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Beyond Surgery: A Critical Evaluation of Gastrostomy Use in Trisomy 21, Necessary Intervention or Overused Resource?

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Abstract

Background. Trisomy 21 (T21) or Down syndrome (DS) is the most common genetic condition, with a prevalence in Mexico of one in 650 newborns. People with DS present various comorbidities that can make sucking and swallowing difficult and lead to aspiration pneumonia. Gastrostomy is a surgical procedure used to improve nutrition and reduce the risk of bronchoaspiration in children with DS, but its indications are not well established and in many cases, it is carried out without a multidisciplinary strategy. There are few reports about gastrostomy in children with DS. **Objectives.** To describe the most frequent indications for gastrostomy and complications related to gastrostomy, and to establish guidelines to consider before carrying out this surgical intervention. **Materials and Methods.** This was a retrospective, observational study of patients with DS and gastrostomy who received care in the Mexican National Institute of Pediatrics from 1 January 2013 to 31 December 2024. **Results.** Approximately 1600 patients with DS were seen in the study period, 800 of whom aged 0 - 7 years, with 47 receiving gastrostomy and 18 having the gastrostomy removed by the end of the study. The most frequent indication was gastroesophageal reflux disease combined with slow weight gain. There were complications in 25 patients, the most frequent of which was periostomal infection. **Conclusions.** Gastrostomy is an overrated procedure that is not without complications. Orofacial rehabilitation should be attempted before it is performed.

Keywords

Trisomy 21, Gastrostomy, Complications

1. Background

Trisomy 21, commonly known as Down syndrome, was first clinically described by John Langdon Down in 1866, while its chromosomal basis was identified by Jérôme Lejeune in 1959 as an extra copy of chromosome 21.

Down syndrome is the leading genetic cause of intellectual disability. Worldwide, it is estimated that one out of 700 newborns will have this condition. Improved knowledge and timely approaches to its various comorbidities has made possible an increase in the life expectancy of people with Down syndrome from 25 to 60 years in recent decades [1].

Disorders in swallowing, gastroesophageal reflux, malnutrition, and immune disorders are common in people with DS, owing to a combination of anatomical, physiological, and neurological alterations (**Table 1**). These disorders increase the risk of aspiration and breathing problems, and have a negative effect on development and quality of life [2] [3]. Care for such problems should be multidisciplinary, including pediatricians, gastroenterologists, ear, nose, and throat specialists, speech therapists, nutritionists, and occupational therapists. Treatment approaches should be based on a detailed clinical history, and where possible should include professional supervision during eating, as well as swallowing therapy from an early age to strengthen oropharyngeal muscles and improve coordination. Dietary changes should also be made to adapt to food consistencies, and gastroesophageal reflux should be treated. A surgical approach is indicated only in severe cases that have not shown adequate response to prior intervention [4].

Table 1. Factors associated with complications by eating disorder.

Anatomical factors	Muscle hypotonia Relative macroglossia High narrow palate Craniofacial anomalies: midline facial hypoplasia, small jaw, mandibular protrusion, micrognathia, cleft palate, etc. Duodenal atresia, Hirschsprung's disease, anorectal malformation, annular pancreas
Physiological and neurological alterations	Delay in oral motor development Sensory dysfunction Deficiencies in swallowing reflex Gastroesophageal reflux
Immunological alterations	Reduced innate and adaptive immune response Low T and B lymphocyte activity Reduction in CD4 T-cell function and macrophages Quantitative and qualitative reduction in immunoglobulins Thymic hypoplasia
Factors associated with malnutrition	Hypothyroidism, congenital cardiopathies, orofacial hypotonia, gastrointestinal alterations (intestinal motility disorders, malabsorption syndromes, etc.)

2. Materials and Methods

2.1. Study Design

Observational, descriptive, retrospective, and longitudinal.

2.2. Inclusion Criteria

Children younger than 18 years of age with a confirmed diagnosis of Trisomy 21 who were followed at the Down Syndrome Clinic of the Instituto Nacional de Pediatría between January 1, 2013 and December 31, 2024 and who underwent gastrostomy placement during the study period.

2.3. Exclusion Criteria

Patients with incomplete medical records regarding gastrostomy indication, procedure characteristics, or follow-up data, and patients who underwent gastrostomy outside our institution without available documentation.

2.4. Study Population

Children with Down syndrome who received care at the Mexican National Institute of Pediatrics from 1 January 2013 to 31 December 2024.

2.5. Study Description

Definitions of Clinical Variables

Slow weight gain was defined as weight gain below expected age-specific growth standards or a decline of two or more major percentile lines on standardized growth charts.

Gastroesophageal reflux disease (GERD) was defined as reflux of gastric contents associated with clinically significant symptoms or complications documented in the medical record.

Aspiration pneumonia was defined as a lower respiratory tract infection secondary to aspiration, confirmed clinically and/or radiologically.

Microaspiration syndrome was defined as recurrent aspiration of small amounts of oral or gastric contents associated with chronic respiratory symptoms.

Malnutrition was classified according to the nutritional assessment documented in the medical record and categorized as mild, moderate, or severe.

Peristomal infection was defined as a localized infection at the gastrostomy site characterized by erythema, edema, purulent discharge, or the need for antibiotic therapy.

Patients could present more than one indication for gastrostomy placement; therefore, indications were recorded individually, and multiple indications were documented when applicable.

Treatment failure was defined as persistent feeding dysfunction, inadequate growth or weight gain, recurrent aspiration-related respiratory complications, or clinically significant gastroesophageal reflux despite optimized nutritional, reha-

bilitative, and medical management.

2.6. Statistical Analysis

Descriptive statistics, with numerical variables summarized by median, minimum, and maximum, as they did not show a normal distribution. Categorical variables were summarized with frequencies and percentages. We used SPSS for the analysis of the data.

3. Results

During the study period, approximately 1600 patients with Trisomy 21 were followed at our institution. Because gastrostomy placement occurs predominantly during early childhood, the analytic denominator was restricted to the 800 patients aged 0 - 7 years who represented the population at risk for gastrostomy placement. Gastrostomy was performed in 47 patients.

By the end of the period, 18 had had the gastrostomy removed. Patients' ages and the duration of their gastrostomies are shown in Table 2.

Table 3 shows the patients' conditions. It is noteworthy that 46 had comorbidities, 26 with one and 20 with more than one. The most frequent of these were cardiological, in 42 patients; 18 received heart or gastrointestinal surgeries or the placement of a central venous catheter [1].

In Table 4, among the 16 patients with multiple indications for gastrostomy placement, the most common combination was gastroesophageal reflux disease (GERD) associated with slow weight gain (43.8%). Less frequent combinations involved aspiration pneumonia and microaspiration syndrome, either alone or in combination with GERD and feeding difficulties.

Type of gastrostomy and associated procedures

Among the 47 patients included in the study, six (12.8%) underwent endoscopic gastrostomy placement, whereas 41 (87.2%) underwent open gastrostomy combined with Nissen fundoplication during the same surgical procedure. Because the vast majority of patients received combined anti-reflux surgery, indications and complications should be interpreted within the context of this combined surgical approach.

Table 5 shows data for the gastrostomies, their indications, and their development. Some patients had two or more indications that the surgery was necessary; There were 27 patients with surgeries following the gastrostomy [2], and 25 with complications, the most frequent of which were periostomal infection [3] with positive swab for Staphiloccocos and Pseudomonas. One patient presented septicemia.

Table 2. Age and duration of gastrostomy.

Variable	*n*	Median	Minimum	Maximum
Age at time of gastrostomy (months)	47	11	Newborn	75
Age at removal of gastrostomy (months)	18	59	10	275
Duration of gastrostomy (months)	18	40.5	6	262

Table 3. Patients' conditions.

Variable	*n*	%
Sex		
Male	21	44.7
Female	26	55.3
Residence		
Mexico City	22	46.8
Estado de México	14	29.8
Other	11	23.4
Karyotype		
Regular	33	70.2
Translocation	4	8.5
Unknown	10	21.3
Gestation		
Term	30	63.8
Preterm	16	34
Unknown	1	2.1
Comorbidities		
One	26	55.3
Multiple	20	42.6
None	1	2.1
Cardiac comorbidities		
Yes	42	89.4
No	5	10.6
Gastrointestinal comorbidities		
Yes	14	29.8
No	33	70.2
Thyroid comorbidities		
Yes	12	25.5
No	35	74.5
Pulmonary comorbidities		
Yes	15	31.9
No	32	68.1
Neurological comorbidities		
Yes	6	12.8
No	41	87.2
Immunological comorbidities		
Yes	4	8.5
No	43	91.5

Continued

Nutrition		
Eutrophic	5	10.6
Slight malnutrition	3	6.4
Moderate malnutrition	13	27.7
Severe malnutrition	26	55.3
Breastfed		
Yes	31	66
No	16	34
Surgeries prior to gastrostomy		
Yes	18	38.3
No	29	61.7

Table 4. Distribution of patients with multiple indications for gastrostomy placement.

Combination of Indications for Gastrostomy Placement	n	% of Multiple Indications (n = 16)
GERD + Slow weight gain	**7**	**43.8**
GERD + Aspiration pneumonia + Microaspiration syndrome	**2**	**12.5**
GERD + Microaspiration syndrome	**1**	**6.3**
Aspiration pneumonia + Microaspiration syndrome	**1**	**6.3**
Aspiration pneumonia + Slow weight gain	**1**	**6.3**
Microaspiration syndrome + Slow weight gain	**1**	**6.3**
GERD + Aspiration pneumonia	**1**	**6.3**
GERD + Aspiration pneumonia + Slow weight gain	**1**	**6.3**
GERD + Aspiration pneumonia + Microaspiration syndrome + Slow weight gain	**1**	**6.3**
Total	**16**	**100**

Abbreviations: GERD, gastroesophageal reflux disease.

Table 5. Gastrostomies and their development.

Variable	*n*	%
Indication for gastrostomy		
Gastroesophageal reflux	9	19.1
Slow weight gain	10	21.3
Aspiration pneumonia	6	12.8
Microaspiration syndrome	4	8.5
Congenital deformity	2	4.3
Multiple	16	34

Continued

Type of gastrostomy		
Endoscopic	6	12.8
Open with Nissen fundoplication	41	87.2
Post-gastrostomy oromotor rehabilitation		
Yes	35	74.5
No	12	24.5
Post-gastrostomy surgery		
Yes	27	34
No	20	66
Gastrostomy complications		
None	22	46.8
Periostomal infection	12	25.5
Fistula	5	10.6
Catheter obstruction	4	8.5
Septicemia	1	2.1
Other	3	6.4
Indications for removal of gastrostomy		
Continue gastrostomy	29	61.7
Eutrophic	11	23.4
Adequate oral rehabilitation	4	8.5
Improvement in respiratory symptoms	2	4.3
Improvement in gastrointestinal symptoms	1	2.1
Indication for gastrostomy		
Gastroesophageal reflux	9	19.1
Slow weight gain	10	21.3
Aspiration pneumonia	6	12.8
Microaspiration syndrome	4	8.5
Congenital deformity	2	4.3
Multiple	16	34
Type of gastrostomy		
Endoscopic	6	12.8
Open with Nissen fundoplication	41	87.2
Post-gastrostomy oromotor rehabilitation		
Yes	35	74.5
No	12	24.5

Continued

Post-gastrostomy surgery		
Yes	27	34
No	20	66
Gastrostomy complications		
None	22	46.8
Peristomal infection	12	25.5
Gastrocutaneous fistula	5	10.6
Catheter obstruction	4	8.5
Septicemia	1	2.1
Other	3	6.4
Indications for removal of gastrostomy		
Continue gastrostomy	29	61.7
Eutrophic	11	23.4
Adequate oral rehabilitation	4	8.5
Improvement in respiratory symptoms	2	4.3
Improvement in gastrointestinal symptoms	1	2.1

4. Discussion

In our study, we found that many patients have eating problems can significantly increase morbidities such as malnutrition, delayed growth, aspiration, persistent respiratory symptoms, and recurrent pneumonia, as we know, the major cause of hospitalization in children with DS younger than two years of age are lower respiratory tract infections [5]. There is not always an etiological agent; the development, chronic nature, and complications in these patients support the idea of a multi-factor origin, where silent aspiration secondary to gastroesophageal reflux and dysphagia associated with a lack of coordination of breathing, sucking, chewing, and swallowing may be related to these respiratory symptoms. It is thus necessary to perform a screening of eating problems through detailed clinical histories, multidisciplinary evaluations, and extension studies. Meanwhile, we know that oromotor therapy can help, even treat this lack of coordination, improve muscle tone in the larynx and therefore reduce the risk of comorbidities involving the respiratory system.

In level III hospitals where people with DS and multiple comorbidities are seen, admission for recurrent respiratory problems is generally common, and in many such cases gastrostomy is proposed as a treatment option. Our study found that slow weight gain and respiratory problems were the major indications for the use of gastrostomy. To date, however, there are few studies of the subject, and thus no consensus on the specific criteria for carrying out this surgical procedure on people with DS. The studies do show a consistency in identifying the major reasons for doing so as malnutrition and respiratory complications [6].

Of the study population, 97% presented comorbidities. The most frequent of

these were cardiopathies and respiratory problems, followed by gastrointestinal disorders; 18 of these patients were hospitalized for cardiac or gastrointestinal surgery, or to place a central venous catheter. There was some degree of malnutrition in 90% of the study population.

Studies have described the association between congenital cardiopathies in people with DS and the use of gastrostomy, related to various aspects of cardiopathies than can make eating and adequate nutrition difficult, such as fatigue, hypoxia, delayed neurological development that complicates the coordination of eating and swallowing, and the lengthy recuperation from surgery that can make it difficult to eat [7]. Poskanzer *et al.* studied 73 children with DS and problems with swallowing, 13.7% of whom required a gastrostomy tube during the first year of life; they found no clinical factors associated with increased risk from its use [8]. Avilés *et al.*, in a cohort study of 220 patients with DS receiving a gastrostomy at a median age of 5 months, found that the majority received tube feeding for at least a year, and that those with a tracheostomy needed it for a longer period [6]. In our study, the median age at gastrostomy was 11 months, which might be related to late diagnosis and a larger number of complications, and the median time with tube feeding was 35 months, with many still receiving it at the end of the study period. More than half of our study population presented a complication after placement of the gastrostomy, most commonly periostomal infections and gastrocutaneous fistulas; one patient presented secondary septicemia. Sealok *et al.*, in a study of a level III hospital over a period of 26 years, reported that the major complications from gastrostomy were local infections, obstruction, stoma dilation, gastrocutaneous fistulas, and granulomas [9].

Although complications were common in our cohort, these findings should be interpreted within the context of a population with multiple comorbidities and complex medical needs. The present study was not designed to evaluate the balance between the risks and benefits of gastrostomy placement, and therefore no conclusions regarding its overall effectiveness can be drawn.

Hypotonia and secondary motor disorders in children with DS have led to early physical intervention programs, but the vast majority of these focus on work with the trunk and extremities, with little or no intervention in the orofacial area. In a 2024 study, Franceschetti *et al.* demonstrated the importance of a global intensive therapy feeding program focused on improving the functions and limitations in children with DS. They found improvement in the ability to swallow, chew, accept foods, and incorporate textures, and a reduction in the number of hospitalizations for problems related to bronchoaspiration [10].

An important finding in our cohort was that most patients continued to require gastrostomy feeding during follow-up. This prolonged dependence may reflect the multifactorial nature of feeding difficulties in children with Trisomy 21, including hypotonia, oral-motor dysfunction, swallowing disorders, gastroesophageal reflux disease, respiratory complications, and associated comorbidities. Gastrostomy removal was considered only when patients demonstrated safe and effective oral feeding, adequate nutritional status and growth, and no longer required enteral nutritional support. These findings highlight the need for ongoing multidisciplinary fol-

low-up and individualized feeding management strategies in this population.

In some cases, in spite of adequate orofacial therapy, it was not possible to achieve a secure plan of oral feeding because of the seriousness of dysphagia or the inability of the patient to consume enough oral nutrition even with adaptations for swallowing. In these situations, methods of tube feeding should be evaluated, either nasogastric, orogastric, or with gastrostomy, considering the possible benefits, challenges, and impact on the future development of oral feeding.

An important consideration when interpreting our findings is that most patients underwent gastrostomy placement in combination with Nissen fundoplication. Consequently, postoperative outcomes and complications cannot be attributed exclusively to gastrostomy placement. This reflects the institutional practice during the study period for children presenting significant gastroesophageal reflux and feeding difficulties.

Our study did not identify whether the children had received myofunctional therapeutic interventions prior to their gastrostomies, but it did find that after the procedure, 35 of 47 patients received oromotor rehabilitation, which is fundamental to ensuring that patients maintain or recover essential oral motor abilities, preventing muscular atrophy and sensory integration disorders. It is also important to consider that the muscles used in eating are also involved in speech. Their lack of use could affect the development or preservation of communicative abilities, especially in children with DS. Oromotor therapy after gastrostomy is therefore of the utmost importance.

We also found that clinical characteristics and the results of the upper gastrointestinal series were taken into account as indicators for a gastrostomy, but consideration of a surgical procedure requires a broader approach [4] that includes the following:

Detailed clinical history. This should include symptoms such as coughing while eating, recurrent respiratory infections, loss of weight, and difficulty in eating certain foods. Ideally it should include professional observation of eating.

Videofluoroscopic swallowing study. This is the gold standard for evaluating the phases of swallowing and for detecting aspiration.

Endoscopic swallowing study. This is useful for evaluating the anatomy and functionality of the upper respiratory tract during swallowing.

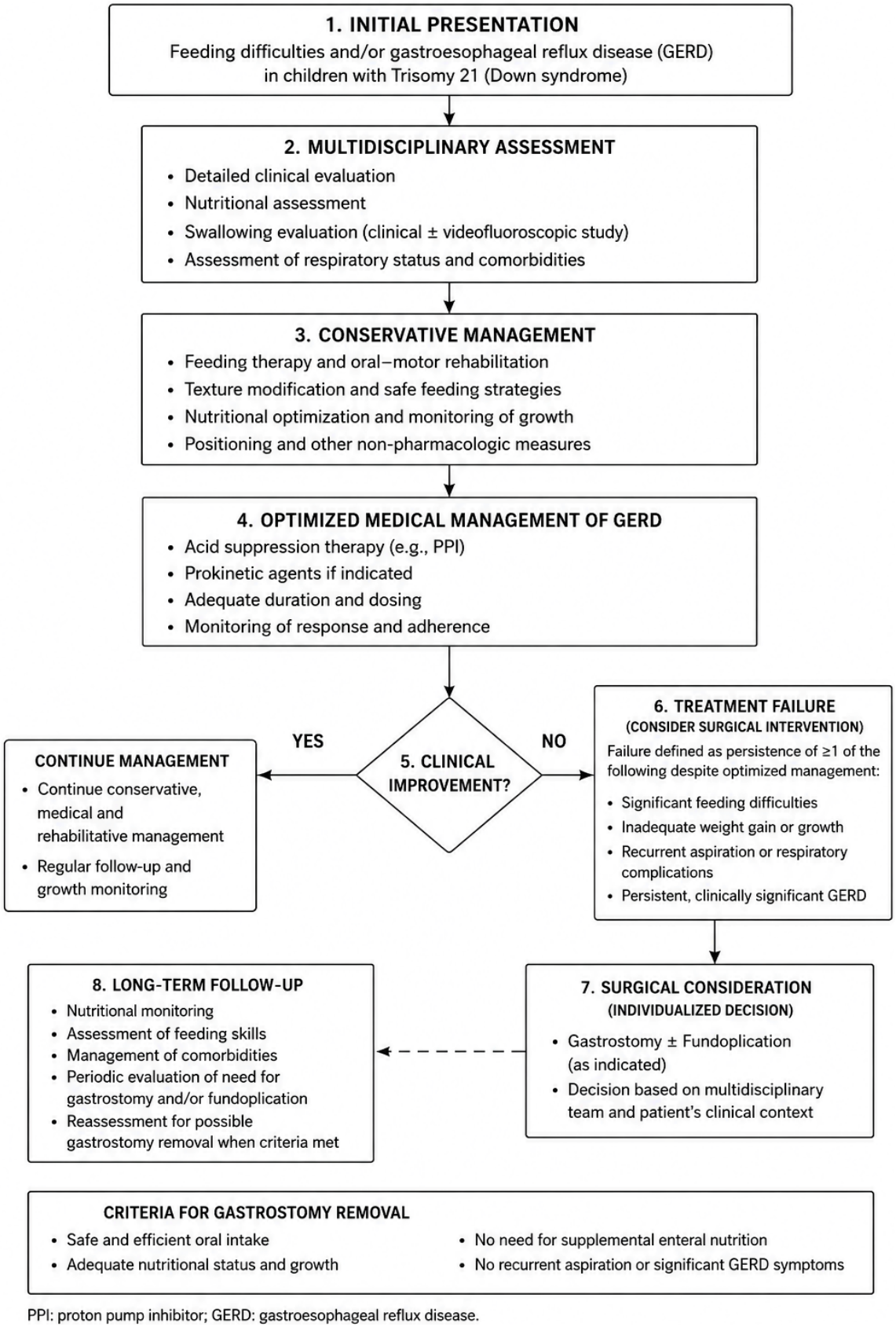
Esophageal motility study. This is indicated if alterations are suspected in the esophageal phase.

Swallowing therapy. Treatment should be multidisciplinary including swallowing therapy, focused on exercises to strengthen the oropharyngeal muscles and improve coordination.

Dietary modifications. The consistency of foods and liquids should be adapted according to individual tolerances.

Medical interventions. Management of gastroesophageal reflux with proton-pump inhibitors or prokinetics.

Surgical interventions. These are indicated only in severe cases.



PPI: proton pump inhibitor; GERD: gastroesophageal reflux disease.

Figure 1. Algorithm for evaluation of feeding difficulties and indications for gastrostomy in children with trisomy 21.

5. Conclusions

In this cohort of children with Trisomy 21, gastroesophageal reflux disease associated with poor weight gain and respiratory complications were the most frequent indications for gastrostomy placement, while peristomal infection was the most commonly reported complication. Notably, only 5.87% of the 800 children aged 0 - 7 years followed over a 12-year period required gastrostomy, highlighting that most feeding difficulties can be managed without surgical intervention.

Our findings emphasize the importance of a comprehensive multidisciplinary evaluation before considering gastrostomy placement. Assessment should include nutritional status, swallowing function, feeding skills, respiratory health, oral-motor performance, sensory integration, and optimization of medical management when appropriate as shown in **Figure 1**. In clinical practice, some patients may undergo gastrostomy without receiving all available therapeutic interventions aimed at improving feeding abilities, including strategies targeting muscle tone, coordination of sucking, breathing and swallowing, feeding rehabilitation, and nutritional support.

Although gastrostomy remains an essential intervention for selected patients with severe feeding impairment or significant medical complications, its indication should be individualized, supported by clinical evidence, and established through a shared decision-making process involving both the healthcare team and the family. The primary goal should always be to promote the child's well-being while carefully considering the potential long-term impact on functional feeding.

6. Declarations

6.1. Ethical Considerations

This study was carried out in accord with the ethical principles of the Helsinki Declaration and research regulations under the Mexican General Law on Health. The study involved only the review of patient records, so informed consent was not necessary. The information obtained was confidential and protected by the researchers. The study protocol was approved by the Research and Ethics Committees of the Instituto Nacional de Pediatría (approval no. 2024/014).

Human Ethics and Consent to Participate declarations: not applicable.

6.2. Consent for Publication

All the authors consent for the article to be published.

6.3. Funding Declaration

This study was financed by the researchers. Publication costs will be financed by the Instituto Nacional de Pediatría.

6.4. Limitations

Our study has several limitations. First, it is a retrospective study, which depends on the data available in medical records. It was not possible to follow up

long-term developments or future limitations arising from the prolonged use of gastrostomy. We also had no control group for comparison, so it is not clear whether patients with DS who received only nutritional interventions, oromotor rehabilitation, or medication had improvements over those with gastrostomies. However, the literature demonstrates the importance of multidisciplinary management, with surgical intervention as a last resort. Finally, our findings are generalizable only to patients with DS seen in our institution, a third level hospital caring for the most critically ill patients, with multiple comorbidities [5]-[7].

6.5. Authors' Contributions

All authors contributed to the protocol design, manuscript review, and final approval of the version to be published. The following outlines the predominant contributions of each author, in addition to other intellectual contributions mentioned above. All authors made substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data.

Dr. Karla Adney Flores Arizmendi conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Drs Karen Nataly Herrera González, Daniela García Poblano, Laura Montserrat Espinosa Méndez, Brenda Janeth Becerril Rojas, and Ritha Alejandra Vázquez Díaz designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr. Piper designed the data collection instruments, coordinated and supervised data collection, and critically reviewed the manuscript.

Dr. Silvestre García de la Puente critically reviewed the manuscript, did the data analysis, and reviewed the final version of the manuscript.

Dr. Alejandra Ochoa Rodríguez critically reviewed the manuscript, helped with the writing and edit and reviewed the final version of the manuscript.

Data Sharing Statement

Deidentified individual participant data (including data dictionaries) will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be made available upon publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal.

Abbreviations

DS: Down Syndrome.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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