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Original Article

Comparison of balloon dacryocystorhinostomy with conventional endonasal endoscopic dacryocystorhinostomy for relief of acquired distal nasolacrimal drainage obstruction and its impact on quality of life: A prospective, randomized, controlled study

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ABSTRACT

Background: We compared balloon dacryocystorhinostomy with conventional endoscopic dacryocystorhinostomy for the management of acquired distal nasolacrimal obstruction and the quality of life post procedure.

Methods: 98 patients, aged 10–73 years, were recruited and randomized into 2 groups of 49 each who underwent conventional endoscopic dacryocystorhinostomy (group 1) and 9 mm balloon assisted endoscopic dacryocystorhinostomy (group 2). Follow-up sessions were conducted at 3, 6 and 12 months post-op.

Results: Group 2 showed significantly shorter mean operative time (25.10 min versus 29.82; $p < 0.001$), lesser pain in the post-op evening (mean 2.12 versus 2.9 on NRS-11 pain scale; $p < 0.001$) as well as on first post-op day (mean 1.08 versus 1.73; $p < 0.001$). Success was achieved in 89.79% in group 1 and 93.87% in group 2 at 3 months ($p = 0.46$) which declined due to recurrences to 85.71% and 87.75% respectively at 12 months ($p = 0.76$). Complications occurred in 14 cases in group 1 and in 10 cases in group 2 ($p = 0.34$). All were minor. Mean GBI scores (for quality of life assessment) at 12 months follow-up were 27.20 and 28.38 respectively ($p = 0.08$).

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Conclusion: The efficacy, safety and quality of life of balloon dacryocystorhinostomy and conventional endoscopic dacryocystorhinostomy were comparable. In addition, balloon dacryocystorhinostomy had significantly shorter operative time and lesser post-op pain.

Introduction

Epiphora (excessive tearing) is a distressing symptom which causes social embarrassment to the patient and adversely affects vision related quality of life (QOL).[1] This symptom can be relieved by dacryocystorhinostomy (DCR) which is an effective procedure for bypassing the obstruction in the distal nasolacrimal apparatus. The external approach of DCR (Ext DCR) described by Toti in 1904 had been the gold standard in the past, but with improvements in the endoscopes, now endoscopic endonasal approaches are becoming popular; especially among ENT surgeons due to shorter operative time, low complications, an absence of visible scar and high success rate which has been quoted as 95–100% in previous studies.[2,3]

The conventional technique of endoscopic endonasal DCR (End DCR)[4,5] has undergone many modifications. These include the use of stents, newer flaps, and mucosal preservation methods, local application of mitomycin C (MMC), use of powered instruments like drills and micro-debriders, use of lasers, radiofrequency, composite technique and balloons. There are published reports for as well as against all of these modifications.[6–13,26,27]

Balloon-assisted endoscopic endonasal DCR (Balloon DCR) is comparatively a newer modification, which was initially introduced by Becker et al. in 1996 as a dilatation technique for congenital nasolacrimal obstruction.[14] The technique has been claimed to have high success, shorter operative time and lower complications. However, studies on Balloon DCR are limited in number and are mostly retrospective case records analyses only.[15] Prospective, controlled trials employing Balloon DCR are even scarcer. One such study conducted by Ragab et al. compared 5 mm balloon assisted DCR with End DCR but did not find any difference in the success rate of the two procedures.[16] Further, we did not find any study on QOL following Balloon DCR in the literature despite an extensive search. QOL studies are available only for End DCR.[17,18]

Lack of enough prospective studies and complete absence of reports on QOL following Balloon DCR prompted us to undertake this prospective, randomized, interventional, controlled study comparing End DCR with Balloon DCR for their success rate, operative time, morbidity and post-surgery QOL.

Material and methods

The study was performed at a tertiary care hospital from August 2014 to March 2017. Ethical clearance was obtained from the Institutional Ethics Committee and the study was approved by the Scientific Review Committee of our institute. Informed written consent was obtained from all participants.

A total of 126 patients were assessed. Finally, 98 patients were selected as elaborated in the flow diagram of the study (Fig. 1).

Inclusion criteria

All patients presenting with features of acquired, complete, distal nasolacrimal drainage obstruction (NLDO) like epiphora, mucopurulent eye discharge, chronic dacryocystitis of more than one year duration were included in the study.

Exclusion criteria

Patients with symptoms due to any other cause except distal NLDO were excluded. This included proximal NLDO like common canalicular block, ocular pump failure, dry eye syndrome or those having post-traumatic bony deformity, bone diseases, Down's syndrome, suspicion of malignancy, radiation therapy, large dacryoliths, Sarcoidosis, Wegener's granuloma, chronic inflammatory disease of nose and sinuses, age less than 10 years, systemic disease likely to jeopardize safety in surgery like bleeding dyscrasia and non-consenting patients.

Sample size calculation

The sample size was calculated based on a projected difference of 20% in the main outcome measure, i.e. success rate of the two procedures. The success rate for sample size calculation was taken as 75% for End DCR and 95% for Balloon DCR based on results of a pilot study on 24 patients conducted earlier. Based on this, we calculated a sample size of minimum 49 patients per group, which would permit a type 1 error (alpha) of 0.05 with a type II error (beta) of 0.5 and power of 0.8 permitting a two tail analysis.

Patients' evaluation

Patients were registered and demographic data recorded. History of various symptoms of NLDO was elicited. Complete Ophthalmologic and ENT evaluation were done.

Lacrimal sac syringing was used to determine the degree and site of obstruction. Reflux of fluid through the opposite punctum indicated distal NLDO, while the reflux from the same punctum indicated proximal NLDO. If the fluid passed into the nose freely with no reflux into the eye, the lacrimal system was labelled as patent not requiring surgery.

Probing was performed by inserting a lacrimal probe through the punctum and led into the canaliculus. If it stopped 'hard' against the bone, it ruled out the canalicular block. If it stopped 'soft', a blockage in the canaliculus was likely.

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