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Original Article

Assessment of Oral Health-Related Quality of Life After Full Mouth Rehabilitation Under General Anaesthesia in A Group of Egyptian Children with Down Syndrome: A Before and After Study

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Abstract

Aim: The aim of the study was to assess oral health-related quality of life (OHRQOL) after full mouth rehabilitation under general anesthesia (GA) in a group of Egyptian children with Down syndrome.

Methodology: This study was conducted in Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, Egypt. Patient's parents or caregivers of Down syndrome children were asked to complete questionnaires about their child's oral health state and well-being at baseline and after three months from performing full mouth rehabilitation. This study used the Early Childhood Oral Health Impact Scale (ECOHIS) and Family Impact Scale (FIS)..

Results: There was a positive change in both ECOHIS and FIS. (ECOHIS) mean value (mean±SD) changed as it decreased from 2.18±1.46 to 1.66±1.23, pvalue <0.001*,(FIS) mean value (mean±SD) changed as it decreased from 1.98±1.55 to 1.16±1.38 (p.value <0.001).

Conclusion: Oral health-related quality of life improved significantly in overall aspects, child symptoms, child interaction, child psychology and child self-image. And non-significantly in family financials, parental stress and child function following full mouth rehabilitation under GA for both Down syndrome children and their families.

Keywords: full mouth rehabilitation,Down,Quality of life.

Introduction

Down syndrome (DS) is the most common chromosomal abnormality among humans. Almost 10,000 children are born with DS in the United States yearly (1 in 691 live births; prevalence of 10.3 per 10,000). In Brazil, the number of individuals with DS is nearly 270,000. Individuals with DS are at greater risk for health conditions such as congenital heart defects, leukemia, thyroid gland disease, and behavioral disorders. Individuals with DS are also of significant concern for oral health issues, among which periodontal disease and malocclusion have been highlighted. Adequate oral hygiene may also be beyond their capabilities **(Abreu et al., 2021).**

Dental caries is a common condition amongst young children which negatively impacts their quality of life. It is an added burden on children with Down syndrome who have an increased risk of developing caries due to various reasons: limited oral healthcare, difficult access to dental services, inadequate diet, xerostomia-causing medication, the high sugar contents in their medications and poor salivary flow **(AlJameel et al., 2020).**

In addition, children with Down syndrome frequently show high anxiety levels, low cooperation levels, and mood swings which form a barrier to dental treatment in the dental chair. Therefore, general anesthesia (GA) presents a very important option for dentists to perform comprehensive management of Down syndrome children. To overcome the potential risks, excessive stress, and inability to offer high-quality dental treatment in the dental chair **(Al-Ogayyel et al., 2018).**

The concept of oral health-related quality of life has been introduced. Expanding the array of traditional medical factors such as symptom and functional status that have been assessed when measuring QOL outcomes in health care settings. (OHRQOL) is measured in relation to how the mouth and teeth affect physical, psychological, and social well-being and daily activities such as eating, speaking, embarrassment, and social interactions **(Al-Ogayyel et al., 2018).**

A systematic review concluded that "Oral rehabilitation under GA results in immediate improvement of children's oral health. As well as physical, emotional, and social quality of life. It also has a positive impact on the child and his family". Dental treatment under GA provides a safe approach and has significant positive effects on quality of life (QOL) for Down syndrome children who cannot accept treatment in a conventional office setting. QOL has been recognized as the most important outcome of medical care for people of all ages and abilities. A complete understanding of oral health-related QOL outcomes is both a necessary and logical goal to assess and significantly improve the impact of dental care for Down syndrome children **(Metwally et al., 2020).**

Subjects and Methods

1-Study design:

A prospective, observational study (before-and-after study) that involved an active attempt to assess OHRQOL after full mouth rehabilitation under GA in a group of Down syndrome children in Egypt over a period of three months.

2-PO elements

Population: Egyptian Children with Down syndrome receiving full mouth rehabilitation under general anesthesia.

Outcomes:

Primary :- oral health related quality of life, measured by parental-caregivers perceptions questionnaire(ECOHIS) using numerical value .

Secondary:-family conflict, measured by family impact scale(FIS) using numerical value.

3-Research Question:

Is there a change in OHRQOL of Egyptian children with Down syndrome after full mouth rehabilitation under general anesthesia?

4-Participants:

Down syndrome Children and their caregivers attending General Anesthetic Unit in Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, Egypt. Children were screened for diagnosis of their chief complaint and enrolled in this study according to inclusion and exclusion criteria.

5-Eligibility Criteria: -

5.1-Inclusion Criteria

- Age range 3 to 14 years.
- Diagnosed with Down syndrome

- Should have a minimum of 12 primary or permanent teeth, or both that had not been treated within the past 12 months.

5.2-Exclusion Criteria

- Participation in any other concurrent clinical trials.
- The presence of serious medical conditions or a transmissible disease.
- Children whose parents had no home landline or mobile phone to enable post-operative contact.
- Parent who refused to sign the informed consent.

6-Sample size determination:

Sample size was calculated based on a previous study **(Metwally et al., 2020)**. A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that family conflict will not change in the children with Down syndrome after full mouth rehabilitation under GA treatment. By adopting an alpha level of (0.05) a beta of (0.2) i.e. power=80% and an effect size (d) of (0.65) calculated based on the results of **(Metwally et al., 2020)**. The predicted sample size (n) was a total of (21) cases which were increased to 30 to compensate possible dropouts.

7-Steering committee

Ethical approval: Ethical approval was obtained from Research Ethics Committee, Faculty of Dentistry, Cairo University on 28\9\2021.

Trial registration no: NCT05146271

8-Informed Consent:

Parents were informed about the nature of this study and were asked to provide a written informed consent **.**Child's name, gender, age, address and contact information were recorded. No participants were admitted to the study before the informed consent form was duly signed by their parents as Down syndrome patient, have difficulty in communication and cannot decide by their own.

9-Study settings

Setting and Location

- The study was conducted in General Anesthetic Unit in Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, Egypt.

- Demographic variables (age and gender), socio-economic condition medical history and dental history were collected from the parent or caregiver.

10-Study procedure

On the day of the GA, parents or caregivers were asked to complete questionnaires about their child's oral health state and well-being over the previous three months through an interview with the researcher and then oral hygiene instructions were provided to the parent.

10.1. OHRQOL assessment

The short-form early Childhood Oral Health Impact Scale (ECOHIS) (appendix 2) and its Arabic version (appendix 3) and Family impact scale (FIS) were used in this study (appendix 4) and its Arabic version (appendix 5). These are components of the child OHRQOL questionnaire which aim to assess OHRQOL of Down syndrome and its effects on the family. Both the ECOHIS and the FIS components of the questionnaires have been recommended for use in health service research **(Thomson et al., 2013)** and have been validated in Arabic language **(Al-Riyami et al., 2016)**. Down syndrome patients cannot fill those questionnaires so parent and caregiver perception questionnaire (P-CPQ);-(ECOHIS) and family impact scale were used with them. The first component i.e. P-CPQ developed by

Jokovic is a measure of parental/caregiver perception of the OHRQOL of the children especially those who have special needs or may be too young to answer questions pertaining to oral health related quality of life.

The short-form ECOHIS consisted of 13 items (closed-ended questions) which were grouped into seven subscales/domains: child symptoms items, child functional limitations items, child psychology, child self-image, child interaction, parental stress and family financial status, respectively. The questionnaire used a 5-point Likert scale and all the scores in each domain were added separately to give a domain score. The sum of the seven domain scores made up the total ECOHIS score for each individual participant.

The FIS was made up of 10 items that measured the effect of a child's oral condition across three domains: parental and family activities, parental emotions, family conflict and financial burden.

Scoring of the FIS also used a 5-point Likert scale calculated in the same manner as the ECOHIS scores; the questionnaires also had a "don't know" response option which is essential in studies in which participants report their perceptions of the health or quality of life of another individual **(Allison et al., 1999)**.

10.2. Demographic data collection of the children

In addition to the caregiver's interviews using the ECOHIS and FIS questionnaires, demographic data was also collected by asking the parents and recorded. The assessment form was used to collect information on the socio demographic status of the child namely: age, gender in appendix 1.

10.3. Follow up

- The questionnaires were researcher-administered and provided to the parents/caregivers at baseline and at the 3-month post- operative follow-up visit. Concerning patients who were not able to attend the follow-up visits the questionnaires were filled up through phone calls.

Results

I-Demographic data

The total number of cases was 30, 26 cases of them completed the follow up and 4 did not. Frequency and percentage values for demographic data were presented in tables (1).

II- Oral health-related quality of life (OHRQOL)

A- Descriptive statistics:

Descriptive statistics for (ECOHIS) score were presented in Table (2).

B- Effect of rehabilitation:

Effect of oral rehabilitation on (ECOHIS) score was presented in Table (3) and in Figure (1) For "Child symptoms", "Child psychology"," Child self-image"," Child interaction" and the overall score, there was a significant reduction of (P-CPQ) score after oral rehabilitation ($p<0.05$). While for other parameters, the effect of oral rehabilitation was not statistically significant ($p>0.05$). Table (3).

III- Family impact scale

A- Descriptive statistics:

Descriptive statistics for family impact scale were presented in Table (4).

B- Effect of rehabilitation:

Effect of oral rehabilitation on family impact scale was presented in Table (5) and in Figure (2) For "Family activity", "Family conflict"," Family burden", and the overall score, there was a significant reduction in family impact scale after oral rehabilitation ($p<0.05$). While for "Family emotions", the effect of oral rehabilitation was not statistically significant ($p=0.063$). Table (5).

Table (1): Summary statistics for demographic data of the study sample

Parameter			Value
Gender	**Male**	**N (%)**	16 (53.3%)
	Female	**N (%)**	14 (46.7%)
Age (years)	**Mean±SD**		6.79±2.34

Table (2): Descriptive statistics for (ECOHIS) score at baseline and after three months

Time	Parameter	Mean	SD	Median	IQR
Baseline before rehabilitation	**Child symptoms**	2.58	0.93	3.00	1.00
	Child function	2.24	1.39	2.00	2.00
	Child psychology	2.25	1.40	2.00	1.00
	Child self image	2.80	1.54	3.00	2.00
	Child interaction	2.37	1.61	2.00	2.00
	Parental stress	2.12	1.60	2.00	2.00
	Family financials	1.25	1.41	1.00	2.00
	Overall	2.18	1.46	2.00	2.00
3 months after rehabilitation	**Child symptoms**	1.62	1.43	1.00	1.00
	Child function	1.97	1.18	2.00	2.00
	Child psychology	1.80	1.13	2.00	1.25
	Child self image	1.60	1.38	1.50	1.75
	Child interaction	1.63	1.25	2.00	1.00
	Parental stress	1.68	1.24	2.00	1.00
	Family financials	1.10	0.90	1.00	2.00
	Overall	1.66	1.23	2.00	1.00

Table (3): Effect of oral rehabilitation on (ECOHIS) score

Parameter	(mean±SD)		p-value
	Before	After	
Child symptoms	2.58±0.93	1.62±1.43	**<0.001***
Child function	2.24±1.39	1.97±1.18	**0.076ns**
Child psychology	2.25±1.40	1.80±1.13	**0.040***
Child self image	2.80±1.54	1.60±1.38	**0.006***
Child interaction	2.37±1.61	1.63±1.25	**0.046***
Parental stress	2.12±1.60	1.68±1.24	**0.104ns**
Family financials	1.25±1.41	1.10±0.90	**0.617ns**
Overall	2.18±1.46	1.66±1.23	**<0.001***

*; significant ($p \leq 0.05$) ns; non-significant (p>0.05)

Table (4): Descriptive statistics for family impact scale at baseline and after three months

Time	Parameter	Mean	SD	Median	IQR
Baseline before rehabilitation	**Family activity**	2.08	1.49	2.00	2.00
	Family emotions	2.05	1.67	2.00	3.25
	Family conflict	1.63	1.47	2.00	2.00
	Financial burden	2.07	1.74	2.00	2.75
	Overall	1.98	1.55	2.00	2.00
3 months after rehabilitation	**Family activity**	1.10	1.37	1.00	2.00
	Family emotions	1.47	1.35	1.50	2.00
	Family conflict	1.13	1.41	0.50	2.00
	Financial burden	0.93	1.44	0.00	2.00
	Overall	1.16	1.38	1.00	2.00

Table (5): Effect of oral rehabilitation on family impact scale

Parameter	(mean±SD)		p-value
	Before	After	
Family activity	2.08±1.49	1.10±1.37	**<0.001***
Family emotions	2.05±1.67	1.47±1.35	**0.063ns**
Family conflict	1.63±1.47	1.13±1.41	**0.035***
Financial burden	2.07±1.74	0.93±1.44	**0.016***
Overall	1.98±1.55	1.16±1.38	**<0.001***

*; significant ($p \leq 0.05$) ns; non-significant (p>0.05)

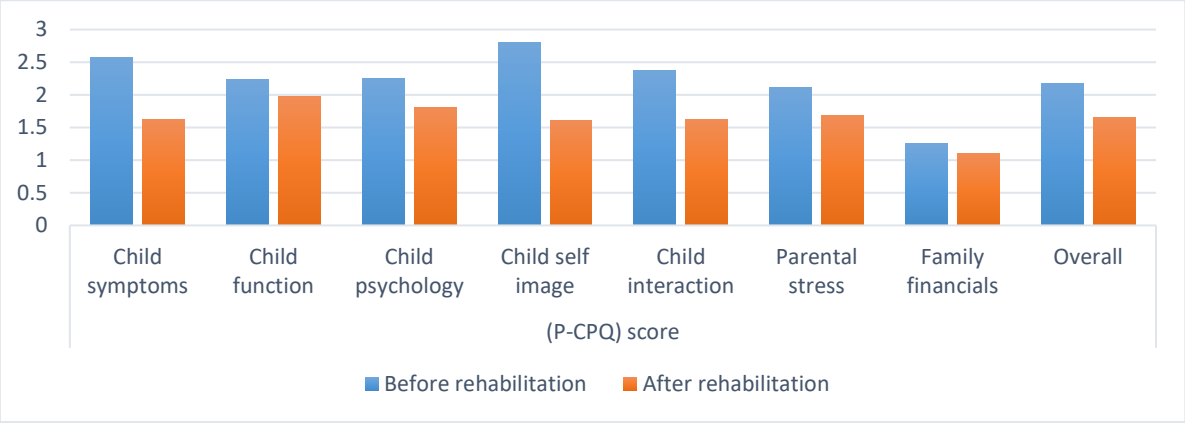

Figure (1): Bar chart showing the effect of oral rehabilitation on (P-CPQ) score

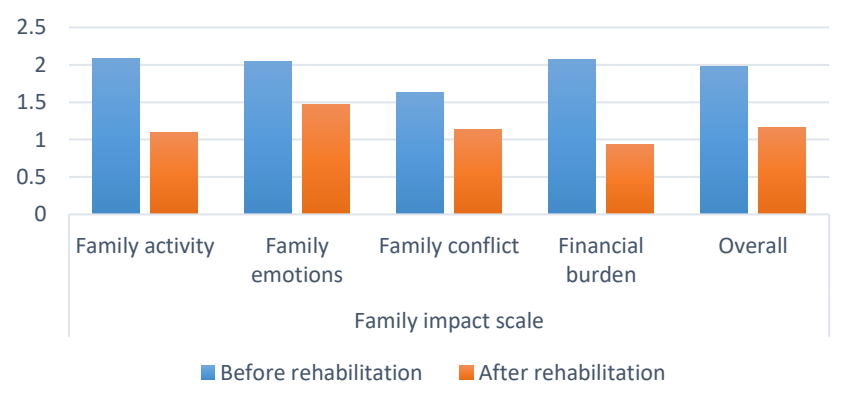

Figure (2): Bar chart showing the effect of rehabilitation on family impact scale

Discussion

A lot of researches are available in the dental literature on oral health surveys done on normal healthy children, however, there are relatively limited data on the oral health conditions in special health care needs children especially Down Syndrome children.

Down syndrome children are complaining of oral health problems, with many experiencing dental pain and difficulty chewing and sleeping before receiving dental treatment. This means that the sensitivity of the instruments to more differences and changes in child oral health related quality of life requires more investigation. However, the ECOHIS and FIS appear to be perfect measures to use in oral health outcomes research among families with young children.

The aim of this study was to investigate the effect of complete mouth rehabilitation under general anaesthesia on the oral health-related quality of life in Down syndrome patients, so it closes an important gap in the literature.

The obtained results before full mouth rehabilitation indicate that oral health status showed negative effects on quality of life at various levels. It was noted that most of cases experienced pain, which was very severe in a lot of cases, difficulty in sleeping, functioning and emotional stresses. As a result, several mothers said that their children's oral health has an impact on them both socially and emotionally, whereby they would withdraw from their friends, social activities and family members. Complete mouth rehabilitation under G.A made a big change in oral health quality of life in Down syndrome children. This was useful to patients, community and practitioners. For patient it will Motivates the caregivers to access oral health services and change in OHRQOL. Evidence shows that costs and resources associated with some treatment protocols are worth the expense. The results of this study showed that full mouth rehabilitation under GA would make a noticeable difference in the life quality of Down syndrome children and their families, giving them a chance to live more freely and to be more useful and productive in their communities.

The study population consisted of caregivers and their Down syndrome children who attended the General Anaesthesia unit, Pediatric Dentistry Department, Faculty of Dentistry, Cairo University, Egypt. The sample size was calculated based on similar data calculated in Alexandria Egypt (Metwally et al., 2020).

In this study, Early Childhood Oral Health Impact Scale (ECOHIS), and Family Impact Scale (FIS) were used as methods of assessment. ECOHIS was used because it is a parental perception questionnaire it was done on Down syndrome children who cannot respond normally to the questions. The second was (FIS) family impact scale to assess the effect on family activities. The total number of cases was 30 cases, 26 cases of them completed the follow-up period, and four didn't come back after full mouth rehabilitation and relief of symptoms.

A dramatic decrease in the mean value of both FIS and ECOHIS scores in this study was observed after complete mouth rehabilitation and a period of 3 months follow-up, it was found in the following results. For ECOHIS scores child symptoms mean value changed from 2,58 to 1.62. Child function from 2.24 to 1.97. Child psychology from 2.25 to 1.80. Child interaction from 2.37 to 1.63. Parental

stress from 2.12 to 1.68. Family financial from 1.25 to 1.10. The overall mean score changed from 2.18 to 1.46. and the greatest change in the mean value was in child self-image from 2.80 to 1.60.

The ECOHIS scores mean value in another study by (Almaz et al., 2014) agreed with this study and showed also dramatic decrease in the scores for example child symptoms decreased from 2.6 to 0.8. Child function from 6.1 to 2.9. Child self-image from 2.3 to 1.3. Child psychology from 2.5 to 1.5. Parental stress from 4.7 to 1.4. The Overall mean score decreased from 20.4 to 8.4.

FIS mean scores in this study also showed a decrease as follows; family activity from 2.08 to 1.10. Family emotions from 2.05 to 1.47. Family conflict from 1.63 to 1.13. Financial burden from 2.07 to 0.93. The overall mean score changed from 1.98 to 1.16.

FIS mean scores also in another study by (Metwally et al., 2020) agreed with this study and showed a remarkable decrease for example family activity decreased from 7.24 to 4.3, parental emotions decreased from 3.7to1.7 and family conflict decreased from 2.8 to 1.3.

The previous result which clearly proves the dramatic decrease in all mean scores in both FIS and ECOHIS in the before and after result make no doubt that complete mouth rehabilitation under General anaesthesia improved oral health-related quality of life for both Down syndrome children and their families. Benefits to practitioner are that it is essential for practitioners to have some appreciation for how the oral health conditions of down syndrome children affect their general well-being and quality of life and demonstrate to clinical researchers and practitioners that improving the quality of patient's well-being goes beyond simply treating dental disease and disorders.

Limitations of the study

- The study did not include a control group, the use of an untreated control group would have been appropriate methodologically but inappropriate ethically.

- The study was conducted in one place, Pediatric Dentistry Department, Faculty of Dentistry, Cairo University, which provides certain treatment startegies.

Conclusions

- Oral health-related quality of life improved in all aspects following full mouth rehabilitation under general anaesthesia for both Down syndrome children and their families.

- Oral rehabilitation under general anaesthesia was effective in minimizing or alleviating oral symptoms, daily life problems, and parental concerns for Down syndrome patients.

Recommendations

- Long-term follow-up for full mouth rehabilitation under G.A. is needed with a larger sample size and different types of disabilities to confirm these findings and to implement effective measures.

- Oral health educators need to educate the caregivers of children with special health care needs on the importance of oral health to general health.

- Training for teachers, institutional staff, and parents is needed to promote

good oral health in children with disabilities.

- Special oral hygiene measures should be developed and tested to be used for children and adolescents with different disabilities.

- Studies in the Future should determine whether there are differences in OHRQOL outcomes associated with different treatment strategies (e.g., multiple extractions versus complete-mouth rehabilitation using different restorative modalities).

o Conflict of interest

No conflict of interest.

o Funding:

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o Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 18-9-2021 approval number: 18921.

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