A Prospective Randomized Study of Medications After Silicone Intubation

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BACKGROUND AND OBJECTIVE: Following silicone intubation, most surgeons prescribe either an antibiotic or an antibiotic-steroid combination medication. No known controlled study has been performed to determine whether steroids in addition to antibiotics improve the postoperative outcome.

PATIENTS AND METHODS: The author performed a prospective randomized study of 108 patients (118 eyes) who underwent silicone intubation over a period of 4 1/2 years. Sixty-seven patients received a combination of neomycin, polymyxin B, and dexamethasone and 41 patients received gentamicin for 2 weeks after surgery. A standardized surgical technique and instruments were used. Follow-up ranged from 8 to 44 months (average 19 months).

RESULTS: No statistically significant difference was found in the failure rates when patients treated with an antibiotic-steroid combination were compared with those treated with antibiotic alone.

CONCLUSION: Following silicone intubation, there appears to be no additional benefit of an antibiotic-steroid combination medication over an antibiotic alone.

INTRODUCTION

Silicone intubation of the lacrimal system in uncomplicated epiphora has enjoyed a relatively high success rate.1-13 Although some complications have been reported, none of these appear to have been serious or irreparable.4-15 In an effort to achieve an even higher success rate, various authors have emphasized such points as careful patient selection, surgical technique and instrumentation, and postoperative steroid coverage. To the best of this author's knowledge, there has been no known study performed to demonstrate scientifically the efficacy of postoperative steroid treatments. This prospective randomized study addresses this issue specifically.

PATIENTS AND METHODS

A total of 123 patients underwent silicone intubation of the lacrimal system between February 1989 and August 1993. When there were no medical contraindications, these patients were randomized to receive either a combination of neomycin, polymyxin B, and dexamethasone (Maxitrol, Alcon Laboratories, Inc., Fort Worth, TX) or gentamicin drops for 2 weeks after surgery.

Follow-up ranged from 8 to 44 months (average 19 months). Fisher's exact test was used to compare the failure rates between the eyes treated with Maxitrol and the eyes treated with gentamicin. This study was scientifically significant.
approved by the Institutional Review Board of the University of Southern California.

Each patient underwent a complete evaluation prior to surgery. Pertinent history was obtained, visual acuity was recorded, and refraction was checked. In addition to ruling out entities such as glaucoma, allergies, and tearing due to exogenous factors, lacrimal function was studied. Eyelid position and closure, blinking, Bell's phenomenon, health of the cornea and conjunctiva, lashes, and the lower eyelid muscle tone were observed. Schirmer's test, tear break-up time, Jones' I dye test, probing, and irrigation of the lacrimal system were used in 7 young children. The ipsilateral nasal cavity, or both cavities in the bilateral cases, was packed with cotton balls soaked in 4% cocaine. An olive-tipped Benger intubation set (Storz, St. Louis, MO) with retrieving hook was used for all cases. The puncta were dilated, followed by insertion of the intubation set. In most cases, the olive-tipped wire was retrieved and removed within minutes without difficulty. Infracture of the inferior turbinate was necessary in only 5 patients. The silicone tube was tied with 8 surgical knots in a 2-2-2-2 overhanded manner (i.e., 4 throws of double knots). To avoid undue tension or leaving an excessive loop of the tube within the lacrimal system, tension on the silicone tube was adjusted so that there was 3 to 5 mm of play in the visible portion between the two puncta. No additional anchoring suture or bolster of any kind was used.

Following installation of the silicone tube, a cold compress was applied immediately to the operative site for 24 hours. The first postoperative visit was scheduled for 1 week later, with additional visits scheduled at 2 weeks and 1 month after surgery. Thereafter, appointments were scheduled at 3-month intervals.

When there were no medical contraindications and no medical reasons to choose one drop over another, each patient was randomly given either Maxitrol or gentamicin drops to use. Maxitrol was to be administered four times daily during the first week and twice daily during the second week. Gentamicin was to be administered four times daily for 2 weeks. Thereafter, either medication was to be used only when necessary and only as directed.

RESULTS

Of the 123 consecutive patients who underwent silicone intubation, 69 (56%) received Maxitrol and 54 (44%) received gentamicin. Fifteen patients, 2 in the Maxitrol group and 13 in the gentamicin group, were excluded from the study (this includes 4 who failed to use the eye drops as instructed, 2 for whom the choice of drops was biased due to medical reasons, 1 in whom the olive-tipped Benger intubation set was not used, and 2 who were unavailable for follow-up examination). The 5 patients with infracture of the inferior turbinate were also excluded from the study, as was a young child who pulled the tube out and in whom a reintubation procedure was necessary. One other patient accidentally pulled the tube out a few millimeters 3 weeks after surgery. He came in immediately, and the tube was repositioned without difficulty and without further incident; this patient was included in the study.

Of the remaining 108 patients, 74 (69%) were
female and 34 (31%) were male. There were 10 bilateral cases, for a total of 118 eyes. The patients ranged in age from 30 months to 71 years (median 58 years). Ten patients were younger than 18 years, 5 in each treatment group.

Following intubation, 67 (62%) of the patients (74 eyes, 69%) used Maxitrol drops four times daily for the first week and twice daily the second week and 41 (38%) of the patients (44 eyes, 31%) used gentamicin four times daily for 2 weeks. Three failures, all unilateral cases, occurred in each of these groups; this constituted an overall failure rate of 5.1% (6 of 118 eyes). In the Maxitrol group, the failure rate was 4.1% (3 of 74 eyes); in the gentamicin group, it was 6.8% (3 of 44 eyes). The difference between the two groups was not statistically significant ($P = .67$).

When one studies the success rate according to the ages of the patients, one is effectively looking at the success rate of silicone intubation in either the congenital (the pediatric group) or the acquired (the adult group, including functional epiphora) nasolacrimal obstruction. Because there were no failures among the 10 children younger than 18 years, the success rate in the pediatric group is 100%. The overall failure rate in the adult group is 5.56%, for a success rate of 94.44%.

**DISCUSSION**

Although the success rates of silicone intubation for treatment of epiphora have been reported to range from 82.5% to 100%, there are no uniform criteria in these reports in terms of patient selection, surgical indications, surgical technique, or instruments used.1-9 It is known that the success rates in children tend to be much higher than the success rates in adults.1,2,4,6,9,12 However, in the current study, the author found the success rate in adults with acquired nasolacrimal obstruction or functional epiphora just as favorable. This finding differs somewhat from the previous reports. The reason for this most likely lies in patient selection.

The postoperative use of antibiotics and/or steroids was mentioned only in passing in most of the previous reports. Although some authors feel strongly about steroid therapy,1 the efficacy of steroid therapy in improving the success rate in silicone intubation has not, to the best of this author's knowledge, been studied in a scientific manner. To obtain meaningful results, variables must be kept to a minimum, hence the patient selection process, the standardized surgical technique and instrumentation, and the random assignment of Maxitrol or gentamicin drops used in the present study.

Because the general standard of practice calls for some antibiotic coverage postoperatively, there was no steroid-only group and there was no "control" group in which patients received no medication. This author was comparing an antibiotic alone versus an antibiotic-steroid combination therapy. Maxitrol and gentamicin were chosen because they are the drugs most commonly prescribed for this purpose in the medical community (i.e., they are chosen for reasons of clinical relevance). Scientifically, a particular antibiotic and its steroid combination would have been preferred.

Since its introduction in the late 1960s, the silicone intubation set (as well as the surgical techniques) has undergone many refinements.16,17 Various types of tubes are now available with different wires, tips, groove directors, and hooks. For each, every surgeon develops his or her own tricks to most efficiently and effectively accomplish the intubation.3,4,8,12-14,18,19 Although a difficult case is encountered occasionally, an experienced surgeon is likely to accomplish this procedure in a few minutes, with minimal bleeding.

This author has used all types of tubes and their accessory instruments. Occasionally, when unable to easily intubate the lacrimal system with one type of tube, he has managed to successfully accomplish intubation by using a different type of tube or a different technique. Different intubation sets have wire of different diameters and rigidities, and the tubes are of different caliber or materials. Theoretically, larger and more rigid wires would cause more trauma to the delicate lacrimal system than would smaller and more malleable ones, and polyethylene tubes reportedly cause more problems.20-25

No matter how refined the instruments and how elegant the surgical technique, however, there may be trauma to the lacrimal system in addition to the presence of a foreign body. Therefore, postoperative use of steroids appears rational. The lacrimal system is not sterile, and with surgical trauma and the presence of a foreign body, the use of antibiotics is prudent. Hence, it is understandable why generally clinicians prescribe either antibiotics or an antibiotic-steroid combination drug. The present study has demonstrated that there was no statistically significant difference between the group treated with an antibiotic-steroid combination (Maxitrol) and the group treated with gentamicin. In other words, steroids appear not to have provided additional benefits.
REFERENCES


