A NEW AIRWAY SPIRAL STENT DESIGNED TO MAINTAIN AIRWAY ARCHITECTURE WITH AN ATRAUMATIC REMOVAL AFTER FULLY EPITHELIZATION; RESEARCH OF FEASIBILITY AND VIABILITY IN CANINE PATIENTS WITH TRACHEOMALACIA.

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Abbreviations:

SS: Spiral Stent

BCS: Body condition score

LL X-ray: Laterolateral radiography

KS: Karnofsky modified scale

ABSTRACT

Objective: Surgical management of tracheomalacia is a challenge and current treatments still present numerous complications. In the field of veterinary medicine this same pathology is present in a significant number of dogs. For this reason, we present an experimental clinical trial performed in canines with tracheobronchomalacia using a new atraumatic removable tracheal spiral stent (SS). Both, implantation procedure and clinical improvement have been analyzed.

Methods: Four small dogs, mean weight of 4.89 kg and body condition score IV to V, were included in this study. SS were implanted by two different surgical approaches. Image and clinical follow-up have been performed during 90 days. Symptoms were evaluated from 1-10 every week.

Results: Technical and clinical success was 100%. Median tracheal diameters were; cervical 10.85 (3.3), inlet 7.75 (2.1) and carina 7.75 (1.9) mm and length 77.5 (26) mm. A 12x10x100 mm SS was implanted in all cases. Goose-honk cough punctuation improves from 8 to 1, also exercise intolerance suffered important changes with a mean weight loss of 8.76%. Karnofsky modified scale varied from 50 (20) pre-surgical to 90 (10) after 30 days. In any case was observed granuloma tissue neither fractures of the prosthesis.

Conclusion: The results in dogs are promising and a new therapeutic alternative seems to be available for veterinarian field. The similarity of this disease between dogs and newborns suggests that this spiral stent design can also be useful for human trials.

INTRODUCTION

Airway collapse is an important cause of respiratory distress in children with malacia of the airway, especially in cases of tracheomalacia [1–3].

Malacia refers to "softness" of a tissue, typically bone or cartilage. The term tracheomalacia refers to softness of the trachea, frequently due to a widened and lax pars muscular, and/or an impaired cartilage integrity, that results in a weakness airway architecture with high collapsibility preventing a normal airflow from the atmosphere to the lungs [4–8].

Collapsing of the airway normally happens when more air is required, such as crying or exercise. Congenital airway malacia includes tracheomalacia, bronchomalacia and tracheobronchomalacia [4]. It can be primary tracheomalacia, in which the pathology is caused by the abnormal trachea itself, or secondary to external compression surrounding the airway. True secondary tracheomalacia is resolved by treating the main pathology such as mediastinal mass [5].

Primary congenital tracheomalacia is generally produced due to abnormal development or maturation of the airway in embryonic stages. In most cases, it is associated with other malacia disorders as part of a syndrome (e.g. Down´s syndrome, Ehlers-Danlos syndrome) or accompanied by other malformations of the digestive system (e.g. tracheoesophageal fistula…) [9–11].

Tracheomalacia is regularly associated with common respiratory symptoms. The main symptoms are: wheezing, persistent cough (caused by expiratory collapse and vibration of the floppy membrane), and dyspnea [1,4]. These symptoms overlap with other respiratory diseases, and therefore, it is not surprising that the diagnosis is delayed with an suboptimal initial treatment [11].

Tracheomalacia management includes medication or interventions that improve airway caliber (stents, aortopexy and continuous airway pressure) enhance mucociliar clearance, avoid infection and reducing intraluminal inflammation [8,11–13].

Stenting the airway has significant advantages in front of conventional surgery. It is a minimally invasive technique that requires short anesthetic time with a fast recovery [3,13]. Several types of stents have been used; currently, silicon stents and self-expandable covered stents, but mucosal obstruction, migration and granuloma tissue development at the ends of the prosthesis are common complications [14–16]. Metallic stents, both balloon-expandable and self-expandable, reduce the likelihood of migration and improve mucus clearance, however, it can be fully epithelized and unable to retrieve it [17–19]. Recently, bioabsorbable airway stents have been implanted in children with tracheomalacia and the results are promising [8,20]. The patency of the airway is recovered but stent fragmentation must be taken into account as a possible complication [20–22]. Nevertheless, more studies are needed to assess safety and efficacy in pediatric patients.

As seen, several alternatives have been proposed and there is a continuous developing on this topic. Studies on pathological animals are a good alternative to study and improve new surgical alternatives. Tracheobronchomalacia is a well-know disease present in veterinary medicine, that mainly affects small and toy dog breeds [23,24]. Similar characteristics are present between dogs and pediatric patients regarding this disease; for this reason pathological canines could be a good alternative as an animal model for tracheal stenting.

The aim of this study is to assess the feasibility and viability of a new spiral airway stent (SS) in dogs with tracheomalacia or tracheobronchomalacia. We hypothesize that

this prosthesis in a near future could be an alternative therapy for the treatment of tracheomalacia or tracheobronchomalacia in pediatric patients.

MATERIAL AND METHODS

The study presented is a prospective, non-randomized, monocentric clinical trial in pathological owned dogs. It was approved by the ethics committee (Code PI50/18), supported by a grant of the University of Zaragoza, Spain, and elaborated according to ARRIVE guidelines [25]. Every owner of the dogs accepted and signed the participation agreement.

Spiral Stent (SS)

The design of the current stent is a type of spiral stent (patent number ES2725273) that pretends to solve the currently described complications of tracheal stents, improving the mucociliary clearance due to the resembling of the tracheal architecture and to reduce the proportion of contact between tissue and prosthesis.

The helical prostheses implanted were manufactured in super-elastic memory shape NiTi (Nitinol) with a wire diameter of 0.3 mm and a gap between loops of 5 mm. NiTi was chosen because its elasticity and biocompatibility.

One conical shaped device was used: 12 mm x 10mm diameter and 100 mm length. The conic diameter was chosen because it resembles dog's tracheal architecture. Both tips of the SS were specially manufactured; on the largest diameter (the cranial) had a small loop to fix the stent to the trachea and on the caudal part (smallest diameter) was rounded and softer to avoid tracheal damage during the introduction (Figure 1).

Surgical procedures

The dogs were premedicated with a combination of acepromazine (0.04 mg/kg intramuscular [IM]) and butorphanol (0.3 mg/kg IM), enough to place an intravenous catheter and induced with alfaxalone intravenously to effect until endotracheal

intubation was allowed. Under fluoroscopy guidance the endotracheal tube was repositioned at the level of the first tracheal cartilage, and the animal was ventilated during the procedure. Under general anesthesia, the patient was positioned in dorsal recumbence with slight hyperextension of the neck. By palpation, the cricoid cartilage was located, and surrounding it a square of 4 x 4 cm was shaved and prepared surgically.

One centimeter caudal to the cricoid cartilage a skin incision of 2 cm, and dissection of the subcutaneous tissue and muscular planes were performed until the exposure of the trachea. To obtain the best vision a small separator was placed.

Two implantation procedures (Twining or packing implantation) were performed depending on four factors: tracheal collapse morphology, collapsed extension and location and the elasticity of the malacia.

Patients with lower elasticity, lateral collapse and shorter extension of the collapse were implanted with the method “Packing”. The decision was taken in a consensus of four professionals to check which procedure was the best for each patient.

Implantation method 1: Twining implantation.

The material used for the implantation was an 18G needle. A hole between two tracheal rings (caudal to the cricoid) was performed using the needle.

Through this hole, the stent was introduced with a rotatory movement. The smallest diameter of the SS was the first introduced, and the cranial part of the stent (biggest diameter) fixed to the cranial tracheal ring. The fixation was done with a non-absorbable monofilament suture that was introduced through the loop of the stent, and stitched to the trachea. The implantation of the stent (Twining) was always performed in collaboration with the anesthetist veterinarian, who did a ventilation with a positive

pressure of 20 cm H_2O to obtain the maximum diameter of the trachea while performing the rotatory movement.

Implantation method 2: Packing implantation

This procedure was performed by introducing the SS though a 4Fr peel-away dilator. The dilator length was adapted to the patient enough to advance 1 cm the intra-thoracic trachea. A minimum incision was done between two tracheal rings (at the desired level of implantation) with an 11 scalpel to introduce the dilator. Under fluoroscopic guidance the position of the dilator was checked then, the SS was introduced through the dilator lumen and rotating from the outside until the stent advanced into the intra-thoracic trachea. Once the SS reached the carina, it was kept from outside and the dilator was removed slowly, using the maneuver of "pinch and pull". When the SS was inside the trachea, it was fixed as previously explained (Figure 2).

Animals: Inclusion and exclusion criteria

Four dogs of three different breeds were involved in this study. Weights ranged from 3.5 kg-7.5 kg, body condition score was IV-V (BCS classified I-V) and, ages from 4.5 to 16 years.

Inclusion criteria were: presence and persistence of symptoms, tracheal collapse grade II-IV, at least one radiological imaging for diagnosis, and owner´s acceptance of the participation agreement.

Exclusion criteria: non-persistent symptoms, tracheal collapse <II, the impossibility of follow-up, another life-threating disease and non-participation agreement signed.

All animals were referred to the Minimally Invasive Department of the Veterinarian School of the University of Zaragoza.

Measurements of the tracheas were performed according to the protocol for tracheal stenting [23,26]; under fluoroscopic guidance with 20 cm H_2O of positive pressure and the

diameter elected was at least 20% bigger than the tracheal diameter. Areas measured were taken at three levels; cervical, inlet and at the level of the carina.

Patient 1: A 4.5 years entire Pomeranian female diagnosed of tracheomalacia two years ago. The collapse was refractory to medical management (corticosteroids, antitussives, and bronchodilators). She had exercise intolerance, continuous cough episodes, dyspnea, panting and persistent cyanosis (bluish tongue).

Patient 2: A 16 years old Chihuahua spayed female was presented with dyspnea episode. At emergency was observed a generalized tracheobronchomalacia. Initially, the treatment with corticosteroids solved the symptoms. After 2-months, cough and exercise intolerance were uncontrollable without high corticosteroids doses (1mg/kg each 12h).

Patient 3: An entire female of 12 years, Yorkshire Terrier was referred to the hospital with the classical presentation of chronic tracheal collapse.

Cardiac remodeling, pulmonary hypertension, constant tachypnea, exercise intolerance, hepatomegaly, and persistent cough.

Patient 4: A 7-year Pomeranian entire male was presented the last three summer seasons to the emergency service due to uncontrollable respiratory distress and cough episodes. He did better in winter but the last year his lifestyle was pretty compromised by the disease.

Diagnosis and follow-up

Pathology diagnosis

Diagnosis confirmation was performed by three different methods. Right laterolateral radiography (LL X-ray) in expiration and inspiration, fluoroscopy examination (awake and under sedation) and endoscopic examination to classify tracheal collapse grade, and bronchial affectation.

In dogs, tracheal collapse is classified in four degrees, being I near normality and IV a lumen reduction of >90% [27].

Clinical and Image Follow-Up

Previous to the intervention the owners were asked to score the symptoms between 0 (total absence) to 10 (maximum frequency), and every week during the first month they complete it to assess the clinical evolution. Moreover, owners evaluate the pet according to a Karnofsky Modified Scale for dogs [28,29] (KS) (0 death and 100 Normal activities of daily living, non-disease evidence).

Medical management was given to all patients during 21 days after surgery; it includes corticosteroids, antitussives and antibiotic.

LL X-ray examination was performed to check the position of the SS, its shortening, and abnormal tissue obstructions. It was done at three controls: 12 hours, 30 days and 90 day after the surgery. The endoscopic evaluation was performed just after twine placement to determine the position and the patency of the airway (Figure 3).

Data analysis

Data was processed and analyzed using a computer software program for statistical analyses with SPSS. IBM SPSS Statistics for Macintosh, Version 21.0; IBM Corp., Armonk, NY, USA). A P value of <0.05 was considered to indicate statistical significance. Qualitative variables were expressed as frequencies and compared using Fisher´s exact test and likelihood ratio.

Quantitative parametric variables were expressed as mean ± SD and, non-parametric variables were expressed as median (range). Previously, the normality was calculated using Shapiro-Wilk test. Paired samples were analyzed using T-Student test for parametric samples and Wilcoxon test for non-parametric variables.

RESULTS

Technical success and feasibility of both implantation procedures was 100%. The two procedures required the same incision length, but procedure-1 produced a minimum aggression of the trachea. Time scored in procedure-2 was 20.5 min inferior than procedure-1, being the media 90.3 min. Stent replacement was performed without complications during the intervention in patient 1 three times, until the caudal tip of the SS was inside the carina. No post-surgical analgesia was necessary and medical treatment was completely removed after the 21 day in any case.

The four animals presented BCS IV to V, with marked fat accumulation surrounding the neck, both Pomerania dogs presented shorter neck and the worse body weight conditions. All clinical data recorded are presented in Table 1.

Median diameter measures were: cervical 10.85 (3.3) mm, inlet 7.75 (2.1) mm and carina 7.75 (1.9) mm, and length 77.5 (26) mm. The SS implanted in all cases was 12 mm cranial, 10mm caudal and 100 mm length.

Symptoms scored before the surgery were recorded during 90 days (Figure 4). Previous exercise intolerance median was 6 (5) points being reduced until 1 (2), on 90 days control it increased to 6 (7) due to other non-associated pathologies (gastritis and hips dysplasia). Dyspnea was reduced to 0 (0) after day 15 post-implantation.

Gosse-Honk cough varied substantially between patients during the first 21 days, being more stable on control 30 and 90 with values 2 (1) and 1 (1) respectively.

Analyzing KS scale was observed a median initial punctuation of 50 (20) and the improvement to 90 (10) 30 days after the surgery. It was not evaluated at control 90 days because two patients suffer from other non-associated pathologies and on patient 4 was necessary to remove the SS because it was too small for him.

The weight reduction was not statistically significant (p=0,102), but the average percentage was 8.87%.

During radiographic imaging, shortening of SS occurred in two cases after 12h post-implantation, the percentage reduced was 20% and 40% in each case without clinical significance with KS, and without statistical significance (p=1,000) (Figure 5). Neither dislocation nor intraluminal tissue was evident in any case. Endoscopic evaluation after surgery demonstrated patency of the trachea in all cases.

DISCUSSION

Airway malacia is a benign pathology that presents many difficulties for its management. Talking about pediatric tracheomalacia, the challenge is still greater due to the reduced diameter of the respiratory tree and the rapid growth of the patient [30]. The study presented is a research in pathological dogs of three different small/toy breeds, with reduced tracheal diameter. Canine tracheomalacia characteristics are pretty similar to pediatric patients, regarding the cartilage degeneration and the hyperlaxity in the pars muscularis. The main difference is the age of presentation, since in dogs it is a degenerative progressive disease in middle-aged canines [27,31,32].

In cases of pediatric congenital diffuse tracheomalacia, it is necessary to give support to the entire trachea, and also it is essential to have the possibility of adapting the support to the growing patient [3]. Numerous surgical alternatives have been described for severe tracheobronchial obstruction in children, with limitations in many cases [3,8,9,11,13,18,19]. Stenting aims to recover the airway architecture giving support to the structure, and to maintain the permeability of the trachea[30].

In our clinical research experience with airway stents in animals, we have tested numerous stents such as steel stain, nitinol, drug-eluting and biodegradable stents. Each one presented pros and cons, but complications were always present [33,34]. The "ideal airway stent" should allow a perfect mucous flow, reduce foreign body reaction and give enough support to maintain permeability of trachea and main bronchus. In pediatric patients the device must allow an atraumatic placement as well as the exchange [35]. For this reason, we have developed a new shape stent with the same characteristics of the classical devices, and avoiding its complications.

Initially, the SS was developed to find a therapeutic alternative for canine patients, but we observed benefits that could be also interesting for children under this condition.

The feasibility and viability of the procedures performed have been demonstrated, with a minimum aggression of the tissue and rapid recovery of the animals. Analgesic medication was not necessary in any case and the recovery period was 12 hour of hospitalization. However, classic stents do not require any incision for its implantation, making them more suitable to use[13].

The first experience reported with metallic stents in children was in 1995 by Filler et al. and since then several cases have been published. Palmaz balloon-expandable metallic stents seemed to be the most acceptable for children [17,36]. On the one hand, they can be easily placed with precision and do not interfere with mucous clearance [11,13]. Conversely, the rapid epithelization and the tissue reaction are a matter that concerns many authors, and it is the reason why they consider these stents as permanent prostheses [7,10,13,37]. Management with self-expandable metallic stents have been also used, but the large diameter is a limitation for newborns, also authors reported that its placement is less accurate on position and performs constant tension on the tracheal wall [10,38]. In this study the spiral design allowed us to introduce it with precision in a small airway without any complications, and it was possible to reposition the SS anytime, as observed in other study with the same stent shape [34,35]. The new surgical approach has the drawback of being an open surgery but screwing or unscrewing the SS enables to change the position until the precise situation is achieved. Furthermore, as with classic stents, we observed early epithelization, but without signs of hyper-inflammation or mucous accumulation.

Polydioxanone biodegradable stent is the newest therapeutic management used in children. The relatively rapid degradation of the stent requires repeated stenting and limits its use for chronic pathologies. Some reports published lower complications

compared to other stents[8], whereas other´s demonstrate important complications such as stent fragmentation and large sharp pieces migration to lowest airway[20].

Silicon stents or hybrid stent are also used, generally in older children [16]. Granuloma tissue formation is one of the main complication arising metallic stents, [3,7,11,13] and still observed with silicone devices [18]. In our experience we did not achieve this phenomenon during the study even though metallic material was used. We hypothesized that the similitude between the trachea structure and the spiral design reduces the foreign body reaction and the radial force is concentrated in determined short areas.

Dislocation and mucous obstruction are probably the other major complications mostly present using silicon and hybrid [12,14]. The impossibility of being re-epithelizated makes them easier to remove them anytime, but recurrent infections caused by mucous accumulation and dislocation must be taken into account [11].

Migration is a complication totally avoided with the SS design, due to, it has a fixation point to the tracheal ring, and it has not been observed in any case. An important improvement achieved is the option to remove the SS once fully epithelized without tissue damage thanks to the helical shape. The removal was performed in one animal locating the fixation point and then unscrewing the spiral stent. The fixation to the tracheal wall has a double function; to avoid migration and to locate and remove the stent. Stent shortening is a frequent phenomenon present in dogs [26].

Patient´s clinical improvement and the absence of disease signs is the treatment´s maximum aim. Immediate clinical improvement is normally observed after stenting [8,13,23,39,40]. However, our patients presented a high variety of symptoms during the first two weeks, substantially improving on the fourth week without medical treatment.

Currently, KS gives a median punctuation of 85, a great result in aged patients with this chronic pathology and with an initial scale of 40-60.

The main limitation of this study is the small number of patients studied, the short-term follow-up and the differences between species compared.

Due to the similitude between the characteristics of the disease in dogs and children, we believe that the study in pathological canines can be used to assess a possible application of the SS in pediatric patients. Furthermore, the pathological dogs can be benefited of this treatment. The results obtained are really encouraging for veterinary professionals; the new spiral stent shape is giving enough support to degenerated tracheas without the associated complications. The largest experience in animals would give to us significant conclusions to extrapolate it to pediatric patients with tracheomalacia for a future consideration.

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