoL researchhas shown its utility in the study of diverse populations includingpatients with oral cancer (Ship, 2002),[7,] toddlers with earlychildhood caries (ECC) or children withcraniofacial anomalies (Broder, 2007).[3]

In 1976 Cohen and Jago advocated the development of sociodental indicators to measure OHRQoL (Cohan &Jago 1976)[8].It includes how oral health affects -

• Aspects of social life

• Self-esteem

• Social interaction

• School performance

• Job performance

OHRQoL reflects people's comfort when eating, sleeping, and engaging in social interaction; their self-esteem; and their satisfaction with respect to oral health.It is the result of interaction between and among oral health conditions, social factors, contextual factors, and the rest of the body.

Contemporary concept of health suggests that oral health should be defined in terms of general, physical, psychological and social wellbeing in relation with oral status. The greatest contribution of dentistry is to improve quality of life.

Disruptions in physical, psychological and social functioning are therefore important measures in assessing oral health. Traditional measures use clinical indices, though there are alternative measures of oral health related quality of life in socio dental approaches for assessment.

The compartmentalization involved in assessing oral cavity separately from the rest of the body ceases because oral health affects general health by causing pain and altering the daily activities. Oral health has a strong impact on chronic diseases which causes the failure to tackle social and material determinants that incorporate oral and general health promotions.

Dental caries detracts children's quality of life: that includes pain, discomfort, disfigurement, acute and chronic infections, and eating and sleep disruptions. A high risk of hospitalization, high treatment costs and loss of school days with the consequently diminished ability to learn is majorly seen. Caries also affects nutrition, growth and weight gain.

ORAL HEALTH RELATED QUALITY OF LIFE

Cohen lk ,Jagojd in 1976 stated thatthe greatest contribution of dentistry is to improve quality of life. Disturbances in physical, psychological, and social functioning are therefore important in assessing oral health.[8]

Kleinman, 1988 stated that the concept of health status embraces the bio- psychosocial model of health into which symptoms, physical functioning, and emotional and social well-being are incorporated Oral Health Related Quality of life (OHRQoL).[9]

Sheiham A in 1982 said that a greater clinical focus on the measurement of quality of life as a complement to the assessment of oral health needs, the prioritization of care and evaluating the outcomes of treatment strategies.[10]

Hetherington E M in 1996 concluded that age specific self-report measures were required to accommodate differences in children's self-concept, understanding of feelings, and ability to interpret other people's behavior across the 6-14 year age range.[11]

Gaffney A in 1999 showed that children's report of their own oral health quality of life is an important diagnostic tool when assessing children's needs for dental care. These data provided support for child who argued that only children themselves can provide a subjective perspective of their oral health and their feelings about their oral health.[12]

US Dept of Health and Human Services in 2000 report on oral health revealed oral health disparities in US population is related to socio economic status, age, sex, race-ethnicity-medical status.[13]

Aleksandra Jokovic in 2004 said that oral health related quality of life measures functional and psychosocial disorders. It is now generally accepted in the research community that they are as essential as clinical indicators when assessing the oral health of individuals and populations, making clinical decisions, and evaluating dental interventions, services, and programs.[14]

Pahel et al 2007 reported that the assessment of quality of life has become integral part of evaluating health programs. Oral health related quality of life is a multidimensional concept related to the impact that poor oral health or disease has on the daily functioning, well being or quality of life of an individuals.[15]

IMPACT OF ORO DENTAL DISEASES ON ORAL HEALTH RELATED QUALITY OF LIFE

Sheiham&Croogin 1981 stated that many consequences of dental disease and dental condition not only involve the physical health but also economical, social and psychological well-being of individuals. Dental diseases are neither life threatening, nor seriously impairing the functioning of the majority of the patients. Instead, in various ways dental disease may hamper the capacity of an individual to live without pain, or physical discomfort to enjoy life, to engage in interpersonal relationship and to maintain favourable self -image etc.[16]

Nikias in 1985 stated that more common oral conditions, such as caries and periodontal disease, which are almost universal in prevalence, chronic but with acute recurring episodes must be of concern because they could also have an effect on the quality of life. The social and physical oral functioning dimensions of oral quality of life have been measured by work performance, school day lost, restricted activity and chewing and eating problems. [17]

Locker D et al in 1987 said that, pain is a common symptom of dental caries and oral conditions and has an immediate and profound impact on the quality of everyday life. It disrupts sleep, work, recreational and leisure activities and relationship with others.[18]

Hollister and weintraub1993 said that infections or a disease of the oral cavity requires as much attention as do the conditions in the other parts of the body. The treatment of dental disease may improve the overall health status if the pathway from the oral disease to systemic disease is interrupted. These oral disorders alter the quality of life by affecting the life style and by restricting activities of daily living. The individual may be affected psychologically as well as economically. These affected individuals must not only deal with the personal deformities that can affect the social

interactions or feeling of wellbeing, but extremely poor aesthetics may evoke negative responses from others.[19]

Strauss and Hunt in1993 stated that the effects of oral disorders on quality of life include pain, poor oral and facial aesthetics, and impairment to eating, chewing and speaking, a decrease desire to interact socially and/or a poor sense of wellbeing. Caries, periodontal disease, and oral cancers as well as functional disorders such as, xerostomia, edentulousness, cleft lip, cleft palate and severe malocclusion may compromise the quality of life. They obtained data from a large population based study of older individuals which showed that a poor dental state may be associated with feeling of reluctances to eat with others.[20]

Chen and Hunt in1996 stated that oral disease is a universal problem but life threatening. Oral disease like dental caries can have a significant impact on both social and psychological aspects of an individual's life. Oral health problems can adversely affect an individual's quality of life by impairing the physical functioning, social function and self-esteem. QOL, in general, relates to the satisfaction of the individual needs for growth, wellbeing, self-esteem, freedom and the pleasures of meaningful relationships and meaningful work.[21]

Reisine S and Douglass JM. In 1998 stated that despite the decline in the incidence of dental caries in many countries, the condition remained a significant problem for poor children. The prevalence of caries varies greatly in both developed and under developed countries and among socioeconomic groups in developed countries.[22]

World Health Organization reported in 2003 that dental caries is the most prevalent oral disease in several Asian and American countries, while it appears to be less common and less severe in most African countries. It is a major oral health problem in most industrialized countries, affecting 60-90% of school children.[23]

Oliveira LB in 2008 said that the negative impact of caries on children's lives include symptoms and functional alterations ,such as chewing and speech impairment, schooling factors such as preschool absentees, psychological issues ,such as trouble sleeping , irritability, among other factors related to social interaction, such as smiling and refraining from speaking.[24]

BiruteJankauskiene, JulijaNarbutaite in 2010 concluded that oral rehabilitation under GA resulted in the immediate improvement of children's oral health, physical, emotional and social quality of life. It also showed a positive impact on the family.[25]

Alsumait A et al in 2013 assessed the impact of children's dental health status (DHS) on their oral health-related quality of life (OHRQoL). They concluded that increase in the number of carious teeth were associated with a limitation in oral functions. Preventive treatment had a positive impact on children's emotional well-being and restorative treatments improved their oral functions.[26]

SudaduangKrisdapong in 2016investigated the caries experience and its impact on preschool children's quality of life and the associations between these outcomes and underlying determinants. It was found that 28% of children experienced high-level impacts on quality of life. Children of low socioeconomic status were more likely to have a high level of dental caries and subsequent OHRQoL impact.[27]

Rane JV in 2017 reported that dental caries have a significant impact on children's overall wellbeing. There was a considerable improvement with relation to eating preferences, amount of food intake, sleep and pain relief before and after dental treatment. There was no significant difference if the child was treated under general anesthesia or local anesthesia.[28]

IMPACT OF EARLY CHILDHOOD CARIES ON ORAL HEALTH RELATED QUALITY OF LIFE

Thomas CW, Primosch RE 1992 conducted a study for analysis of young children with early childhood caries that weighed less preoperatively. They demonstrated significant improvement postoperatively in percentile weight gain and quality of life. Results indicated a significant improvement in the quality of life of the children.[29]

AcsG, LodoliniG, Kaminski,Cisneros GJ in 1992 stated that severe caries distracts children's quality of life. They experience pain, discomfort, disfigurement, acute and chronic infections, and eating and sleep disturbance as well as high risk of hospitalization, high treatment cost and loss of school days with the consequently diminished ability to learn. Children with caries in 3 years of age weighed about 1 kg less than control group children because toothache and infection altered eating and sleeping habits, dietary intake and metabolic processes. [30]

Grindefjord M in 1995 concluded that the consequences of ECC include a higher risk of new carious lesions, hospitalizations and emergency room visits, increased treatment cost and time, delayed or insufficient physical development, loss of school days and increased days with restricted activity.[31]

Mark Piotrowski in 1999 stated that the incidence of early childhood caries is low, but their effects on individuals who develop this disease are severe. Early childhood caries consist of rapid decay of

the primary teeth which affects the well - being of the child. Treatment can be costly and sometimes it requires to be done under general anesthesia.[32]

Aces G in 2001 reported in earlier research on the relationship between early childhood caries and oral health related quality of life had shown that parents can perceive an improvement of their child well being after dental treatment.[33]

Filstrup SL et al in 2003 investigated the effects of early childhood caries on children's oral health related quality of life before and four weeks after its treatment, as assessed by the children themselves as well as by their parent/ guardians at baseline. The children with ECC who received dental treatment had significantly improved oral health related Quality Of Life at the follow up assessment when compared with their base line measurement as measured both with the children's self -rating of oral health related quality of life and the parents perception of their child's oral health related quality of life.[34]

S Acharyaand S Tondonin (2005) reported that children with early childhood caries had significantly lower oral health-related Quality of Life than children who were caries free.[35]

Sandra, Colares and Pinkham in 2005 analysed the psychological effects of severe caries in four years old children in Brazil. The clinical examination was conducted by a single examiner in children with severe caries and without caries. 861 children were examined and found that 77 had severe caries and 225 were caries free. Data were collected on the basis of questionnaires answered by parents and guardians .Most of the parents and guardians of affected children reported that their children complained of toothache, and a significant portion stated that their children had problems eating certain kinds of food, and missed school because of their teeth. Children with severe caries were found to have a negative impact on oral health related quality of life.[36]

A. Sheiham in 2006 concluded that severe dental caries affects young children's' growth and well-being. Severe untreated dental caries is common in pre-school children in many countries. Treating

dental caries in pre-school children would increase growth rates and the quality of life of millions of children. Children with severe caries were noticed more undernourished than caries-free, and after treatment of decayed teeth there was more rapid weight gain and improvements in their quality of life.[37]

Clarke M et al. 2006 reported that S-ECC may be a risk marker for iron deficiency anemia. Since iron deficiency has permanent effects on growth & development, so the study strongly suggested that S-ECC patients should have a complete blood count test, a serum ferritin test, a careful measurement of height and weight and a dietary intake assessment, preferably performed by a clinical dietitian.[38]

Foster T, Perinpanayagam in 2006 reported that treatment of ECC is important because untreated caries can lead to pain, sepsis and spreading infection, malnutrition due to the inability to eat, and poor general health.[39]

Livny A, Assali R, Sgan-Cohen H.in 2007 reported that ECC is a serious public health problem in both developing and industrialized countries. ECC can begin early in life, progresses rapidly in those who are at high risk, and often goes untreated. Its consequences can affect the immediate and long-term quality of life of the child and family, and can have significant social and economic consequences beyond the immediate family as well.[40]

Do LG, Spencer A in 2007 said that oral disorders can have a significant negative impact on the functional , social and psychological well being of young children and their families.[41]

Paul S. Casamassimo 2009 stated that, ECC exacts a toll on children, affecting their development, school performance and behavior, and on families and society as well. In extreme cases, early childhood caries and its treatment can lead to serious disability and even death. In finding access to

care and managing chronic pain and its consequences, families experience stress and, thus, a diminished quality of life.[42]

D.T. Cunnion in 2009 reported that children's oral health shows an impact on their well-being, as assessed by their parents. Children with early childhood caries were rated by their parents as worse oral health-related quality of life (QOL) than the caries-free children.. The positive effects of a dental intervention for ECC children are significant at 6- 12months follow-up, and enhance QOL in multiple domains.[43]

Ana Carolina Scarpelli 2011 said that oral disorders can have a negative impact on the functional, social and psychological wellbeing of young children and their families. Oral health-related quality of life has emerged as an important health outcome in clinical trials and health care research.[44]

D. Finucane in 2012 reviewed that early childhood caries had implications for both the dental and general health of the affected child. Such problems are potentially serious and even life-threatening. They provided the beneficial effects on dental and general health after dental rehabilitation of children with caries.[45]

Marcus HT Fung, May CM Wong, Edward CM Lo and CH Chu in 2013 reported that early childhood caries is a transmissible infectious disease, but these hazardous effects can be prevented by early effective interventions. Progression of early childhood caries can lead to pain and reduced ability to chew and eat, which may also lead to malnutrition and reduction of quality of life of children.[46]

Martins junior et al 2013 studied on 638 children aged 2-5 years and their parents in Brazil and concluded that ECC has a negative impact on OHRQOL of children and their parent.[47]

Simratvir Met al in 2013 reported that Early Childhood Caries is a serious public health problem in both developing and industrialized countries. ECC can begin early in life, progresses rapidly in those who are at high risk, and often goes untreated. Its consequences can affect the immediate and long-term quality of life of the child's family and can have significant social and economic consequences beyond the immediate family as well.[48]

Fernandes IB et al, 2014 conducted a cross-sectional study to evaluate the impact of untreated caries in different stages on the oral health related quality of life (OHRQoL) in one- to three-year-olds children and their families. They concluded that untreated caries in advance stages were associated with poorer quality of life among children and their families.[49]

Abanto J et al in 2014 concluded that dental caries, without traumatic injuries , was associated with worse OHRQoL in 5to 6 years old children in terms of perceptions to both children and their parents. Families with higher income reported better OHRQoL at this age, independent of the presence of oral diseases.[50]

MonalisaCesarino Gomes in 2014 concluded that cavitated lesions on anterior and posterior teeth , traumatic dental injuries and parents /caregivers perception of their child's oral health as poor are determinants of negative impact on the oral health related quality of life of preschool children and their families.[51]

Garcia R in 2015 concluded that the severity of early childhood caries has a negative impact on the oral health-related quality of life of preschool children and their parents.[52]

P Arrow et al 2016 showed that the Child Oral Health Related Quality Of Life improve with primary dental care for early childhood caries ,and there was no statistically significant difference between test and control group in the extent of improvement.[53]

ValérieCollado, in 2017 studied that children with ECC experienced significant OHRQoL alterations in the symptomatic, functional and psychological domains and in the parents' distress domain. After rehabilitation, the quality of life of children with ECC improved drastically compared to the preoperative evaluation.[54]

This interventional study was carried out in the Department of Pedodontics and Preventive Dentistry Babu Banarasi Das College Of Dental Sciences, BBD University, Lucknowafter a thorough review and approval by institutional research ethical committee of BabuBanarasi Das College Of Dental Sciences, (annexure-1), in which we evaluated the effect of early childhood caries on quality of life of children and their parents.

Inclusion criteria:

1- Childrenbetween 3-5 years of age, free from any carious lesion.

2- Children between 3-5 years of age with ECC and atleast onetooth pulpally and 2-4 maxillary teeth involved.

3- Children with ASA class I health status .

Exclusion criteria:

1. Children whose parents were not willing to participate in the study.

2. Children with chronic systemic diseases.

SAMPLE SIZE:

The study consisted of 200 children between 3 to 5 years of age and their parents.

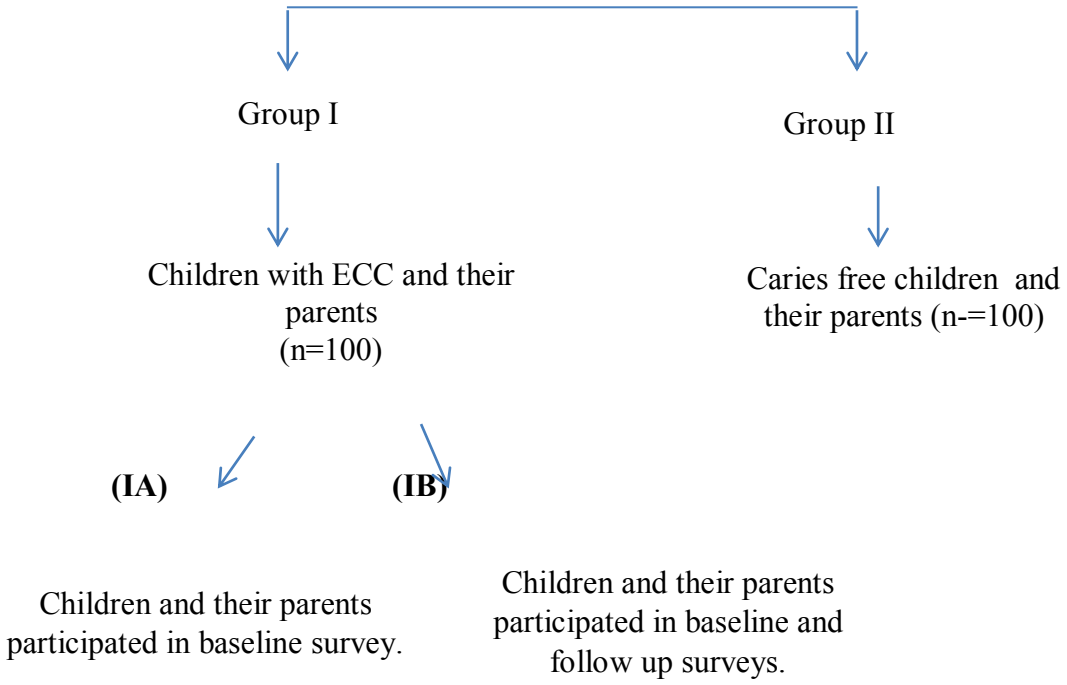
The children were divided into two groups:

GROUP 1 (Caries Group):

100 childrenwith ECC and their parents.

GROUP 2 (Control Group):

100 caries free children and their parents.



ARMAMENTARIUM:

1.Mouth Mirror

2.Probe

3.Explorer

4.Tweezer

5.Kidney tray

6.Cotton and Gauze pieces

7.Disinfectant for instruments

8.Weighing machine

9.Height measuring tape

METHODOLOGY:

This interventional study evaluated the effect of ECC on children's oral health-related quality of life and parents' /guardians' perceptions of their child's oral health-related QOL. 200 children and parents/guardians were reported at the Department of Pedodontics and Preventive Dentistry at Babu Banarasi Das Dental College , BBD University Lucknow.

Healthy children (ASA 1) in the age group of 3-5 years were included in the study. The respondents categorized into two groups. Group I consisted of 100 children diagnosed with ECC and their parents/guardians who participated in the baseline and follow-up surveys. Group II was the control group. It comprised of 100 caries free children in the same age range

as the children in the ECC group I. Children in group I were subdivided into two groups –I A and I B. Group I A children and their parents participated in baseline survey and group I B participated in both baseline and follow up survey. To analyze whether children with ECC differ in their oral health-related QOL from children without ECC and whether the parents'/guardians' evaluations of their child's oral health-related QOL differ for these two groups.If the child fulfilled the criteria, the principal investigator would inform the parent/guardian about the current study and obtain formal consent for participation. All child and parent/guardian baseline and follow-up surveys were conducted in face-to face interviews. The baseline data of the children and parents/guardians in groups I (Group A and Group B) were combined and compared with the data of the respondents in Group II.

Michigan oral health related quality of life scale-child and parent version, was used in this study. The questionnaire was given in English which was translated in Hindi too for the convenience of the children and their parents. Responses were either 'yes' or 'no' for child version and responses were given on 5-point rating scale,ranging from 1=strongly disagree to 5=strongly agree for parents/guardians.

Calculation of index:

Total no of decay surfaces=d

Total no of missing surfaces=m

Total no of filled surfaces=f

The data was analyzed and evaluated using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical software and Chi square test.

$$t = \frac{\overline{X}_1 - \overline{X}_2}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

where $S^2 = \frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2}{N_1 + N_2 - 2}$

where $\overline{X}_1$, $\overline{X}_2$ are means of group 1 and group 2

N_1, N_2 are number of observation group1 and group 2

SD_1, SD_2 are standard deviation in group1 and group 2

STATISTICAL ANALYSIS

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical analysis software. The values were represented in Number (%) and Mean±SD.

The following Statistical formulas were used:

1. Mean: To obtain the mean, the individual observations were first added together and then divided by the number of observation. The operation of adding together or summation is denoted by the sign Σ.

The individual observation is denoted by the sign X, number of observation denoted by n, and the mean by $\overline{X}$.

$$\overline{X} = \frac{\Sigma X}{\text{No. of observations (n)}}$$

2. Standard Deviation: It is denoted by the Greek letter σ.

$$\sigma = \sqrt{\frac{\Sigma (X - \overline{X})^2}{n}}$$

3.Median: For the distribution with odd number of data point, the middle value on arranging the data in ascending or descending manner. For a series with even number of data points, average of two consecutive middle values were taken as the median value.

4.Chi square test:

$$\chi^2 = \sum \frac{(O-E)^2}{E}$$

Where O = Observed frequency

E = Expected frequency

5.Student's' test: To test the significance of two means, the student 't' test was used

$$t = \frac{\overline{X}_1 - \overline{X}_2}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

$$\text{where } S^2 = \frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2}{N_1 + N_2 - 2}$$

where $\overline{X}_1$, $\overline{X}_2$ are means of group 1 and group 2

N_1, N_2 are number of observation group1 and group 2

SD_1, SD_2 are standard deviation in group1 and group 2

6.Mann-Whitney U test: The value of U in this test is calculated in following manner:

$$U_a = n_a n_b + \frac{n_a(n_a+1)}{2} - \sum R_a$$

and

$$U_b = n_a n_b + \frac{n_b(n_b+1)}{2} - \sum R_b$$

7.Paired "t" test: To compare the change in a parameter at two different time intervals paired "t" test was used.

$$t = \frac{d_{av}}{SD/\sqrt{N}}$$

Where:

d_{av} is the mean difference, i.e. the sum of the differences of all the datapoints (set 1 point 1 - set 2 point 2, ...) divided by the number of pairs

SD is the standard deviation of the differences between all the pairs

N is the number of pairs.

8. The Wilcoxon signed rank statistic W+ is computed by ordering the absolute values |Z1|, ..., |Zn|, the rank of each ordered |Zi| is given a rank of Ri. Denote where I(.) is an indicator function. The Wilcoxon signed ranked statistic W+ is defined as

$$W_+ = \sum_{i=1}^{n} \phi_i R_i$$

$$Z = \frac{(W - \mu_W) \pm 5}{\sigma_W}$$

$$\sigma_W = \sqrt{\frac{[N(N+1)(2N+1)]}{6}}$$

where μ_w is the mean of population.

9.Level of significance: "p" is level of significance

p> 0.05	Not significant
p <0.05	Significant
p <0.01	Highly significant
p <0.001	Very highly significant

RESULTS

The present study was carried out with an aim to study the effect of ECC on Oral Health related quality of life of children with child and parent perspectives. For this purpose, a total of 200 children falling in the sampling frame were enrolled. Group wise distribution of children is as follows:Group I consisted of 100 children diagnosed with ECC and their parents/guardians who participated in the baseline and follow-up surveys. Group II was the control group. It comprised of 100 caries free children in the same age range as the children in the ECC group I. Children in group I were subdivided into two groups - A and B. Group A children and their parents participated in baseline survey and group B participated in both baseline and follow up survey.

Table 1: Group wise distribution of children enrolled in study

SN	Group	Description	No. of children	Percentage
1.	Cases	100 children with ECC and their parents.	100	50
2.	Controls	100 caries free children and their parents	100	50

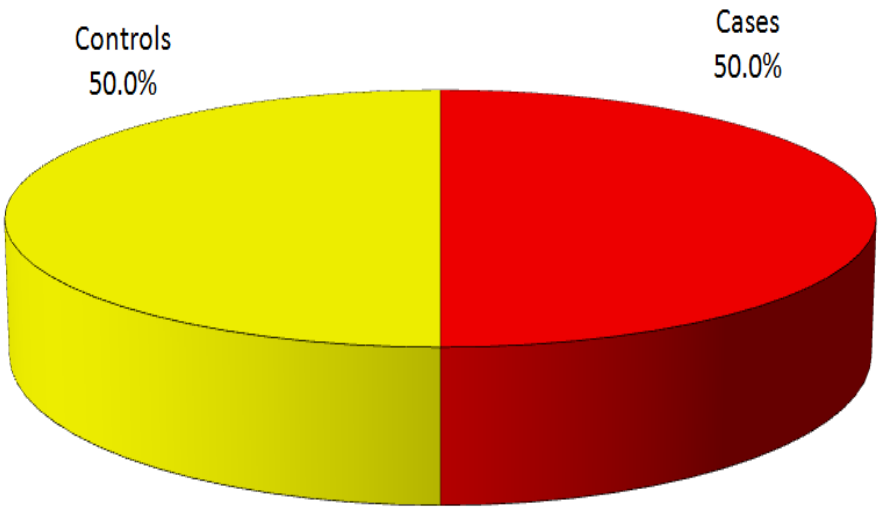


Fig. 1: Pie diagram showing distribution of study population

Out of 200 children enrolled in the study, a total of 100 (50%) were cases having early childhood caries and remaining 100 were caries free children comprising the control group of the study.

Table 2: Comparison of Clinical Parameters between two groups

SN	Parameter	Cases (n=100)		Controls (n=100)		Statistical significance	
		No.	**%**	**No.**	**%**	**χ^2**	**'p'**
1.	Gender						
	Male	56	56	56	56	0	1
	Female	44	44	44	44		
		Mean	**SD**	**Mean**	**SD**	**'t'**	**'p'**
1.	Age (Years)	4.79	1.11	4.82	0.97	-0.203	0.839

2.	Height in cm	84.90	9.60	85.76	9.43	-0.639	0.524
3.	Weight in kg	15.53	2.67	14.95	2.92	1.467	0.144

Fig. 2.1:

Comparison of gender between two study groups

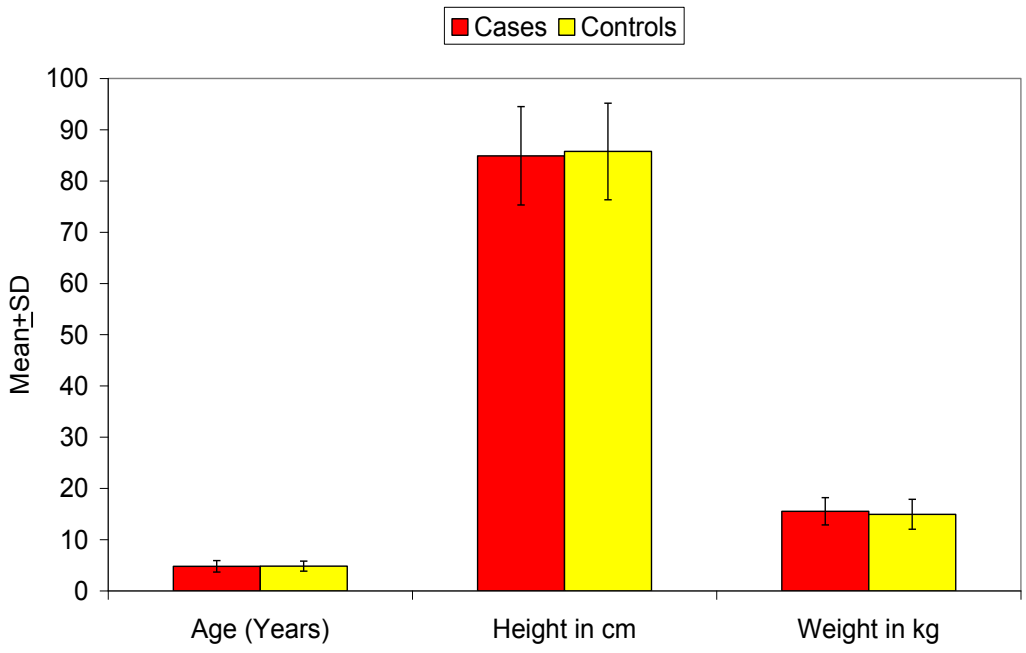


Fig. 2.2: Comparison of age, height and weight between two study groups

The two groups had a perfect gender matched study population with 56% males and 44% females.

Mean age, height and weight of cases was 4.79±1.11 years, 84.90±9.60 cm and 15.53±2.67 kg respectively as compared to 4.82±0.97 years, 85.76±9.43 cm and 14.95±2.92 kg respectively in controls. Statistically, for all the three parameters the two groups did not show a significant difference ($p>0.05$).

Table 3: dmft Status of Cases

	N	Minimum	Maximum	Mean	Std. Deviation
dmft score	100	2	20	6.34	3.05

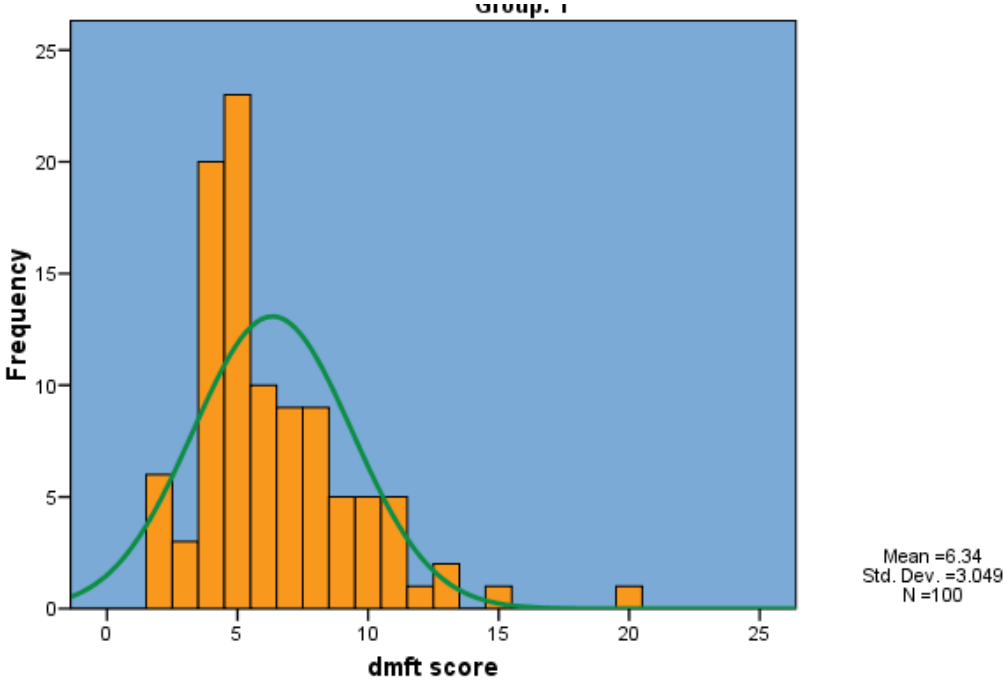


Fig. 4: Histogram showing dispersion of dmft score among cases

Among cases, dmft scores ranged from 2 to 20 with a mean of 6.34±3.05.

Table 4: Itemwise Comparison of Quality of Life Scores as perceived by Parents

SN	Item	Cases (n=100)			Controls (n=100)			Statistical significance	
		Mean	SD	Md	Mean	SD	Md	'z'	'p'
1.	Difficulty in chewing	2.92	1.47	4	1.05	0.22	1	9.98	<0.001
2.	Difficulty in biting	3.03	1.39	3	1.04	0.20	1	11.32	<0.001
3.	Sensitivity to hot and cold	3.07	1.17	3	1.09	0.29	1	11.25	<0.001
4.	Sensitivity to sweet food	2.67	1.17	2	1.07	0.26	1	10.81	<0.001
4.	Toothache or pain now	3.50	1.27	4	1.04	0.20	1	11.64	<0.001
6.	Toothache resulting into night awakening	2.98	1.46	2	1.17	0.38	1	9.90	<0.001
7.	Happy with his /her teeth (reversed)	3.46	1.10	4	1.12	0.33	1	12.08	<0.001
8.	Complains about teeth	3.44	1.22	4	1.05	0.22	1	11.91	<0.001
9.	Barrier in playing	2.51	1.16	2	1.01	0.10	1	10.99	<0.001
10.	Barrier in school learning	2.33	1.21	2	1.04	0.32	1	9.99	<0.001
11.	Your's child feel shy, in presence of people.	2.89	1.46	3	1.03	0.17	1	10.08	<0.001
12.	Your's child have any problem while cleaning the teeth .	2.91	1.56	3	1.03	0.17	1	9.85	<0.001

Md = Median; *Higher scores depict poorer quality of life.The responses were given on a 5-point rating scale ranging from 1="disagree strongly" to 5="agree strongly. "The responses to the question "My child is happy with his/her teeth" were reversed to achieve unidirectional.*

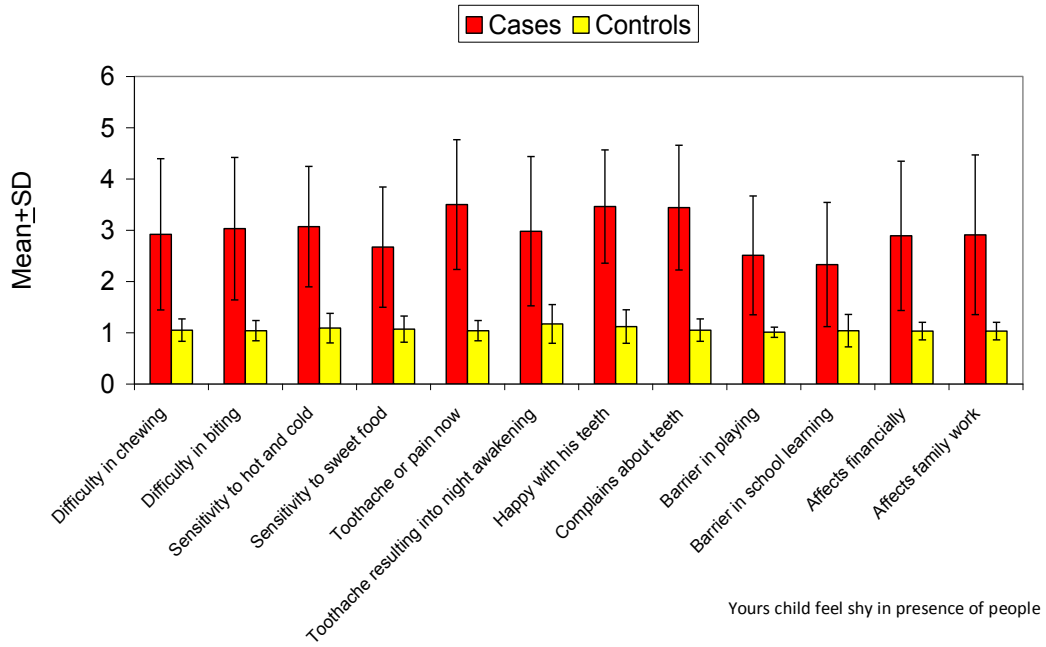


Fig. 5: Comparison of Itemwise Quality of Life Scores between cases and controls

For all the items mean scores of cases were significantly higher as compared to that of controls.

Table 5: Comparison of Total QOL Scores between cases and controls

SN	Group	Min	Max	Mean	SD	Median
1.	Cases	12	58	35.69	10.72	38
2.	Controls	10	23	12.74	1.84	12

$z=11.852$; $p<0.001$

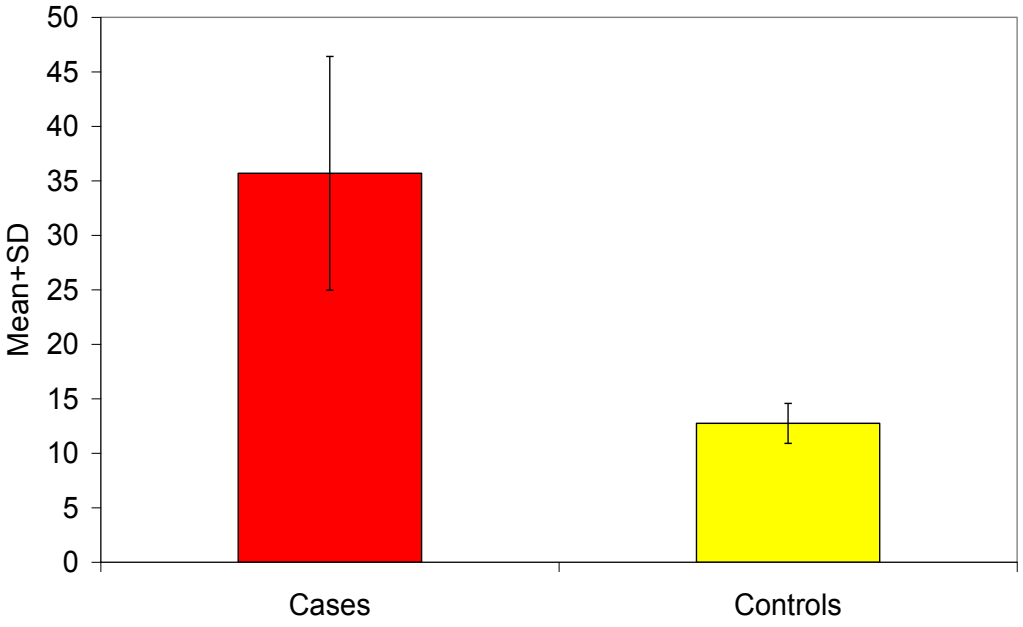


Fig. 6: Comparison of Total QOL Scores between cases and controls

Among cases, total QOL scores ranged from 12 to 58 with a mean of 35.69±10.72. Median value was 38.

Among controls, total QOL scores ranged from 10 to 23 with a mean of 12.74±1.84. Median value was 12.

On evaluating the data statistically, the total QOL scores of cases were found to be significantly higher as compared to that of controls ($p<0.001$).

Table 6: Itemwise Comparative Evaluation of Children's Quality of Life Perceptions between cases and controls

SN	Item	Cases (n=100)		Controls (n=100)		Statistical significance	
		No.	%	No.	%	χ^2	'p'
1.	Teeth hurting at time of evaluation	74	74	0	0	117.46	<0.001
2.	Hurt when eat hot/cold	48	48	0	0	63.16	<0.001
3.	Hurt when eat sweet	23	23	0	0	25.99	<0.001
4.	Hurt when wake up at night	41	41	0	0	51.57	<0.001
5.	Hurting tooth stops from playing	27	27	0	0	31.21	<0.001
6.	Hurt when chew and bite	66	66	0	0	98.51	<0.001
7.	Like your teeth	52	52	100	100	63.16	<0.001
8.	Happy with teeth and smile	38	38	100	100	89.55	<0.001
9.	Kids make fun of your teeth	53	53	0	0	72.11	<0.001

The responses to the questions "Do you like your teeth?" and "Are you happy with your teeth and smile?" were reversed to achieve unidirectional scores.

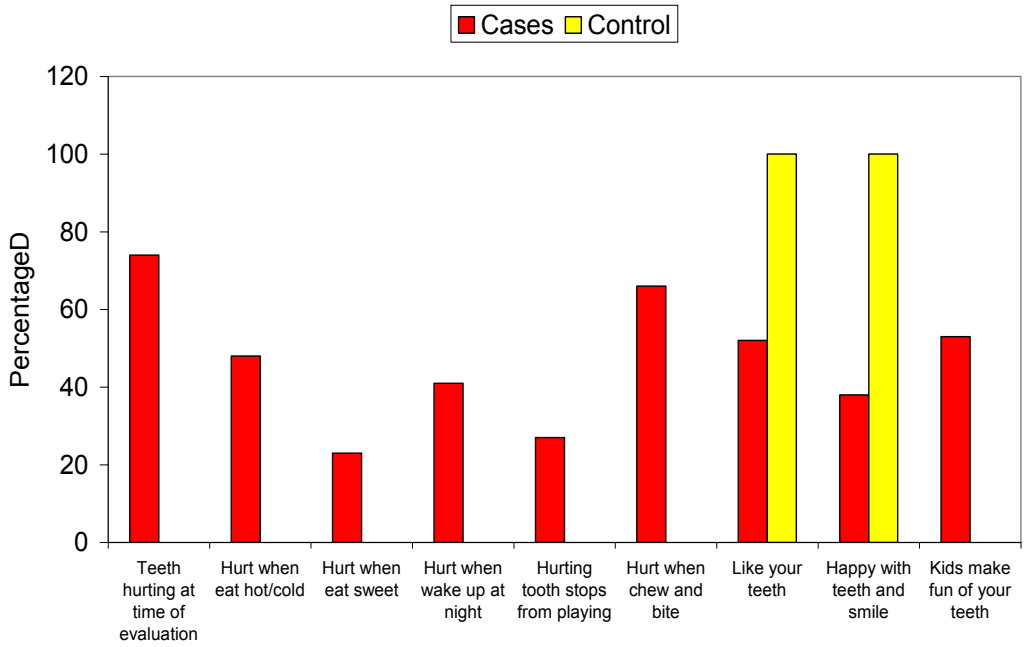


Fig. 7: Itemwise Comparative Evaluation of Children's Quality of Life Perceptions between cases and controls

For all the items, except items "like your teeth" and "happy with teeth and smile", the case group children answered response in "No". Both items"like your teeth" and "happy with teeth and smile", were positive in nature. For both these items all the children in control group provided response "Yes". For other items which were negative in nature, although no affirmative response was obtained from controls however, among cases, the affirmative responses were obtained from 27% (hurting tooth stops from playing) to 74% (teeth hurting at the time of evaluation). Overall, a significant difference between two groups was observed for all the negative items.

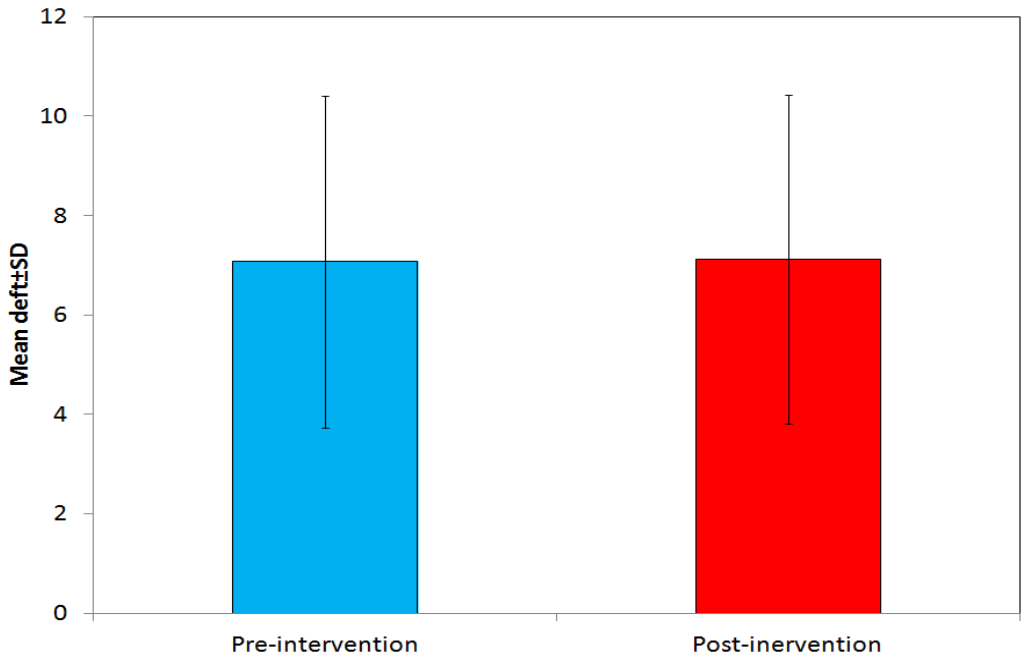
Intervention

Out of the 100 ECC respondents who participated in the study, 44 completed both the baseline and follow-up surveys, while 56 completed only the baseline survey. Table 7 below shows post-intervention dmft assessment.

Table 7: Post-Intervention Evaluation of dmft and its comparison with baseline dmft in intervention group of cases (n=44)

	N	Minimum	Maximum	Mean	Std. Deviation
Before-intervention	44	2	20	7.07	3.337
After-intervention	44	2	18	7.01	3.302
Mean Change = 0.05±0.267 (% Change = 6%)					

't'=0.028; p=0.978 (Paired 't'-test)



Before intervention mean dmft was 7.07±3.337. Following intervention, mean dmft was 7.01±3.302, thus showing a mean change of -0.05±0.267 (% Change 0.6%). Statistically, this change was not significant (p=0.978).

Table 8: Itemwise Comparison of Quality of Life Scores as perceived by Parents

SN	Item	Before intervention (n=44)			After intervention (n=44)			Statistical significance	
		Mean	SD	Md	Mean	SD	Md	'z'	'p'
1.	Difficulty in chewing	3.25	1.48	4	1.18	0.39	1	-5.119	<0.001
2.	Difficulty in biting	3.57	1.35	4	1.20	0.41	1	-5.360	<0.001
3.	Sensitivity to hot and cold	3.39	0.99	3	1.20	0.41	1	-5.516	<0.001
4.	Sensitivity to sweet food	3.20	1.11	3	1.25	0.46	1	-5.362	<0.001
5.	Toothache or pain now	3.68	1.12	4	1.34	0.48	1	-5.585	<0.001
6.	Toothache resulting into night awakening	3.34	1.31	4	1.34	0.48	1	-5.247	<0.001
7.	Happy with his/her teeth	3.25	0.94	3	1.61	0.69	1.5	-5.152	<0.001
8.	Complains about teeth	3.68	0.98	4	1.95	0.78	2	-5.262	<0.001
9.	Barrier in playing	2.84	1.10	3	1.45	0.50	1.5	-4.768	<0.001
10.	Barrier in school learning	2.67	1.16	2	1.50	0.51	1	-4.617	<0.001
11.	Your's child feel shy, in presence of people.	3.89	0.84	4	1.70	0.55	2	-5.698	<0.001
12.	Your's child have any problem while cleaning the teeth .	4.16	0.86	4	1.75	0.53	2	-5.794	<0.001

Md = Median; *Higher scores depict poorer quality of life. The responses were given on a 5-point rating scale ranging from 1="disagree strongly" to 5="agree strongly. "The responses to the question "My child is happy with his/her teeth" were reversed to achieve unidirectional.*

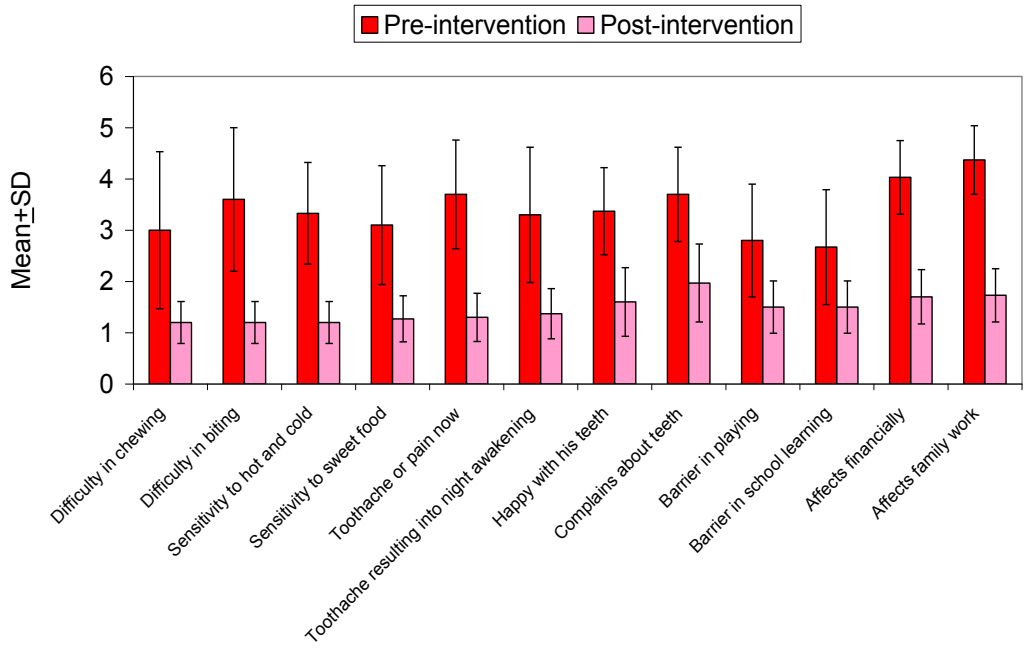


Fig. 8: Comparison of Itemwise Quality of Life Scores between pre-intervention and post-intervention time intervals

For all the items mean scores of post-intervention interval were significantly lower as compared to that of pre-intervention values ($p<0.001$).

Table 9: Comparison of Change in Total QOL Scores following intervention (n=44)

SN	Group	Min	Max	Mean	SD	Median
1.	Pre-intervention	22	58	41.00	8.11	41.5
2.	Post-intervention	12	24	17.45	3.79	17.5
Mean Change±SD = -23.55±9.65 (% Change = 57.4%)						

$z=5.778$; $p<0.001$ (Wilcoxon signed rank test)

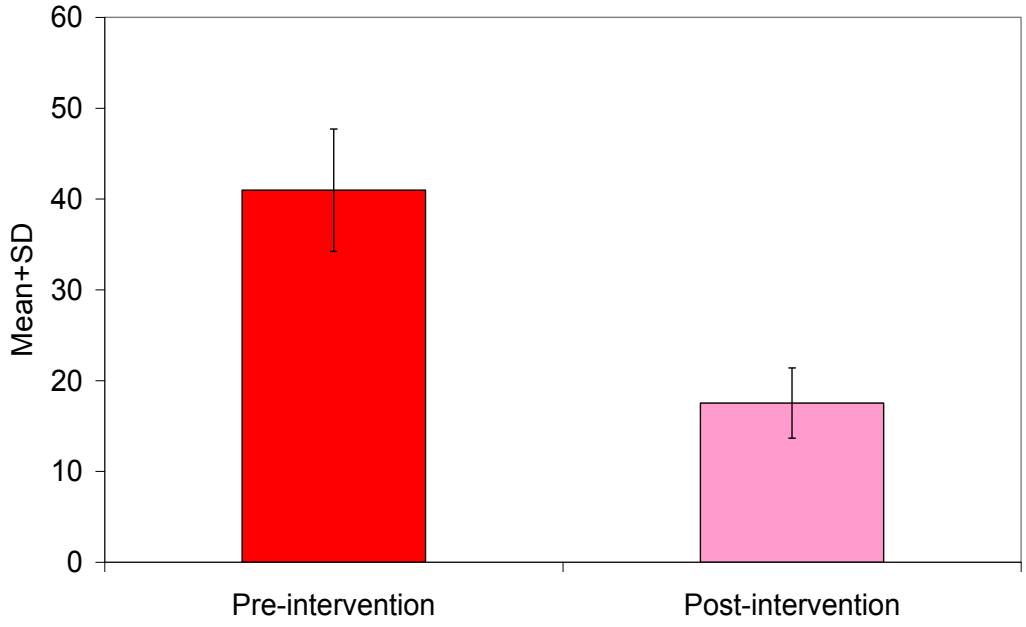


Fig. 9: Comparison of pre- and post-intervention Total QOL Scores

Prior to intervention, mean parental QOL scores were 41.00±8.11 which declined to reach at 17.45±3.79 following intervention, thus showing a mean decline of 23.55±9.65, *i.e.* a mean change of 57.4%. Statistically, this change was significant ($p<0.001$).

Table 10: Itemwise Comparative Evaluation of Children's Quality of Life Perceptions between pre-intervention and post-intervention time intervals in intervention group

SN	Item	Before intervention (n=44)		After intervention (n=44)		Statistical significance	
		No.	%	No.	%	χ^2	'p'
1.	Teeth hurting at time of evaluation	32	72.7	0	0	34.74	<0.001
2.	Hurt when eat hot/cold	24	54.5	0	0	21.82	<0.001
3.	Hurt when eat sweet	13	29.5	0	0	10.59	<0.001
4.	Hurt when wake up at night	23	52.3	0	0	25.71	<0.001
5.	Hurting tooth stops from playing	18	40.9	0	0	18.26	<0.001
6.	Hurt when chew and bite	30	68.2	0	0	37.30	<0.001
7.	Like your teeth (reversed–"no")	38	86	0	0	60.00	<0.001
8.	Happy with teeth and smile. (reversed–"no")	32	71.5	0	0	60.00	<0.001
9.	Kids make fun of your teeth	21	47.7	0	0	15.56	<0.001

The responses to the questions "Do you like your teeth?" and "Are you happy with your teeth and smile?" were reversed to achieve unidirectional scores.

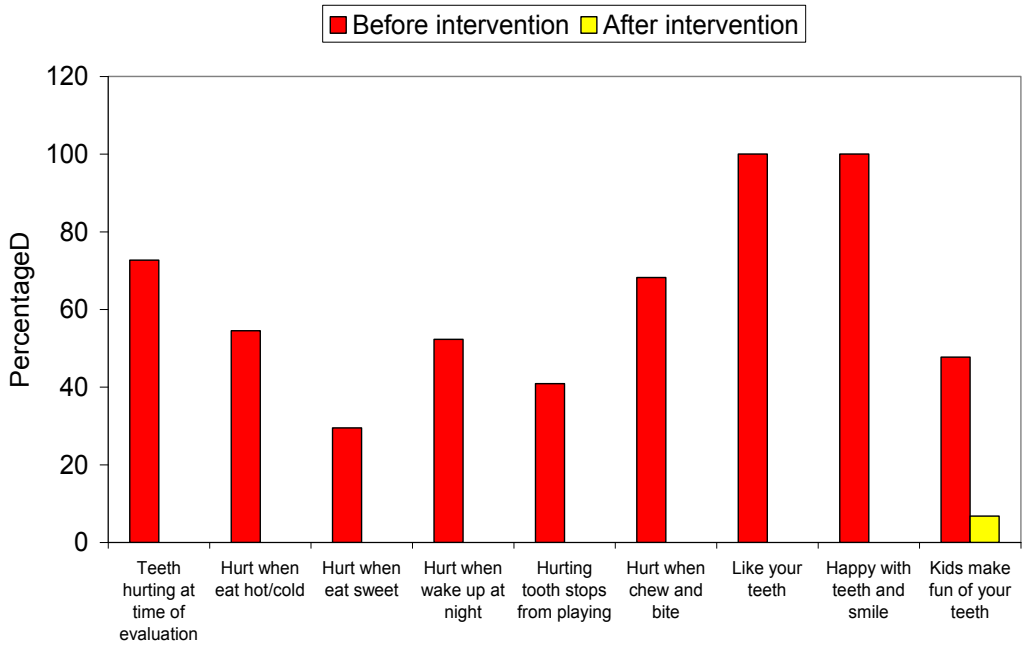


Fig. 10: Itemwise Comparative Evaluation of Children's Quality of Life Perceptions between cases and controls

Pre-intervention except items "like your teeth" and "happy with teeth and smile", the control group children answered response in "No". Both these items"like your teeth" and "happy with teeth and smile", were positive in nature. For which all the children provided response "Yes". For other items which were negative in nature, the proportion of affirmative responses ranged from 29.5% (Hurt when eat) to 72.7% (hurt when chew and bite). Following intervention, for all the items no affirmative response was observed except, items like kids make fun of your teeth where 3 (6.8%) children responded in affirmative. Statistically, for all the items, the change was significant.

"*Human beings are not being passive creature and they are constantly undergoing changes*"

Oral Health Related Quality Of Life is a concept that describes the impact of the oral health status on general health and everydaylife. Measuring children’s OHRQOLenables to evaluate the child’s oral health status and treatmentefficiency. The present study emhpasises on the fact that oral healthis often neglected as a factor affecting OHRQOL in children.Most of thes childrenaffected by ECC havea poor OHRQOL as perceived by them as well as by their parents.

Based on this study's results, the following conclusions were drawn:

1. Children's self-reported oral health related QOL significantly correlated with their oral health.
2. Parents were able to correlate child’s QOL with ECC.
3. Childrenwith early childhood caries (ECC) had significantlypoor oral health-related quality of life (QOL) than caries-free children.
4. Children with ECC had significant improvement in OHRQOL after treatment.

Dental caries remains one of the most prevalent diseases of childhood irrespective of the efforts to improve its prevention and management. Pediatric patients differ from adult

patients as they cannot self- regulate their oral hygiene so it is the parent's responsibility, to maintain their oral hygiene.

According to the child psychology, (Cognitive theory – Jean Piaget 1952)the age 2-6 years is a landmark for inception of abstract thinking and building of own self-image[55]. At this age, children start comparing their physical characteristics and personality traits with those of other children .Their ability to make judgments about their appearance, the quality of their friendships, their thoughts, their emotions and the behavior of others also develops gradually at this age.

The idea of aestheticslinked to the health, now begins to be incorporated in the mind of the child, interfering with his /her concept of self-esteem.[56]

ECC encompasses all dental caries occurring in primary dentition, in young children from birth to 71 month of age. Early childhood caries can have a negative impact on the functional, social and psychological well- being of young children and their families, causing pain and discomfort to the child.[57]

This interventional study was conducted to analyse whether oral health-related quality of life was found impaired in ECC children. 200 preschool and school going children and their parent/guardian reported to Outpatient Department of Pedodontics and Preventive Dentistry at BabuBanarasi Das Dental College , BBD University Lucknow, were enrolled in the study.

Healthy children (ASA 1) in the age group of 3-5 years were included in the study. The respondents were categorized into two groups. Group I consisted of 100 children diagnosed with ECC and their parents/guardians .Group II was the control group that comprised of 100 caries free children. Children in group I were subdivided in two groups I A

and I B. Group I A consisted of 56 children who completed only baseline survey while group I B consisted of 44 children who completed both baseline and follow up survey.

The baseline data of the children and their parents/guardians in groups I were combined and compared with the data of the respondents in group II.

Out of the 100 ECC respondents who participated in the study, 44 completed both the baseline and follow-up surveys, while 56 completed only the baseline survey. Out of the 56 respondents who completed the baseline survey, 46 children could not complete the treatment till assigned date and 10 children completed the treatment but did not report for the 1-month follow-up survey.

OHRQoL plays an important role in understanding subjective patient evaluations of and experience with oral healthcare. The subjective evaluations of OHRQoL reflect people's comfort when eating, sleeping and engaging in social interaction; their self-esteem, and their satisfaction with respect to their oral health. Incorporating OHRQoL creates a shift from traditional medical/ dental criteria to assessment and care that focus on a person's social and emotional experience and physical functioning. [58,59]

Michigan Oral Health-related Quality of Life Scale was used in this study that was applied for both child and parent. On evaluation, responses obtained were either "yes" or "no" for child's version. A 5-point rating scale ranging from 1-"strongly disagree" to 5-"strongly agree" was used for Parent/Guardian Version.

A similar study was done by Filstrup et al (2003)to investigate the effects of early childhood caries (ECC) on children's oral health- related quality of life (QOL) before and 4 weeks after its treatment. The questionnaire was available in English language only. They used Michigan oral –health related quality of life scale which originally had seven questions each for child and parent. In their study, modifications with nine questions for child and ten

for parents were done on the basis of impact of ECC on children's parents . It showed no effects for ECC on the quality of life of parents. [34]

In the present study, nine questions for child and twelve for parents were chosen which consisted of the same variables as taken in Michigan questionnaire.Further modification in questionnaire given by Filstrup et al was done in the present study that included two more questions to assess the effect of ECC on children'squality of life. It is important to explore whether children themselves perceive their own QOL as impaired by ECC and whether they themselves are able to communicate their own oral health related QOL. This study was, therefore, designed to assess the child's self-reported oral health related QOL as well as the parent's/guardian's perception of their child's oral health-related QOL. Immediately following dental rehabilitation, a child and parent/guardian may be tuned into the fact that the child's disease was treated and thus evaluate the child's oral health-related QOL in an optimistic manner despite the fact that a clear improvement may only follow consequently over a period of time. To assess the child's actual oral health-related QOL after dental rehabilitation, this study measured the child's self-reported oral health-related QOL and the parent's/guardian's proxy assessment of the child's oral health-related QOL 4 weeks after the dental rehabilitation when the child had returned to life's routines(Guyatt et al., 1997; Theunissen et al., 1998; Parsons et al., 1999; Le Coq et al., 2000). Since recent researches have demonstrated that children's reports of their health-related quality of life are valid and reliable, child questionnaires should always be used in the documentation of outcomes of specific clinical conditions.[62,63,64,65]

In presentstudy the population targeted were the children between 3-5 years with mean value of 51.18 months (Group I) and 52.94 months (Group II) as below 3 years children won't be able to participate in the study and will not be responsive to the questionnaire framed.

Filstrup et al in 2003 conducted a similar study on 112 children with same age group , with mean value of 50.4 months .

A comparison was done between these two groups on the basis of clinical parameters. Study population included 56% males and 44% females in both caries and control group. Mean age was 4.79±1.11 years, height was 84.90±9.60 cm and weight was 15.53±2.67 kg in case group . In control group mean age was 4.82±0.97 years, height was 85.76±9.43 cm and weight was 14.95 ±2.92 kg respectively . Statistically, all the three parameters of two groups showed no significant difference ($p>0.05$).

In our study,the mean weight of children was more in group I (caries group) in comparison with group II (control group),which can be attributed to the improper diet habit of children of caries group.

Acs et al in 1999 studied on 115 children with early childhood caries (ECC) weighed significantly less than caries-free children. They found 8.7% had significant weight loss due to caries in children.[33]

In the present study the dmft scores ranged from 2-20 with a mean of 6.34 ±3.05. This was similar to mean dmft 6.32 in study done by AcharyaS,Tandon S in 2011.[35] Comparison of total QOL scores between cases and controls was done. The overall mean score for the effect of ECC on QOL was 35.69±10.72, while in the control group, total QOL mean score was 12.74±1. On statistical evaluation, the total QOL scores of cases were found to be significantly higher as compared to that of controls ($p<0.001$).

In present study for difficulty in chewing, biting, due to caries , the mean value for group I were 1.09 and mean value for group II were 2.9 which was found to be highly significant ,that resulted as highly poor impact of ECC on oral health related quality of life of children. A similar study was done by Filstrup et al in 2003 with mean value of 1.08, for caries free group and 2.61 for caries group for the same questionnaire.

In present study, 41% of children had problem in sleeping because of pain. In a similar study,Low,Tan and Schwartz in 1999,evaluated 77 children (age 35-66 months, mean=44 months) with caries and resulted that 35% children had shown problem in sleeping. Another study was done by AcharyaS,Tandon S[35] where they found 44% children had effect on sleep due to caries.

In our study 27% preschool and school going children showed problems while playing whereas in another study, P.A. Martins-Júnior in 2013, evaluated 438 children out of which 23% children showed problem in their behavior while playing[47].

In our study 48% children reported pain on having hot and cold beverages. A similar study done by filstrup et al in 2003 in which 58% children were affected by pain.

Similar study was done by Sandra Feitosa, Viviane Colares, Jimmy Pinkham in 2005.Of the 861 children examined, 77 (8.1%) had severe caries and 225 (23.6%) were caries-free, and remaining were excluded according to exclusion criteria.Most of the parents or guardians of children with caries reported that their children had problem of toothache, had problems on eating certain foods, were absent from school, were ashamed to smile, and stopped playing with other children because of their teeth .[60]

All pre-intervention questionnaire except “like your teeth” and “happy with teeth and smile”, the control group children answered response in “No”. Both these‘like your teeth” and “happy with teeth and smile”, questions were positive in nature and provided response in

"Yes". For other questions which were negative in nature, the proportion of affirmative responses ranged from 30% (Hurt when eat) to 76.7% (hurt when chew and bite). Following intervention, for all the items, no positive responses were observed for all the questions except "kids make fun of your teeth" where 2 (6.7%) children responded in affirmative. Statistically, for all the questions, the change was found to be significant.

Pre-intervention evaluation of dmft and its comparison with post intervention in group of cases (n=44) were assessed. Before intervention mean dmft was 7.07±3.337. After intervention, mean dmft was 7.01±3.302, thus showing a mean changes of(0.6%). Statistically, this change was not significant (p=0.978).

Comparison of change was seen in total QOL scores following intervention. Prior to intervention, mean parental QOL scores were 40.97±6.74 which declined to reach at 17.53±3.87 following intervention, thus showing a mean decline of 23.43±8.70, i.e. a mean change of 57.2%. Statistically, this change was found to be highly significant ($p<0.001$) which showed that the quality of life improved significantly after treatment.

In a study, Parsons, 1999 showed relationship between ECC and oral health-related QOL and observed that parents can perceive an improvement of their child's well-being after dental treatment. The results of study additionally showed that children themselves, even as young as 36 month of age, can communicate their oral health-related quality of life. Children with ECC reported significantly lower oral health-related QOL than children who were caries free.[61]

Low and Tan 1999 in their study, found thatdental treatment was shown to have a statistically significant effect in alleviating the complaint of pain, of reversing certain eating

problems, and improving sleep habits (P<0.001) whereas the difference relating to changes in behavior was found not to be statistically significant.[62]

We can say that, the parent /guardian scale is an acceptable criteria forcommunication as per study of Filstrup et al in 2003. Children in the age group (3-5 years) are not in the position to refer them for treatment, even when they are experiencing sharp pain. Ultimately, it may lead to the parent's / guardian's perceptions of their child oral health related quality of life that may decide whether care will be sought for children.

Additionally, the use of a proxy rater is also necessary when the patient is either unable or unwilling to complete the questionnaire to assess oral health related quality of life measures. Furthermore, when differences emerge in parent versus child reports about the child oral health related quality of life, dental health care provider could share and discuss these discrepancies with parent/ guardian and children as a way to facilitate and improve communication between them.

Quality Of Life may be defined as subjective well-being. Recognizing the subjectivity of QOL is a key to understanding this construct. QOL reflects the difference, the gap between the hopes and expectations of person and their present experiences. Concepts of health have broadened in recent years. The WHO in 1948 has defined health as the state of physical, mental and social wellbeing and not merely the absence of infirmity. Dental caries, particularly in young children, can be associated with diminished quality of life, not only for the affected children, but also for their families, as well. The presence of early childhood caries may have adverse changes in quality of life, such as oral pain and inability to eat or sleep has been demonstrated, as it has the beneficial effect of comprehensive oral rehabilitation.

This interventional study was conducted with an aim to assess the effects of ECC on oral health-related QOL as reported by the children themselves as well as by their parents/guardians, to explore how the treatment of ECC affects the child patient's oral health-related QOL after they return to their "normal" life, and to develop multidimensional and differentiated scales for measuring children's self-reported oral health-related QOL as well as their parent's/guardian's proxy reports of their child's oral health-related QOL. 200 healthy children (ASA 1) in the age group of 3-5 years and their parents were included in this study. The respondents were categorized into two groups. Group I consisted of 100 children, diagnosed with ECC and their parents/guardians .Group II was the control group that comprised of 100 caries free children. Children in group I were subdivided in two groups 1A and 1B. Group 1A consisted of 56 children who completed only baseline survey while Group 1B consisted of 44 children who completed both baseline and follow up survey.

This study summarizes that oral health has definite effects on quality of life of children. Children have self-reported their oral health-related QOL which was significantly correlated to oral health. On the other hand, children with ECC had significantly poor oral health-related QOL than caries-free children. However, children with ECC showed significant improvement in oral health-related QOL after treatment.

Since India is a vast country having more than 39% child population, there is a need to involve more regions to conduct similar study with more sample size before any definite conclusions are drawn.

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Annexure-II

CONSENT FORM (ENGLISH)

Title of the Study:
Study Number……..
Subject's Full Name…….
Date of Birth/Age ……
Address of the Subject…….
Phone no. and e-mail address……
Qualification ……
Occupation: Student / Self Employed / Service / Housewife/
Other (Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject…… (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [ ] No [ ] Not Applicable [ ]**
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:……...
Signatory's Name……. Date …….
Signature of the Investigator…… Date……..
Study Investigator's Name..... Date……..
Signature of the witness…… Date……..
Name of the witness……
Received a signed copy of the PID and duly filled consent form
Signature/thumb impression of the subject or legally Date……..
Acceptable representative

सहमति पत्र

अध्ययन शीर्षक.....
अध्ययन संख्या.....
प्रतिभागी के पूर्ण नाम.....
जन्म तिथि / आयु.....
प्रतिभागी का पता .....
फोन नं. और ई-मेल पता .....
योग्यता .....
व्यवसाय: छात्र / स्व कार्यरत / सेवा / ग्रहिणी .....
अन्य (उचित रुप मे टिक करें) .....
प्रतिभागी की वार्षिक आय .....
प्रत्याशीयो के नाम और प्रतिभागी से संबंध...(परीक्षण से संबंधित मौत के मामले मे मुआवजे के प्रयोजन के लिए)

1. मेरी पुष्टि है कि मैने अध्ययन हेतु सुचना पत्र दिनांक ..... को पढ व समझ लिया तथा मुझे प्रश्न पुछने या मुझे अध्ययन अन्वेषक ने सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पुछने के समान अवसर प्रदान किए गये।

2. मैंने यहॉ समझ लिया कि अध्ययन में मेरी भागीदारी पूर्णतः स्वैच्छिक है और किसी भी दबाव के बिना स्वतंत्र इच्छा के साथ दिया है किसी भी समय किसी भी कारण के बिना , मेरे इलाज या कानूनी अधिकारो को प्रभावित किए बिना , अध्ययन में भाग न लेने के लिए स्वतंत्र हुँ ।

3. मैंने यह समझ लिया है कि अध्ययन के प्रायोजक , प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को मेरे स्वास्थ्य रिकार्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति की जरूरत नही है, चाहे मैने इस अध्ययन से नाम वापस ले लिया है। हॉलाकि मै यह समझता हुँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नही दी जायेगी।

4. मै इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबंध नही है।
5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हुँ।
हॉ [ ] नही [ ] अनउपयुक्त [ ]

6. मै परीक्षण की अनुमति देता हुँ। मुझे इसके द्वारा यदि कोई परेशानी होती है, इसके बारे में जानकारी दे दी गई है। मैने रोगी जानकारी सूचना पत्र को पढ तथा समझ लिया है।
प्रतिभागी / कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर (या अंगूठे का निशान.....

Child Assent Form

Study Title_____
Study Number_____
Subject's Full Name _____
Date of Birth/Age_____
Address _____
_____

I_____, exercising my free power of choice, hereby give my consent for participation in the study entitled:

"....."

I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug. I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

Signature of the study participant _____Date:_____
Name of the study participant_____

Signature of the Witness _____Date_____
Name of the Witness _____

Signature of the attending Physician_____Date:_____
Name of the attending Physician

शिशु सहमति पत्र

मैं _____में भाग लेने के लिए अपनी सहमति प्रदान करता हूँ | मुझे इस अध्ययन के हेतु और उसमे की जाने वाली प्रक्रिया के बारे में चिकिस्तक द्वारा बता दिया गया है| मुझे पता है कि अध्ययन सम्बन्धी किसी हानि जिसका अध्ययन की दावा से सम्बन्ध है उसका खर्च मेरे माता पिता अथवा अभिवाहक को नहीं वहां करना है | मुझे यह भी पता है कि मैं इस अध्ययन से किसी समय बिना कोई कारण बताये बाहर हो सकता हूँ |

अध्ययन में भाग लेने वाले का नाम और हस्ताक्षर
_____दिनांक_____

गवाह के हस्ताक्षर _____दिनांक _____

गवाह का नाम _____

चिकिस्तक का नाम और हस्ताक्षर_____दिनांक_____