Original Article

Comparison of outcome following dacryocystorhinostomy with or without silicon stent appliance; a randomized clinical trial

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ABSTRACT

Objective: to evaluate the effect of silicone stent appliance in Dacryocystorhinostomy through comparing it with conventional Dacryocystorhinostomy. Materials and Methods: In this randomized clinical trial patients with Nasolacrimal duct obstruction attending to Otolaryngology clinic of Baqiyatallah hospital were randomly allocated to two groups regardless of age, gender and disease duration; group A patients underwent endoscopic Dacryocystorhinostomy (DCR) with silicon stent and group B patients underwent conventional endoscopic Dacryocystorhinostomy. Silicon stent was removed one month after intervention. Patients in both groups were evaluated for symptom resolution, peri-, and post-operational complications in first and sixth months after intervention. Results: Eventually 50 patients (32 female and 18 male) with Nasolacrimal duct obstruction underwent analysis in two groups; stent group with a mean age of 44.40 years and control group with a mean age of47.66 years. In a six-month follow-up, Epiphora was resolved in 24(96%) of patients in stent group and 22 (88%) of patients in control group (p=0.808). Also success rate of endoscopic DCR was not significantly different between two groups after six months of follow up (p=0.08). Conclusion: In conclusion applying silicon stent has no superiority to conventional DCR in terms of Epiphora resolution and post-operational complications. However further studies with a larger sample size are needed.

Keywords: Endoscopic dacryocystorhinostomy, epiphora, nasolacrimal duct obstruction, silicon stent

Introduction

Involving 9% to 10 % of people in fifties and 35% to 40% in nineties; Epiphora is one of the most common causes for patients' attending to ophthalmology clinics [1]. It has a wide range of differential diagnosis from compensatory hypersecretion to nasolacrimal duct obstruction [2, 3]. Etiology of nasolacrimal duct obstruction includes two main idiopathic and secondary categories [4]. It may be due to local inflammation, systemic inflammatory disease, trauma, previous surgery or sinonasal neoplasia [5].

Dacryocystorhinostomy (DCR) is the common treatment for nasolacrimal duct obstruction which is done through three external, endonasal and endoscopic endonasal techniques [6]. Endoscopic DCR has a success rate of 82% to 86% and is superior to external DCR because of no need for incision as well as providing sufficient anatomical view of nose [7]. Previous studies have mentioned lack of convenient osteotomy, fibrosis formation and lacrimal sac location misdiagnosis as reasons for external DCR treatment failure [8].

Some previous studies have mentioned that applying silicone stents in DCR may decrease stenosis risk and adhesion in endoscopic and external techniques [9]. While others have reported no difference between DCR with and without stent application and that stent application may be even associated with more complications [10-12]. Superiority of silicone stent application in DCR has remained controversial. So in the present study we aimed to evaluate the effect of silicone stent appliance in DCR through comparing it with conventional DCR.

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Materials and Methods:

This randomized clinical trial was conducted between May 2014 and February 2015 in Baqiyatallah hospital, Tehran, Iran. The present study was registered in ethics committee of Baqiyatallah University of Medical Sciences (Reference code: IR.BMSU.REC.1393.31) and Iranian Registry of Clinical Trials (Reference code: IRCT2016101717413N18). (Figure 1) shows a flowchart of the trial. Patients with Nasolacrimal duct obstruction attending to Otolaryngology clinic of Baqiyatallah

hospital were assessed for eligibility. After confirmation of diagnosis by history taking, physical examination and Dacryocystography and signing a written informed consent form, patients were randomly allocated to two groups regardless of age, gender and disease duration; group A patients underwent endoscopic Dacryocystorhinostomy (DCR) with silicon stent and group B patients underwent conventional endoscopic Dacryocystorhinostomy. Silicon stent was removed one month after intervention. Etiology of disease and method of surgery were explained for patients prior to intervention. Patients with previous DCR or concurrent sinus disease were excluded from the study.

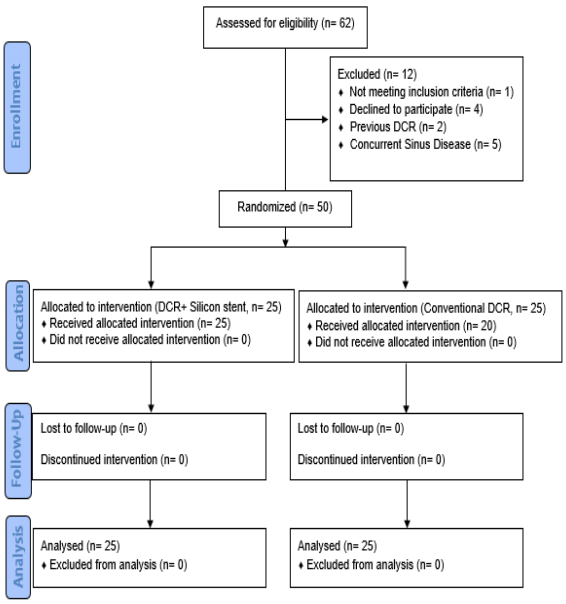

Figure 1: Study flowchart

Demographic and main complaints of patients were recorded in a predesigned checklist. Patients in both groups were evaluated for symptom resolution, peri-, and post-operational complications such as bleeding, discharge, adhesion and punctate granuloma formation in first and sixth months after intervention. In every visit patients underwent diagnostic endoscopy in terms of obstruction evaluation and results were recorded for each patient separately.

Statistical analysis:

Data was analyzed using SPSS software version 21 (SPSS Inc., Chicago, IL) for Microsoft Windows. Normal distributed variables (approved by 1-sample Kolmogorov-Smirnov test) were compared using independent sample *t* test between the groups. The chi square test was used to compare categorical variables in the 2 groups.

Results

Eventually 50 patients (32 female and 18 male) with Nasolacrimal duct obstruction underwent analysis in two groups; stent group with a mean age of 44.40 years and control group with a mean age of47.66 years (p=0.086).

All the study individuals had a complaint of Epiphora; while other complaints such as mucoid secretions, mucopurulent secretions and medial canthus swelling were present in 31(62%), 23(46%), and 17(34%) of patients, respectively.

In a six-month follow-up, Epiphora was resolved in 24(96%) of patients in stent group and 22 (88%) of patients in control group. There was no statistically significant difference between two groups for resolution of Epiphora (p=0.808). Also success rate of endoscopic DCR was not significantly different between two groups after six months of follow up (p=0.08).

Peri- and post-operational complications have been summarized in (Table 1). Granulation tissue formation was responsible for unsuccessful DCR of 2 (8%) patients in control and one patient (4%) in stent group. Canalicular obstruction resulted in unsuccessful DCR for one patient in control group. Two patients underwent early stent removal; one because of punctate granuloma and one for foreign body sensation.

Table 1: Peri- and post-operational complications in study individuals

Complications	Stent group	Control	P Value
Small lacrimal sac	2(8%)	1(4%)	0.675
Peri-operational Bleeding	4(16%)	1(4%)	0.443
Difficult stent detection	2(8%)	0	0.926
Cannalicular trauma	1(4%)	0	0.317
Granulation tissue formation	1(4%)	2(8%)	0.456
Early stent removal	1(4%)	0	0.185
Post operational adhesion	1(4%)	1(4%)	0.274
Cannalicular obstruction	0	1(4%)	0.856

Discussion

We found that there is no significant difference in terms of success rate and ductal complications by using silicon stent in Dacryocystorhinostomy in comparison with conventional DCR. The main goal of treatment in DCR is obstruction removal and establishing tear flow. There is a controversy in gold standard method; techniques such as probing, silicon stent and balloon Dacryocystoplasty are used for obstructed lacrimal duct treatment. Success rate for these techniques have been reported to be 50% or lower in long-term follow up [13, 14].

After about three decades DCR with endonasal endoscopy has turned to a common choice among surgeons and stent application has been effective in this success. DCR with endonasal endoscopy is commonly used for creating fistula between lacrimal duct and sac and application of silicon stent was first described by Gibbs et al. [15, 16].

In the present study, silicon stent resulted in 96% success rate in patients; while this rate was 88% in patients without stent application. Although Epiphora resolution rate was more in stent group but it was not statistically significant which is in concordance with Acharya et al., Harvinder et al. and Feng et al. studies [17-19]. Also Kakkar et al. and Unlu et al. did not find any significant differences between silicon stent DCR and conventional DCR [10, 11]. Dortzbach et al. reported that using silicon tubes in children is associated with complications [12].

In a retrospective study, Allen et al. concluded that silicon stents significantly increase failure rate of primary DCR. They mentioned that application of silicon stents should be avoided unless in cases with especial cannalicualr obstruction. Granulation tissue formation has been expressed as the reason for this conclusion [8].

Rosen et al. concluded that application of silicon stent in DCR prevents common cannalicule obstruction and osteotomy. They reported a 91.3% success rate for this method which is in agreement with Elmorsy et al. study [20, 21].

Conclusion:

In conclusion we found that applying silicon stent has no superiority to conventional DCR in terms of Epiphora resolution and post-operational complications. However further studies with a larger sample size are needed.

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