PAEDIATRIC PATIENTS WITH A TRACHEOSTOMY. SPANISH MULTI-CENTRE EPIDEMIOLOGICAL STUDY

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ABSTRACT

Introduction. Changes in the indications for tracheostomy in children have led to the progressive involvement of the paediatric pulmonologist in the care of these patients. The aim of this study was to review the current profile of tracheostomised children in Spain

Patients and Methods. We undertook a longitudinal, multicentre study over 2 years (2008-2009) of all patients aged between 1 day and 18 years who had a tracheostomy.

Results. The study, involving 18 Spanish hospitals, included 249 patients, of whom 150 (60.2%) were younger than 1 year of age. The main indications for the procedure were prolonged ventilation (n=156; 62.6%), acquired subglottic stenosis (n=34; 13.6%), congenital or acquired cranio-facial anomalies (n=25; 10%) and congenital airway anomalies (n=24; 9.6%). The most usual underlying disorders were neurological diseases (n=126; 50.6%) and respiratory diseases (n=98; 39.3%). During the two years, 92 (36.9%) children required ventilatory support, achieving decannulation in 59 (23.7%). Complications arose in 117 patients (46.9%). Mortality attributed to the underlying condition was 12.5% and that directly related with the tracheostomy, 3.2%.

Conclusions. The respiratory complexity of tracheostomised children necessitates prolonged, multidisciplinary follow-up, which can often extend to adulthood.

Key words. Airway pathology. Childhood disease. Mechanical ventilation. Paediatric tracheostomy.

INTRODUCTION

Despite it being an age-old technique, paediatric tracheostomy has lately undergone a notable transformation, both in its indications and in the profile of the tracheostomised patient. Until some 40 years ago it was considered an emergency procedure for just a short time, mainly to resolve acute upper airway obstruction, mostly for infectious causes, such as diphtheria, epiglotitis, or laryngotracheitis. Later, the wide use of vaccination programmes, mainly against *Corynebacterium diphteriae* and *Haemophilus influenzae,* together with the development of new anaesthetic materials and techniques to stabilise the upper airway, spectacularly reduced the number of emergent procedures in most series [1-4]. Nevertheless, despite these advances, the incidence of tracheostomy in children has not fallen; indeed, it has even risen in some hospitals [5-8]. This has been attributed to the increased survival of assisted patients in paediatric and neonatal intensive care units, with the progressive appearance of what has been termed the "technology-dependent paediatric patient" [9], referring mainly to children with long-term assisted ventilation or congenital or acquired upper airway anomalies. This notable change in the indications for tracheostomy has transformed the technique into a programmed, long-term, elective procedure, just the opposite to its original indications as an emergency procedure [2,5,10].

Although paediatric ENT services have traditionally been entrusted with the care of these patients, the changing profile of these children with tracheostomies has resulted in the paediatric pulmonologist being incorporated into the work started by the paediatric and neonatal intensive care units, acting as a link between these areas and the surgical specialities, given the need for the prolonged, multidisciplinary management of these children [6,11,12].

Up until now, the general characteristics of tracheostomised children in Spain have remained unknown. Though each centre may have the information for its own cases, no study has yet collated all the general information from the various sites. In order to obtain a more global view, therefore, the Techniques Group of the Spanish Society of Paediatric Pulmonology (SENP) undertook a multicentre study to determine the profile of the child with a tracheostomy in Spain.

PATIENTS AND METHODS

At the 2007 annual meeting of the SENP, several paediatric pulmonology representatives expressed concern about the adequate management and follow-up of children with a tracheostomy. Accordingly, it was agreed that a longitudinal registry over two years should be elaborated. The SENP then published on its web page (http//www.neumoped.org) a letter explaining the aims of the study and inviting any interested hospitals to participate. The various paediatric pulmonology sections were also asked to extend the invitation to other units involved in the care of these patients, such as ENT, paediatric and neonatal intensive care, and maxillofacial surgery. The target population was to be patients aged between 1 day and 18 years who had had a tracheostomy at some time between 1 January 2008 and 31 December 2009. A survey, detailing the variables to be collected, was uploaded and could then be downloaded by the various participating centres (Table 1). The identification of the patients remained hidden, each one being identified by the initials of the centre and a consecutive number. Data were recorded, prospectively, about any associated complications, decannulation, start of preschool/school support and the circumstances of death if this happened during the two-year study period.

After receiving the completed surveys, the study coordinators evaluated them and then sent them to the researchers of each centre with the request that they review any missing or mistaken

data, and give the reasons for the exclusion of any patient. Up until 31 December 2009, the physicians responsible for data collection continued including patients who fulfilled the inclusion criteria and updated the clinical data of those who were already included in the event of any variation.

After a final review at the end of the data-collection period, a database was designed (Microsoft Office Access 2007) to process and analyse the primary variables and the secondary variables (age of each patient at the end of the study and duration of the tracheostomy). An Excel (Microsoft ® 97-2003) spreadsheet was used to analyse the data, provide statistical evaluations and produce tables and figures.

The whole study was undertaken with the maximum confidentiality and data protection according to current legislation.

RESULTS

Replies were received from 22 hospitals. Four of these stated that they did not follow-up tracheostomised children during the study period. The other 18, from 11 different cities in Spain, comprised the participating centres. Of the 270 patients initially recorded, the final study included 249 as 21 were excluded, 10 because they had been decannulated before the start of the study, 5 because they were older than 18 years of age at the start of the study, 5 because they were already included in the details reported by another hospital, and 1 who died before the start of the study. Table 2 shows the number of patients per centre. There were 150 (60.2%) males and 99 (39.7%) females.

The age at which the tracheostomy was done varied between the first hours of life (a boy with congenital laryngeal atresia) and 17 years 10 months (a boy with a lung transplant due to cystic fibrosis). The mean age was 33.7 months (2 years 8 months) ± 52.2 months and the median age was 6 months. Given the wide age range and the variability of the underlying disorders, the patients were grouped according to age, the largest group being that of the newborns <6 months (n=113; 45.3%), followed by those aged 6 months to 1 year (n=37; 14.8%) (Figure 1).

Independently of the underlying disorder, the indications leading to the procedure varied. The main reason was prolonged ventilation (n=156; 62.6%), followed at some distance by acquired subglottic stenosis (n=34; 13.6%) and the others (Figure 2). Most notable among the underlying conditions were neurological disorders (n=126; 50.6%), with 67 (53.1%) children having neuromuscular problems. Second was respiratory disorders (n=98; 39.3%), mainly bronchopulmonary dysplasia (n=32; 32.6%). Most patients, though, had various different processes. Of the 249 patients, 35 (14%) had been born prematurely. Given that a high percentage of the children (60.2%) were younger than 1 year of age at the time of the tracheostomy, Figure 3 compares the conditions in these children versus the rest.

The duration of the cannula ranged from 1 day (due to perioperative death) to 19 years 6 months (a patient with a perinatal medullary lesion). Over the 2-year study period, decannulation was achieved in 59 (23.7%) patients. The mean duration of the cannula in these 59 patients was 24.1 ± 37.8 months, with a median of 7 months. In the remaining 190 patients who were not decannulated, the mean duration of the tracheostomy at the end of the study was 50.6 ± 50.2 months, with a median of 34 months.

In addition to the tracheostomy, 92 (36.9%) patients required ventilatory support during the study period, either in intensive care units (n=12; 4.8%), or at home (n=79; 31.7%), or both (n=1). Of the 249 patients, 5 (2%) required a second tracheostomy.

At the end of the study, the mean age of the patients still alive was 7.4 years ± 9 years. Of the 127 patients older than 4 years of age, 101 (79.5%) were receiving preschool/school support, either attending a centre or at home or hospital, independently of whether they had been decannulated and the need for ventilatory support.

Concerning mortality and morbidity associated with the procedure, one or more complications were reported in 117 (46.9%) patients. Figure 4 shows those during the tracheostomy procedure itself as well as those during the perioperative period or during later care, either at home or in hospital. At the end of the study, only 1 patient had been lost to follow-up, and 31 had died (Figure 5).

DISCUSSION

Although paediatric tracheostomy is now unusual, it still remains necessary for the management of a few "technology-dependent" children, enabling them to be discharged from the intensive care unit [4,12-14]. The best data regarding its true incidence stem from a study by Lewis et al [15], which analysed the data from 2521 American hospitals and estimated the rate to be 6.6 children per 100 000 child-years during 1997. Another observation concerns the transformation in the technique from its indication for emergency use to that as a programmed procedure in children with chronic disorders. Indeed, Corbert et al found that just 6% were for emergency airway management in a series of 122 children between 1987 and 2003 [3].

Over recent years, numerous studies in different countries have reported the individual experience of various hospitals, with the number of patients varying from 36 to 362 over periods of time ranging from 2 to 37 years [3,5,6,8,9,16-18]. Review of these reports reveals differences between the various centres. Whilst the frequency of the technique has fallen and is almost absent in smaller hospitals, it has remained the same, or even risen slightly in referral hospitals, due to its complexity and the need for multidisciplinary management of the children referred [5,3,9,16]. Comparison among the hospitals in this series (Table 2) shows that the number of children reported per hospital is proportional to the number of beds, never surpassing 11.6% per centre, though Madrid and Barcelona, large cities with several hospitals, accounted for 32% and 26%, respectively, of all the patients referred.

Concerning the age at which the tracheostomy was done, the study with the most patients published so far [15] indicates two peaks: younger than 1 year (32%) and 15-18 years (10.3%), the latter mainly resulting from cranioencephalic trauma. Others have reported figures for children under 1 year of age of between 50% and 66% [3,8,19], which is more like the 60.2% in our series. There has also been a growing trend for the procedure to be used in premature infants (10.8%) [15,20] and in children with multiple chronic disorders or severe congenital diseases in neonatal or paediatric intensive care units [9,21,22]. The mean age of the tracheostomy in most series ranges from 3.2-7.8 months [3,6,8,17], or around 3 years of age [2,16]. The higher mean age in our series may be due to its multicentre nature and the inclusion of referral centres for lung transplantation, which greatly raises the upper limit for the procedure. We did not detect the second peak in the incidence of tracheostomy in adolescents seen by Lewis [15], probably because the age for admission to many children's hospitals in Spain is below 16 years, though chronic patients are usually followed-up to a later age. As in our series, most studies have found a slightly higher frequency in boys (60-63.8%) [6,15,18], though not all (48%) [17].

The percentage of cases due to prolonged ventilation, the main indication in our series, varies (22-66%) [2,3,5,6,9,16,19]. The low percentages in some reference centres [5,6] may be related with the greater use of non-invasive ventilation or the higher number of interventional procedures in chronic obstructive airway disorders [8]. Whereas in earlier decades acquired subglottic stenosis only accounted for a small proportion of tracheostomies (0% [23] to 5% [24]), it was the second most common indication in our series (13.6%), a similar percentage to that found by others [3,8,19], though yet others have reported much higher rates (20-36%) [5,6,16,17,25]. This increase is particularly surprising, as interventional techniques now exist to resolve this condition, often without the need for tracheostomy [5,16]. The third indication for tracheostomy in our series, upper airway obstruction secondary to craniofacial malformations or anomalies (10%), is becoming more usual in tertiary referral hospitals (5-32.7%) [3,5,6,8,19]. And finally, specific congenital airway malformations, such as tracheal stenosis, laryngo-tracheo-bronchomalacia, suglottic haemangiomas, or laryngo-tracheo-oesophageal cleft, represented the fourth reason for tracheostomy (9.6%). This figure is lower than that for some tertiary referral centres (19.8% [5] or 21.4% [3]), which are seeing a notable increase as a result of the new interventional possibilities. Of interest among the other indications was that conditions associated with the classical pathogens, like *Corynebacterium diphteriae* or epiglottis due to *Haemophilus influenzae,* have disappeared from the statistics over the last 10 years [3], though *Papilloma Virus* still persists (1.6%), as it does in other studies (1% [5] or 2.6% [3]).

The underlying disorder (Fig 4) was more varied in the patients younger than 1 year of age, as occurs in other studies [15]. The most usual were neurological disorders, in both the younger patients (68 of 159; 45.3%) and those older than 1 year (58 of 99; 58.5%). The high percentage of patients with neurological involvement is also noted in other series (42%) [12]. Of note, too, in our

series was chronic respiratory disease (46%) in those younger than 1 year, mainly due to bronchopulmonary dysplasia.

Comparison of our 23% of patients who achieved decannulation with other series, which report decannulation figures of 29-52.7% [2,3,6,16,17,26], or even 75% in New Zealand [8], gives a notably lower percentage. Possible reasons for this include the shorter period of our study, the high percentage of patients with chronic neurological and respiratory indications for long-term ventilation, and the high percentage of patients younger than 1 year of age. Studies in decannulated patients indicate a mean duration of the tracheostomy that can vary from 12.4 [3] to 22 months [19], depending on the underlying disorder. One of these studies found that patients under 1 year of age had the tracheostomy for much longer periods (829 days) than the children older than 1 year (94 days) [3]. Another study analysed the possible risk factors related with the duration of the cannulation, noting that the only determining factors were the type of disorder and the indication for tracheostomy, but not the age of the patient [28]. It is nevertheless interesting to note that despite the chronicity and compexity of thee patients, 79.5% of the survivors still managed to achieve social insertion appropriate for their age via the preschool/school support system, independently of whether they had been decannulated or were receiving ventilatory support.

The frequency of complications in our series (46.9%) is high, as it is in other paediatric series (51-77%) [1,8,26], in comparison with the frequency in adults. In a multicentre survey, 22% of paediatric surgeons reported perioperative complications during the tracheostomy, leading to a change in practice by 58% of them [22]. A study of 54 patients with home mechanical ventilation (45 via tracheostomy and 9 via nasal mask) reported that 66% of the severe emergencies were related with the tracheostomy [29]. Whereas infection is reported to be the main complication [26,28], as high as 90% in some series [6], in our series it only accounted for 8.8% of complications. This difference may be related with both the shorter follow-up and the question of

differentiating infection *versus* colonisation, under- or overestimating the true incidence. Different percentages have been reported for endotracheal granulation in various paediatric series, ranging from 12.3 -56% [1,6,8]. We only considered infection to be a complication when it led to symptoms and was subsidiary to intervention (8.4%). The main life-threatening complications in our study were severe obstruction of the cannula by a mucous plug (29.3%) and accidental decannulation (15.2%), this latter percentage being similar to that of other series [3,6]. The other life-threatening complications, like pneumothorax, subcutaneous emphysema or tracheo-innominate artery fistula, were much less usual [2,3,19,26].

Mortality from the underlying condition, 9.7% in our series, varies greatly according to the main underlying disease (6.9-39.2%) [2,3,6,8,9,19,23]. Mortality directly related with the procedure, however, (3.2% in our series), was higher than that of other studies (0.7-3%) [2,3,8,18,26]. Of note was the high mortality associated with the procedure in preterm infants (4 in our series) in comparison with other studies in which tracheostomy is presented as a safe technique at that age [20].

Our study does have certain limitations, though. It did not record a series of data that would, with hindsight, have proved interesting, such as the time between the respiratory failure and the tracheostomy, given the high percentage of children with long-term ventilation as the main indication for elective tracheostomy. Unlike adult patients, this time is not clearly defined in children. Very variable intervals have been reported, even in the same centre (0-148 days) [6,9], which explains why the indication for tracheostomy in a child is usually personalized according to the clinical status, the endoscopic findings, the experience with non-invasive ventilation and the family circumstances [1,12,30].

It would also have been of clinical interest to determine whether, before doing the tracheostomy, non-invasive ventilation had been attempted, how long the patient had been in the ICU and in hospital after the tracheostomy, the cost per patient and the percentage of readmissions after the tracheostomy, as it is easy to assume that the battle ends with the tracheostomy, when in fact a new one begins [4,12,30]. Indeed, in our series 31.7% of the patients required assisted ventilation at home at the time of hospital discharge. This circumstance was also noted in a series from Houston (61%), in whom 81% had additional support devices or techniques besides the tracheostomy, such as feeding tubes or central venous access [9].

CONCLUSIONS

Tracheostomy remains prevalent in tertiary children's hospitals because of the profound change in its indications. The high number of patients in our study, the different centres involved, and the study period, current and short, provide an approximate profile of the tracheostomised child in Spain: a young patient, generally under 1 year of age, with a complex underlying disorder, usually neurological or respiratory, in hospital or at home, and sometimes dependent on supplementary oxygen or assisted ventilation. These patients demand a multidisciplinary follow-up involving various specialities (ENT, paediatric surgery, neurosurgery) and paediatric areas (neonatology, intensive care, children's pulmonology), as well as additional consultations in specific paediatric areas, work with speech therapists and the work of other care institutions for family, home and school support. The complexity of the clinical status of these patients not only necessitates a prolonged follow-up during childhood, but sometimes this does not even end when

they reach adolescence, the children requiring transfer to adult pulmonology and ENT services without sufficient progress in the underlying disorder to enable decannulation.

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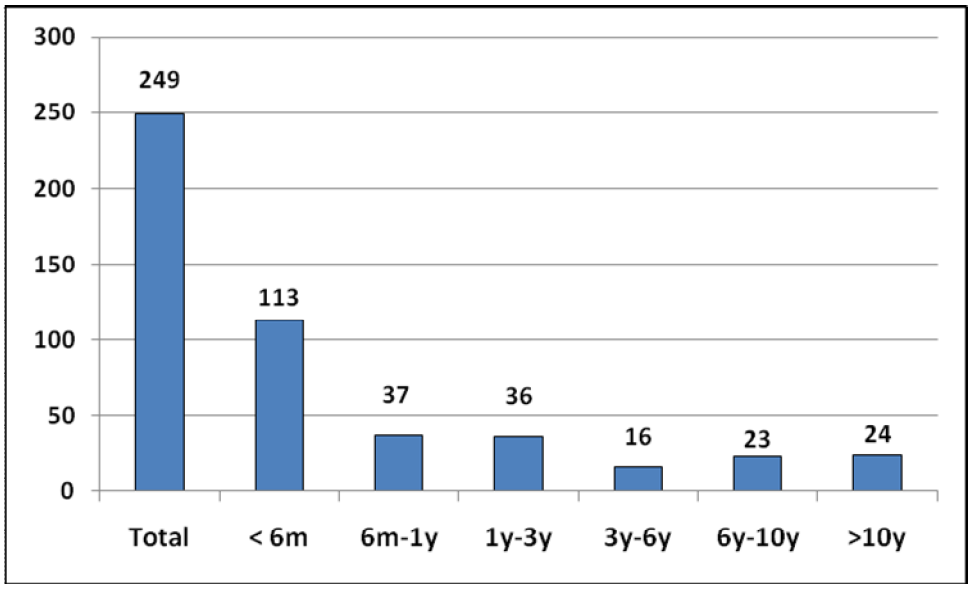
Table 1. Patient variables collected

- Personal data (coded identification)
- Date of birth
- Sex
- Underlying disorder
- Date of tracheostomy
- Main indication for tracheostomy
  - Prolonged ventilation
  - Acquired laryngotracheal-subglottic stenosis
  - Craniofacial anomalies with upper airway obstruction, either acquired or congenital
  - Specific congenital airway anomalies
  - Miscellaneous
- Complications related with the tracheostomy
  - Accidental decannulation
  - Granulation tissue
  - Severe obstruction of the cannula
  - Other
- Requirement for respiratory support
  - Home/Hospital
  - Supplementary oxygen
  - Assisted ventilation
- Date of decannulation
- Preschool/school support
- Death
  - Directly related with the tracheostomy
  - Not related with the tracheostomy

Table 2. Participating hospitals. Number and percentage of patients

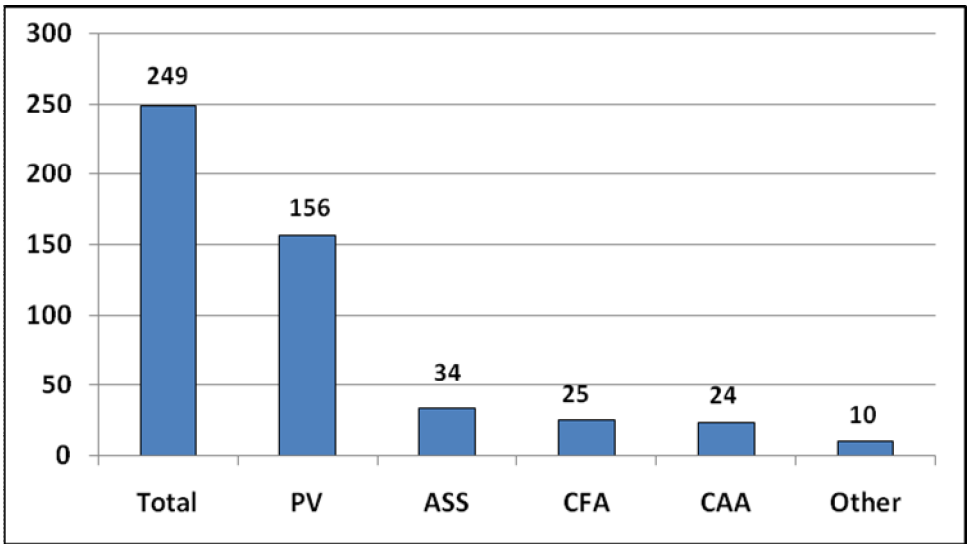
	n	**%**
Hospital Sant Joan de Deu, Barcelona	30	11.6
Hospital Val D´Hebron, Barcelona	27	10.8
Hospital Carlos Haya, Malaga	25	10
Hospital La Paz, Madrid	24	9.6
Hospital Niño Jesús, Madrid	24	9.6
Hospital Virgen de la Arrixaca, Murcia	20	8.06
Hospital 12 de Octubre, Madrid	19	7.66
Hospital Reina Sofía, Cordoba	15	6.04
Hospital Son Dureta, Palma de Mallorca	13	5.24
Hospital Gregorio Marañón, Madrid	10	4.03
Hospital Clínico Universitario, Valencia	10	4.03
Hospital La Fe, Valencia	8	3.22
Hospital Sabadell, Barcelona	8	3.22
Hospital Universitario Salamanca	6	2.4
Hospital Virgen de las Nieves, Granada	4	1.61
Hospital Ramón y Cajal, Madrid	3	1.20
Hospital Virgen de la Salud, Toledo	2	0.8
Hospital General, Jaén	1	0.40
Hospital Virgen de la Candelaria, Tenerife	0	0
Hospital San Juan de la Cruz, Úbeda, Jaén.	0	0
Hospital de Jerez, Cadiz	0	0
Hospital los Arcos, Murcia	0	0
Total	249	100%

Figure 1. Age at which the tracheostomy was performed. Stratification by age group



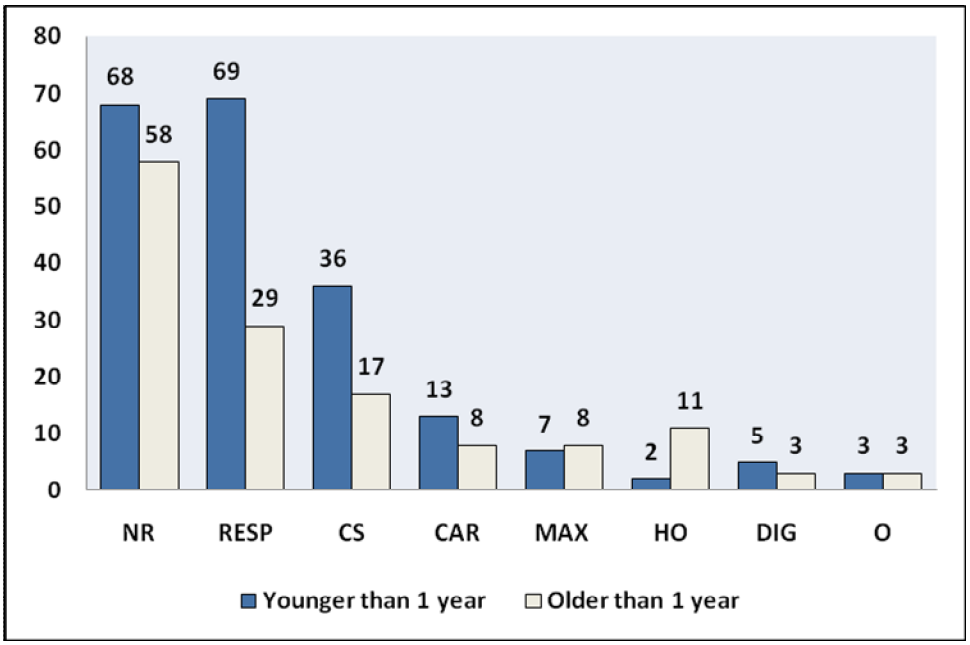
m: months. y: year

Figure 2. Indication for tracheostomy



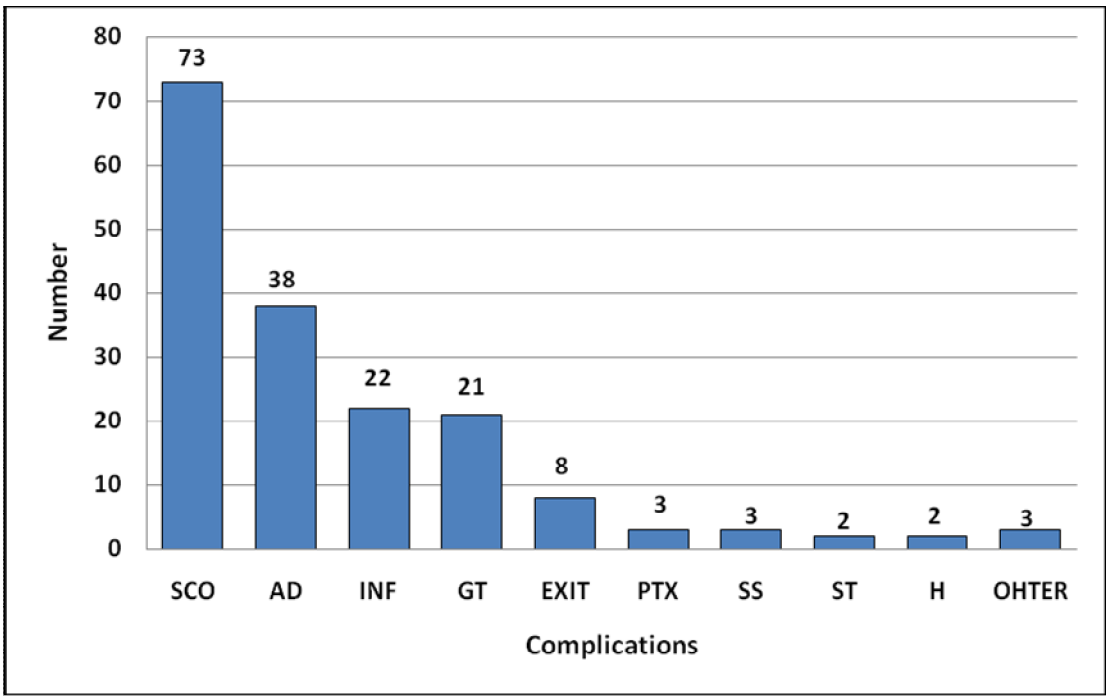
PV: prolonged ventilation. ASS: acquired subglottic stenosis. CFA: craniofacial anomalies. CAA: congenital airway anomalies. Other: acquired bilateral vocal cord paralysis, 4/10; Laryngeal papillomatosis 4/10. Acquired tracheo-oesophageal fistula 1/10; Postoperative central apnoea after cerebral tumour: 1/10

Figure 3. Most frequent disorders in the children with tracheostomy. Comparison between those younger and older than 1 year of age. NB A patient may have more than one disorder.



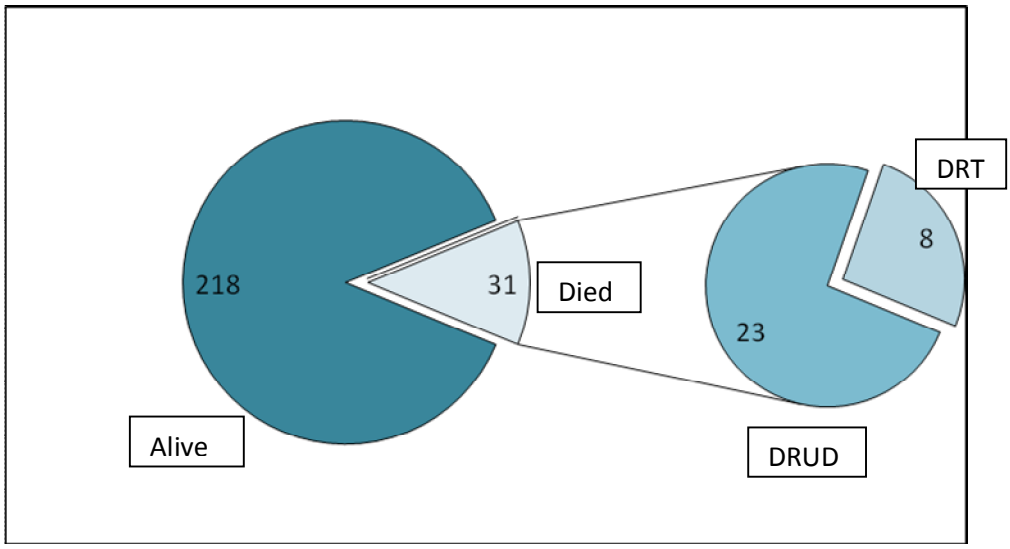
NR: Neurological. RESP: Respiratory. CS: Congenital syndromes. CAR Cardiopathies. MAX: Maxillofacial. HO: Haematological-oncological. DIG: Digestive. O: Other (Patients with various comorbidities)

Figure 4. Complications associated with the tracheostomy



SCO: Severe cannula obstruction. AD: Accidental decannulation. INF: Infection related with tracheostomy cannula. GT: Important granulation tissue. EXIT: Death directly related with the tracheostomy. PTX: Pneumothorax. SS: Stomal stenosis. ST: Suprastomal tracheomalacia. H: Haemoptysis. OTHER: 1 Trachea-innominate artery fistula, 1 Tracheal stenosis after tracheostomy, 1 Rupture of the cannula

Figure 5. General mortality and mortality directly related with the tracheostomy



Patients alive at the end of the study: 218/248 (87.9%). Patients dead at the end of the study 31/248 (12.5%). DRUD: Death related with the underlying disorder: 23/31 (9.7%). DRT: Deaths directly related with the tracheostomy 8/31 (3.2%): 4 newborns during the immediate postoperative period, and 4 patients due to severe obstruction of the cannula and failure of the resuscitation measures at home