TREATMENT OF LACRIMAL DUCT OBSTRUCTION WITH A TEAR-LEADER STENT

TRATAMIENTO DE LA OBSTRUCCIÓN DEL CONDUCTO LACRIMAL CON EL STENT TEAR-LEADER

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ABSTRACT

Purpose: To compare the effectiveness and patency of the TearLeader stent (PBN) for treatment of lacrimal system obstruction.

Methods: A prospective study of 68 patients referred from the ophthalmology department with suspicion of lacrimal system obstruction. We placed 74 TearLeader PBN stents. Inclusion criteria were: complete obstruction of lacrimal duct with canalicula and lacrimal puncta patency, and absence of acute infection. We studied the clinical improvement by means of an opinion survey, and the patency of stents was evaluated with Kaplan-Meier survival curves.

Results: Follow-up of patients was two years. A painful procedure was reported in 10% of cases. Minor dacryocystitis appeared in 18.9% of cases, while complete resolution of epiphora was confirmed in 77% of cases (23% of cases showed grade I epiphora). Patency of stents: median patency 490 days (15 months), range 11 to 730 days; 1 year after stent placement patency was 0.51 and long term patency rate for 2 years was 0.31. Opinion survey of the 68 patients: satisfaction with the technique, the procedure and prosthesis placement was 41%; satisfaction whilst the stent remained patent was 60.8%.

RESUMEN

Objetivo: Describir los resultados clínicos y estudiar la permeabilidad del stent de Tear-Leader (PBN) en el tratamiento de la obstrucción del conducto lacrimal.

Método: Estudio prospectivo de 68 pacientes, remitidos desde el Servicio de Oftalmología para estudio de epífora por sospecha de obstrucción del conducto lacrimal. Hemos colocado un total de 74 stents Tear-Leader. Los criterios de inclusión fueron: obstrucción completa del conducto lacrimal con permeabilidad de canalículos y de puntos lacrimales así como ausencia de infección aguda. Hemos realizado en todos los pacientes el control clínico y una encuesta de satisfacción. Se realizó un estudio estadístico descriptivo y se evaluó la permeabilidad de la prótesis usando las curvas de Kaplan Meier.

Resultados: El seguimiento de los pacientes se realizó durante dos años. Se confirmó la resolución total de la epífora en el 77%, (en el 23% persistió una epífora grado I). Permeabilidad del stent: la mediana fue de 490 días (15 meses) con rango de 11-730 días, al año la permeabilidad fue de 0,51 y a 2 años de 0,31. Refieren implantación dolorosa el 10% de los casos implantados. Aparecieron episodios de dacriocistitis leve en el 18% de los casos.

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Conclusion: Tearleader stent placement is easy to perform and comfortable for patients. TearLeader placement gave a patency outcome similar to other stents *(Arch Soc Esp Oftalmol 2009; 84: 515-522).*

Key words: Lacrimal gland and duct, interventional procedures, chronic dacryocystitis, lacrimal orbital stent, Wacrees upright protheses.

Encuesta de satisfacción a los 68 pacientes: con respecto a la técnica, procedimiento y prótesis estaban satisfechos un 41%. Mientras la prótesis se mantuvo permeable se encontraban satisfechos un 60,8%. **Conclusión:** La prótesis Tear-Leader es de fácil colocación, con escasas molestias para el paciente. Presenta una permeabilidad similar al resto de stents del mercado.

Palabras clave: Glándula y conducto lacrimal, radiología intervencionista, dacriocistitis crónica, stent orbitario lacrimal, prótesis recta de Wacrees.

INTRODUCTION

Dacryocistitis is the consequence of chronic infection and inflammation of the lachrymal pathway, which develops an obstruction of the lachrymal tube and produces epiphora. This symptom is a frequent ophthalmological problem which accounts for 3% of visits to the clinic. It usually associates secretions and conjunctival hyperemia which cause discomfort for the patient (1).

In recent years nasal-lachrymal prostheses have been developed. These are fitted under fluoroscopic control and have been described as an alternative treatment to surgery for lachrymal pathway obstruction (2-4).

The purpose of this study is to analyze the Tear-Leader stent (InterV/PBN Medicals, Denmark) for treating lachrymal pathway obstruction, assessing the clinical results and the degree of patient satisfaction as well as study the stent permeability.

SUBJECTS, MATERIAL AND METHOD

During the two years of the study, 74 PBN Tear-Leader nasolachrymal stents have been fitted for treating epiphora due to lasolachrymal conduit obstruction in our Radiology Service (Intervention Radiology Section). The Ophthalmology Service referred patients after a clinical assessment comprising an initial exploration of the epiphora. According to Munck's classification, epiphora was graded from 0 to 4 (based on the number of times per day the eye had to be cleaned). Grade 0: No epiphora; Grade 1: less than twice a day, Grade 2: 2-4 times a day, Grade 3: 4-10 times a day, Grade 4: more than 10 times a day.

When patients arrived at the Radiology Service, a dacryocystograph was made to assess the level of the obstruction. After the radiological study, the procedure was explained and the informed consent obtained.

The image was checked in an Allura Xper FD 20 (Philips, Holland) digital angiography room with 3DRa station and view forum.

The inclusion criteria for stent placement were: complete obstruction of the lachrymal conduit with presence of lachrymal sac, patency of lachrymal canalicules and lachrymal points as well as absence of acute infection. The patients who abandoned the study and did not visit the practice for the evolution controls were excluded from the study.

The nasolachrymal stents were fitted by interventionist vascular radiologists with considerable experience in the specialty and familiar with the use of stents. After placing the stent, monthly evolution checkups were prescribed for 3 months, making appointments for the patients during which the lachrymal conduit was cleansed with saline. If any event occurred or the patient referred a relapse of the epiphora, an additional dacryocystograph was performed to assess the patency of the prosthesis with greater precision. After the 3-month period, contact with patients was by telephone on a quarterly basis. If any event occurred they were requested to get in touch with us for a radiological exploration and, if the stent was obstructed, it was removed by the ENT service. After 3 months of wearing the stent, the patients were surveyed over the telephone to determine their degree of satisfaction on a scale from 1 to 4. In the interview, they were asked

Table I. Lachrymal stent data collection

Name: .....

Age: ..... years

NHC: .....

Stent fitting date: dd/mm/yy .....

Date of symptoms relapse: dd/mm/yy (approximate).....

While the stent was operational:<

Symptoms: ..... Without epiphora ..... with some epiphora

Dacryocystitis events ..... YES ..... NO .....

Local pain ..... YES ..... NO .....

Degree of satisfaction with stent performance:

1. *Very satisfied*
2. *Quite satisfied*
3. *Somewhat satisfied*
4. *Not satisfied*

Degree of general satisfaction:

1. *Very satisfied*
2. *Quite satisfied*
3. *Somewhat satisfied*
4. *Not satisfied*

if they were satisfied while the stent was operational and with the procedure in general, including the fitting procedure, the treatment given by our staff and the clinical improvement of the epiphora and any subsequent complications.

If during said period there was any contingency or if the prosthesis was suspected to malfunction, the patients got in touch with us for a new clinical-radiological exploration which included the evolution of the epiphora and the apperance of contingencies such as acute dacryocystitis events or local pain (table I).

Stent description

The Tear-Leader set (TearLeader Stent, interV/PBN Medical, Denmark) comprises a stent having a diameter of 6 F and a length of 35 mm, a dilator, a plunger for placing the endoprosthesis, a non-traumatic nitinol guide with a 7-cm flexible and hydrophyllic tip and a catheter for the dacryocystograph. The stent has an S-shaped configuration which is sharper at the proximal end (fig. 1).

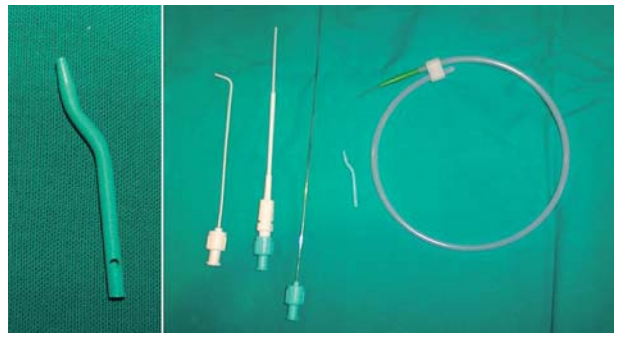

Fig. 1: Components of the Tear Leader nasolachrymal prosthesis.

The procedure was on an out-patient basis in all cases, with peri-orbitary local anesthetic (1% lidocaine) and sedation when necessary. For decongesting the nasal mucosa, a gauze imbibed in local anesthetic and adrenaline was introduced. The patients were given oral amoxicilin 500 mg/8 hours, 24 hours before the procedure and 6 days thereafter. At the time of manipulation, antibiotics were administered and drops of topical steroids. In all cases, after placing the stent the lachrymal conduit was washed with saline.

The study was prospective with descriptive statistics studying the patency of the nasolachrymal stent, utilizng the Kaplan Meier survival curves.

RESULTS

All the patients in the study exhibited epiphora grade IV with complete obstruction of the lachrymal conduit. None of the patients had epiphora of traumatic origin. The age range of patients was of 18-84 years with a mean of 61.8 years, 22 men and 46 women. We included in the study only the patients whose stent insertion was successful.

The necessary fluoroscopy time during the manipulation was of 59 seconds (range 40 seconds to 1.5 minutes).

No major complications arose during the stent insertion. The prostheses implantation procedure was described by patients as painful in 10% of cases. It must be emphasized that 81% of patients described said procedure as «not bothersome at all». Only 3 patients exhibited slight epistaxis during the manipulation, which remitted spontaneously after the procedure and cleaning the stent with saline.

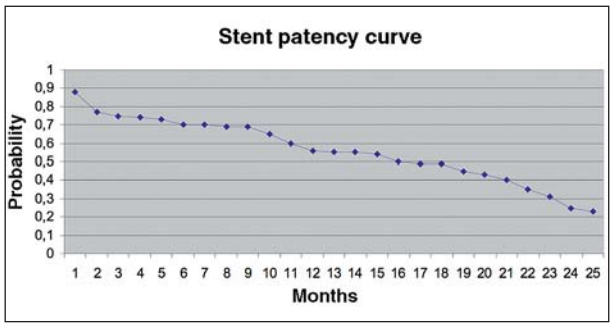

Fig. 2: Kaplan Meier actuarial curve, expressing the nasolachrymal stent patency probability through the follow-up months up to a total of 2 years.

Clinical follow-up

(Monthly clinical exploration for 3 months and subsequent quarterly telephone consultation. If any event occurred, a dacryocystograph was performed).

During the time in which the stents were permeable there was a marked improvement in what concerns tearing although grade I epiphora persisted in 23% of patients. After the stent was inserted and functioned properly, some acute and isolated dacryocystitis episodes appeared in 18% of cases which were successfully resolved after the administration of topical antibiotics. Even so, in 4 patients it marked the beginning of a subsequent stent obstruction. In 5 cases the stent inadvertently came out (6.1%) and this occurrence was noticed during a control dacryocystograph.

A total of 31/68 patients were reassessed due to clinical suspicion of obstruction and in fifteen the stent obstruction was demonstrated.

Stent patency

The stent patency study achieved a mean of 490 days (15 months) with a range between 11 and 730 days. After one year 51% of stents were permeable and 31% after 2 years. The patency graph is represented by the actuarial Kaplan Meier curve, expressed in months to make it more understandable (fig. 2).

Satisfaction survey

While the prostheses was operational and the symptoms improved noticeably, 60.8% of patients were satisfied with the stent (here we include satisfied and very satisfied patients). If we asked the patients about the overall satisfaction with the procedure (including the technique and health staff service) as well as the clinical improvement after insertion of the prostheses including the stent obstruction, only 41% of patients were satisfied.

Table II. Patency analysis. Descriptive statistics

Days	Maximum	Mean	Average
Tear-Leader stent	731	267.9 *desviación típica* *214.1*	490

DISCUSSION

Epiphora is one of the most frequent symptoms of patients who visit an ophthalmology practice. This problem can be due to multiple causes which can be grouped in two main categories: irritative alterations which produce a reflex tearing and a functional or organic deficit of drainage, with the acquired lachrymal conduit obstruction being more frequent. This disease can appear as repetition conjunctivitis, irritative eyelids dermatitis, chronic secretion, formation of dacryoceles and even acute dacryocystitis (occasionally relapsing). It is usually unilateral but it can be bilateral and affects about 2% of the population. It is more frequent in aged individuals although it can appear at any age.

The traditional treatment is external dacryocystorhinostomy. This technique has a success rate of 90% in expert hands. At present it is the rescue technique for all the other techniques (4). In recent years new techniques have emerged such as laser endoscopic dacryocystorhinostomy, which has the advantage of not requiring an external incision and lower risk of hemorrhage. The drawback is its failure rate, which ranges between 17 and 30% of cases (5).

In 1995 a new treatment was published as an alternative to dacryocystorhinostomy. Song et al (6) described a new retrograde insertion method for a polyurethane prosthesis. The initial results were promising, with a patency percentage of 85-98% (7-9). However, the patient follow-up was under 1 year. Many interventionist radiologists began to use this stent because it was safe, relatively simple to implant and allowed subsequent surgical maneuvres if the prosthesis became obstructed. But the

medium and long-term results did not fulfill their promise. Even Song recommended not using said stent as a first option for treating nasolachrymal conduit obstruction (10). A paper by Yazini et al reached the same conclusion (11), i.e., that patency was considerably reduced after some time, yielding success rates of 69%. In addition, this study did not include patients whose lachrymal conduit obstruction was traumatic because in these cases it was demonstrated that the stent failure rate is greater (6,12). Other authors reached similar conclusions and obtained patency rates of 56% after following up for 2 years (13). An additional drawback of Song's stent was that it required large lachrymal sacs to achieve an adequate expansion of the prosthesis proximal end (11). There are studies that describe higher stent patency percentages, including that of Lanciego et al where 15 months after insertion, 85.8% of stents remained functional (16).

The main cause of stent failure was demonstrated to be due to chronic inflammation occurring around the prosthesis which generated granulation tissue (14). In addition, the lachrymal sac morphology worsened after the removal of an obstructed stent because it contracted and became smaller, hindering the insertion of a new prosthesis (11).

We began to use Song's stent because it was the only one available in the market (Ferrer-Puchol M, Esteban-Hernández E, Jornet-Fayos J. Obstruction of the lacrimal system. Treatment and long term results with polyurethane Song stent versus TearLeader-stent. In: Annual Meeting and Postgraduate Course of the Cardiovascular and Interventional Radiological Society of Europe, 2005 Abstract Book poster 30. p 164). The main drawback we observed was that its insertion was painful and bothersome for the patient (mainly the introduction of the hook through the nasal fossa to capture the guide). We were surprised to find that the literature does not emphasize this. We also observed cases of temporary nasal bleeding which was described by other authors, including some cases of severe epistaxis (17).

One point to be taken into account is that, as Song's stent is the most widely used stent there are longer term patency studies. It is known that after 5 years of fitting the prosthesis, only 19.2% of cases are permeable (18). All these factors have contributed to the emergence of Song stent modifications as that described by Lanciego et al, in which a modified design improves patency (19), or entirely new designs such as the TearLeader stent (20) which does away with the rounded portion in the proximal end, in addition to having an Italic s-shaped morphology. In our view, the main advantage of the new stent is that it doesn't require a hook to extract the guide through the nasal fossa because it includes a catheter which, once the obstruction is overcome, can be directed to the anterior part so that, when the guide is introduced, it spontaneously comes out through the nasal orifices.

Our group began to utilize this new stent design which immediately facilitated an easier handling and became a virtually painless procedure for the patient (only 10% of surveyed patients described the procedure as irritating). In addition, the time required for its insertion was considerably lower, with the added advantage of a minimum fluoroscopy time.

However, a negative result must be noted, i.e., that while the TearLeader stent remained functional a minimum epiphora persisted (grade I) in 23% of patients, and that some dacryocystitis cases emerged (18%). We attributed these results to the fact that the proximal portion of the stent (which impinges on the lachrymal sac) is too narrow and in some cases prevents adequate drainage of the tear through the prosthesis. A further shortcoming we observed in the design of this new stent is the possibility that it might inadvertently come out, as referred in the results of our study: in 5 patients who visited the practice due to increased epiphora, the stent was not in the lachrymal conduit.

In what concerns the patency of the stent, our data can overlap those published in the literature, with the limitation that our study comprises only 2 years and we are unable to determine the long-term patency rate. We found only a few studies with this new stent design. Wilhelm et al (20) evaluated the TearLeader stent agains Song's stent and surprisingly patency is greater in the TearLeader stent and also the hydrophyllic covering prevents granulomatous reactions in response to foreign bodies. This was emphasized as crucial for the patency of the prosthesis, but the limitation of this study is that it was carried out in rabbits and the follow-up is of only 3 months.

We believe that the stent is relatively safe with the appearance of a small number of complications and ease of handling, although we would like to underline an important complication which emerged recently with this stent as described by Lanciego et al (21): after the insertion of the prosthesis, the patient exhibited intense edema due to cellulitis and

loss of vision. The eye fundus exploration revealed atrophy and paleness in the optic disc. One month later a dacryocystorhinostomy was performed without complications. The loss of vision was attributed to a compression of the nerve by the orbitary cellulitis which extended from the orbit floor to the internal straight muscle, causing irreversible ischemia in the optic nerve. However and setting this complication aside we did not find in the literature other similar complications. Accordingly, we believe that initially this is a low-risk procedure but it is important to emphasize the administration of prophyllactic antibiotic therapy for preventing possible infections.

The patient survey gave a satisfaction rate of 60.8% while the stent was functional and the satisfaction of patients when asked about the procedure in general was low (only 41%). We know that these results have important limitations which constitute a bias because the patient replies are subject to multiple influences (mood, concomitance with other pathologies, etc). Even so, we believe the patient expectations were much higher.

In summary, we consider that nasolachrymal prosthesis represent an interesting therapeutic alternative in lachrymal conduit obstructions. The main advantage of the TearLeader prosthesis is that its insertion is simple and not very disturbing for the patient. However, in our view the designs must improve to obtain larger patency rates and additional studies are needed with longer follow-up times. Perhaps the future lies in easy to fit and time-limited prosthesis because it appears that stents tend to become obstructed in the majority of cases.

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