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Abstract

Objectives. To conduct a prospective randomized controlled study to investigate the safety and efficacy of endocanalicular, high-pressure, 5-mm balloon catheter, endoscopic dacryocystorhinostomy (DCR) in adult patients with acquired complete nasolacrimal obstruction.

Study Design. Prospective randomized controlled study.

Setting. General hospital.

Subjects and Methods. Sixty-six adult patients with a total of 70 procedures were recruited to undergo endoscopic DCR. They were prospectively, equally randomized into 2 groups: endocanalicular, high-pressure, 5-mm balloon catheter, endoscopic DCR (group I) and conventional endoscopic DCR (group II). Regular follow-up sessions were conducted to document the patient's subjective improvement, judge ostium patency on irrigation, and record any complications.

Results. Both groups demonstrated a success rate of 91.4%. There was a shorter mean operative time (25.7 minutes) in group I ($P < .001$). The number of adverse events was significantly higher in group II ($P < .05$). Group I showed statistically significantly more comfort during surgery under local anesthesia with minimal sedation ($P < .05$).

Conclusion. Endocanalicular balloon catheter endoscopic DCR shares the advantages and success rate of conventional endoscopic DCR. In addition, the former is simpler, requires less manipulation, consumes a shorter operative time, has a better safety profile, and can be conducted under local anesthesia with minimal sedation.

Keywords

balloon catheter, endoscopic, dacryocystorhinostomy, lacrimal randomized, prospective, controlled

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Tearing is a challenging condition that can be induced by hypersecretion, lacrimal pump dysfunction, and lacrimal outflow obstruction. The advent of dacryocystorhinostomy (DCR) provided a revolution in the management of tearing secondary to nasolacrimal duct obstruction. This procedure can be performed through an external or endonasal approach. Success rates of greater than 90% are common with the external DCR procedure.¹ Disadvantages of external DCR include scarring of the facial skin, risk of copious hemorrhage, and disruption of medial canthal anatomy. The endonasal approach was introduced in 1893 by Caldwell² but has been of limited use mainly because of the difficulty of visualizing the endonasal anatomy during surgery. However, the popularity of endonasal DCR increased in the 1980s. In 1988, Rice³ demonstrated in cadaver studies that endoscopy was a viable option in DCR. The first clinical study of endonasal DCR was published by McDonogh and Meiring in 1989.⁴ Success rates up to 94% have been reported with endonasal DCR.¹

High-pressure balloon dilatation has been used in different fields of medicine. In lacrimal surgery, balloon catheter dacryoplasty has been used in cases of incomplete and persistent nasolacrimal obstruction in children and adults after failed probing and silicon intubation.^{5,6} Endonasal balloon-assisted endoscopic DCR was studied retrospectively, attaining a success rate of 92%.⁷ To our knowledge, no report in the literature describes the use of endocanalicular high-pressure balloon catheters in performing DCR. Therefore, we conducted a prospective randomized controlled study to investigate the safety and efficacy of endocanalicular, high-pressure, 5-mm balloon catheter, endoscopic DCR in adult patients with acquired complete nasolacrimal obstruction.

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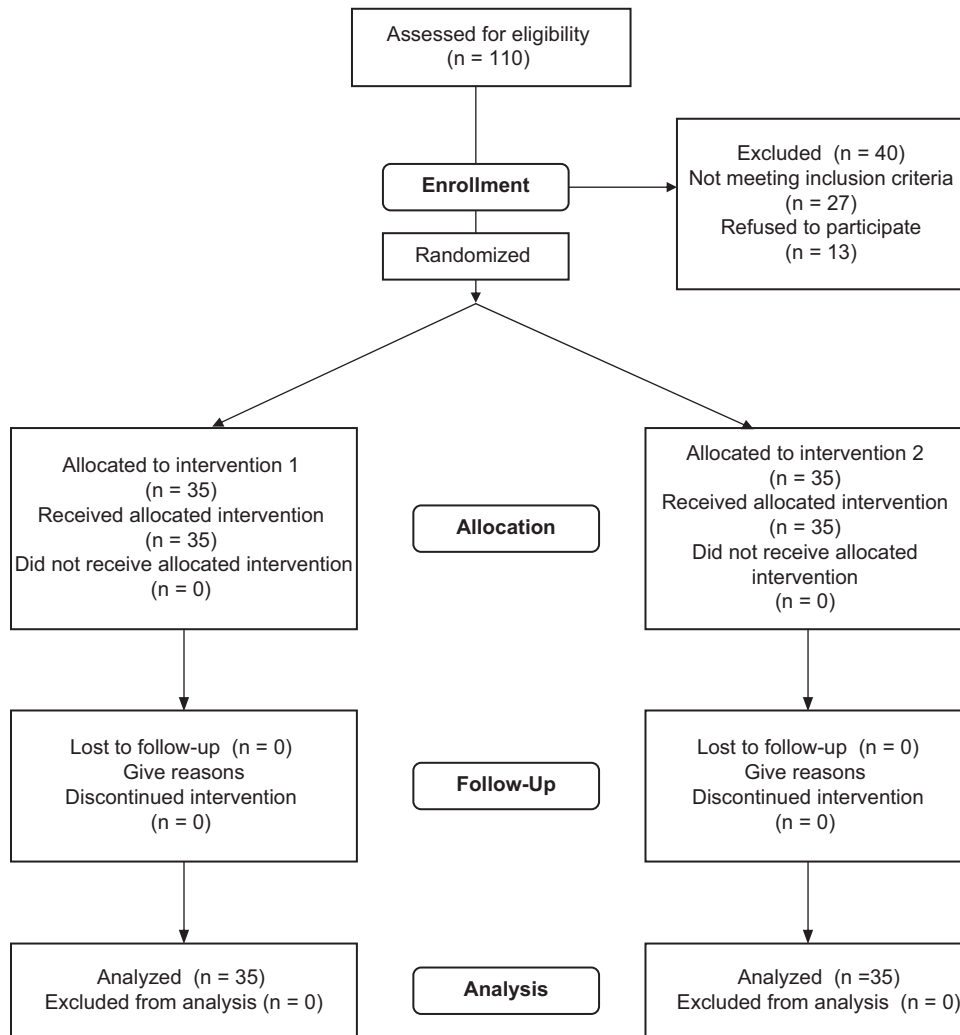


Figure 1. Flow chart of the study.

Materials and Methods

Adult patients with a history of watering of the eye were investigated using lacrimal irrigation and probing of the canaliculi with a blunt-tipped Bangerter lacrimal cannula up to the intact bony wall of the lacrimal sac fossa. The lids were inspected, focusing on the positions of the lacrimal puncta and the function of the orbicularis muscle. Dacryocystography was performed on all patients in the Department of Radiology Taiba Hospitals. Examination of the nose was done using 0° and 30° rigid endoscopes to reveal any nasal abnormality. Only patients with patent canaliculi, normal eye lid function, no suspected lacrimal sac neoplasia, no nasal pathology, and acquired complete nasolacrimal obstruction due to chronic dacryocystitis and with duration of symptoms more than 1 year were included in this study. Exclusion criteria were canalicular or common canalicular obstruction ascertained with probing, noticeable lower lid laxity, age younger than 18 years, Down syndrome, suspicion of malignancy, radiation therapy, posttraumatic bony deformity, and bone diseases. The protocol of the study and the methods of consent were approved by the ethics committee of

Taiba hospitals. After application of the inclusion and exclusion criteria, 66 adult patients with a total of 70 procedures during the past 5 years were recruited to undergo endoscopic DCR. There were 13 males and 53 females. The mean age was 43 ± 9 years with a range of 22 to 64 years. They were prospectively equally randomized into 2 groups: endocanicular, high-pressure, 5-mm balloon catheter, endoscopic DCR (group I) and conventional endoscopic DCR (group II). **Figure 1** shows the flow chart of the study.

Group I

Surgery was performed under local anesthesia and minimal sedation. According to the American Society of Anesthesiologists, minimal sedation is a drug-induced state during which patients respond normally to verbal commands. Cognitive function and coordination can be impaired, whereas ventilatory and cardiovascular functions are unaffected.⁸ To reach such a state of minimal sedation, all patients received 50 mg of pethidine 30 minutes before the operation. Local anesthesia consisted of infratrochlear and infraorbital blocks using lidocaine 2% with

1:100,000 epinephrine. Lidocaine with epinephrine was infiltrated into the anterior part of middle turbinate and along the lateral wall of the nose at the proposed site, and nasal packs soaked in 1:100,000 epinephrine were applied as well. The procedure started with lacrimal punctal dilatation, and then a reinforced stainless steel 3-4 Bowman probe was used to enter the lacrimal sac through the superior canaliculus. Under guidance of 0° and 30° nasal rigid endoscopes, the probe was pushed posteroinferiorly through the thinnest portion of the medial sac wall and adjacent fossa and into the nose. Three or four additional entrances were made and joined together by manipulating the probe to form slits in the thin posterior lacrimal bone, lacrimal sac, and nasal mucosa. The entrance areas were joined together using a nerve hook. Bone chips and hanging mucosal flaps were removed using pediatric angled endoscopic scissors and forceps. A 5-mm balloon catheter (Atrion Medical Products, Arab, Alabama) was then introduced through the superior canaliculus until its tip appeared inside the nose. The catheter was connected to a saline-filled inflation device (**Figure 2**) and the balloon was inflated (**Figure 3**) to 8 atm for 90 seconds. The balloon was then deflated and reinflated to 8 atm for 60 seconds. This was repeated until the size of the ostium looked satisfactory. Finally, the balloon was deflated and the catheter was extracted in a clockwise direction. A pediatric backbiter forceps was used to widen the stoma anteriorly. A stent tube (**Figure 4**) with a larger diameter (1.32 mm) and a thin central segment (0.86 mm) (Atrion Medical Products) was inserted bicanalicularly, and the 2 ends of the tube were tied with 4-0 prolene suture and pushed back to the nasal cavity.

Group II

Surgery was performed under local anesthesia and minimal sedation similar to group I. The procedure started with lacrimal punctal dilatation, and then a 20-gauge vitrectomy light pipe was threaded through the upper canaliculus until it touched the bony medial wall of the lacrimal sac. Using 0° and 30° rigid endoscopes (Karl Storz, Tuttingen, Germany), the nasal cavity was assessed. The transillumination was seen and the position of the lacrimal sac was defined. A DCR radiofrequency probe, connected to a radiofrequency apparatus (Ellman Surgitron 4 MHz, Ellman International, USA), was used to remove a square of nasal mucosa centered over the transillumination light target. The underlying bone was drilled with a diamond burr to allow the light pipe tip to indent the lacrimal sac mucosa when held almost horizontally in the superior canaliculus. The lacrimal sac mucosa was tented with the light pipe, and the widest possible window was opened in the medial wall of the lacrimal sac using a knife blade. Further resection of the medial wall of the sac was performed using pediatric angled endoscopic scissors and forceps. Last, a standard bicanalicular silicon intubation of the lacrimal passages was done and the tube was tied and left in the nasal cavity.

Postoperative Course and Follow-Up

A course of postoperative oral antibiotics, steroid-decongestant nasal spray, alkaline nasal douche, and nonsteroidal anti-inflammatory medications was prescribed after surgery.



Figure 2. The inflation device, balloon catheter, and stent tube.

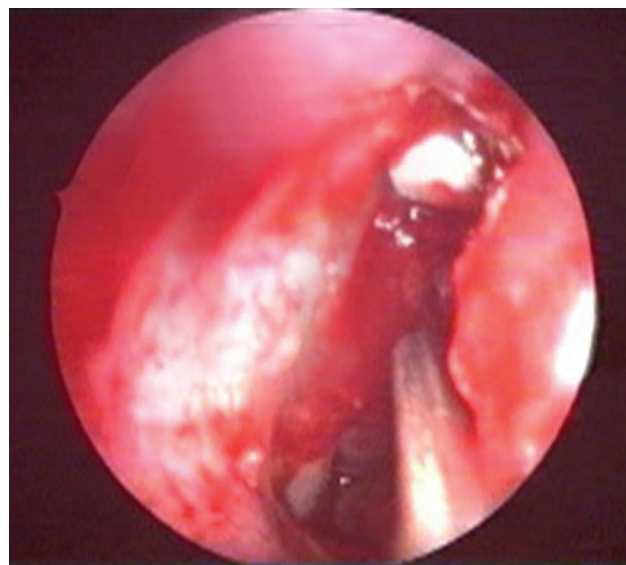


Figure 3. Inflated balloon catheter passing through the stoma.

Patients were asked to complete a questionnaire asking whether they were comfortable having the surgery under local anesthesia with minimal sedation and whether they preferred that the surgery had been done under general anesthesia. Patients were sent home the same day of surgery. Regular follow-up sessions were conducted the first week and then monthly after that to document the patient's subjective improvement, judge ostium patency on irrigation, and record any complications. The silicone stent was removed at the third month follow-up session. Patients with surgical failure 6 months after removal of the silicon tube after surgery were offered a revision surgery, whereas those with successful

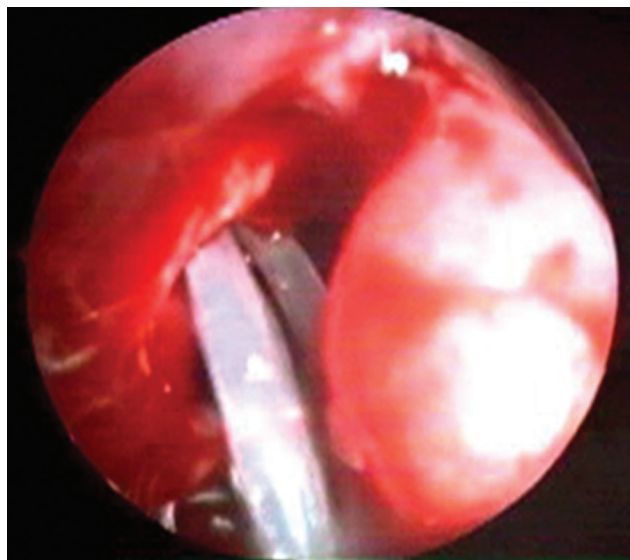


Figure 4. Large diameter stent tube passing through the stoma.

elimination of tearing were asked to return if their epiphora recurred.

Statistical Methods

To maintain exactly equal treatment numbers in both groups, randomization was done using random blocks, which is a stratified random sampling that allows homogenous blocks of the sample size. At the time of randomization, both the patient and the investigators were not aware of the group assignment. A sample size of 70 procedures was calculated at the 5% level of significance to give the study a statistical power of 80%. The primary end point was determined to be the success of the surgery as defined by the subjective disappearance of symptoms. The analysis was done using SPSS for Windows (SPSS, Chicago, Illinois). Data were expressed as mean \pm standard deviation (SD). P values $<.05$ were considered significant. Parametric tests such as paired t test, 2-sample t test, and analysis of variance were applied for data that followed or were transformed to a normal distribution. Nonparametric tests such as Mann-Whitney U test, Wilcoxon signed rank test, sign test, chi-square test, and Kruskal-Wallis test were applied for data that did not follow a normal distribution.

Results

Thirty-five procedures in each group were included in the analysis. No significant difference between the 2 groups was found in the patient demographic characteristics.

Success of the Surgery

The operation was classified as successful by the subjective disappearance of patient symptoms 6 months after removal of the stent tube. Both endocanalicular balloon catheter and conventional endoscopic DCR demonstrated a success rate of 91.4% (3 failure cases in each group).

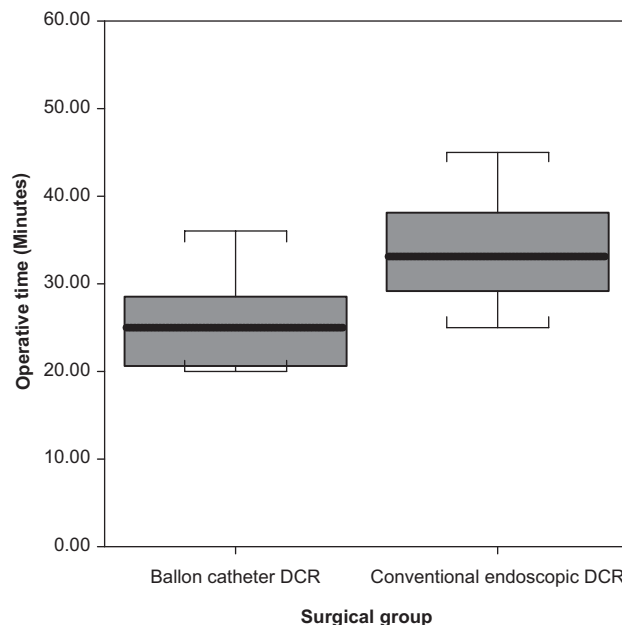


Figure 5. Box plots of the operative time. DCR, dacryocystorhinostomy.

Operative Time

There was a shorter mean operative time (25.7 ± 4.7 minutes) in group I ($P < .001$) compared with group II (33.6 ± 5.8 minutes). **Figure 5** shows box plots of the operative time.

Postoperative Sequelae and Complications

Two patients experienced epistaxis in the conventional endoscopic DCR group and were managed with merocel nasal packs for 1 day. Three cases of synechiae were reported with conventional endoscopic DCR: 2 between the middle turbinate and lateral nasal wall and 1 between the middle turbinate and the septum. The difference between the 2 groups was statistically significant ($P < .05$).

Comfort during Surgery under Local Anesthesia with Minimal Sedation

Group I showed a statistically significant better comfort during surgery under local anesthesia with minimal sedation ($P < .05$) than group II. In group I, 11.4% of the patients claimed that they were not comfortable during surgery under local anesthesia with minimal sedation and preferred that it had been done under general anesthesia. This is in comparison with 37.1% in group II.

Discussion

The evolution of new surgical practices strives toward minimally invasive approaches that can attain better safety with at least the same efficacy. Lacrimal surgery has experienced this trend with the introduction of endoscopic DCR as an alternative approach to external DCR. Recent studies have shown comparable success rates for endoscopic and external DCR.¹ However, endoscopic DCR has several advantages compared with external DCR.⁹ These include lack of a cutaneous incision and the

possibility of assessment of intranasal pathology and an assortment of secondary procedures at the time of surgery. Blood loss and risk of cerebrospinal fluid rhinorrhoea are minimal in experienced hands. Endoscopic DCR can be used as an office-based procedure and is safely performed under local anesthesia as well. However, ophthalmologists and less experienced rhinologists are still reluctant to popularize endoscopic DCR. This may be attributable to a false perception that external DCR has a higher success rate, a lack of knowledge about the endoscopic nasal anatomy, unfamiliarity with using nasal drills with endoscopes, and the possible adverse events of endoscopic DCR such as bleeding, synechia, orbital injury, and cerebrospinal fluid (CSF) rhinorrhoea.^{10,11}

In a trial to refine the safety and efficacy of endoscopic DCR, this study was designed to introduce the new, less invasive approach of endocanalicular, high-pressure, 5-mm balloon catheter, endoscopic DCR. The new technique provided a similar success rate of 91.4%, with shorter operative time, less adverse events, and greater tolerance by patients under local anesthesia with minimal sedation compared with conventional endoscopic DCR. Although the new technique does not require excessive bony manipulations such as burring and the size of osteotomy seems to be smaller than those attained in conventional endoscopic DCR, the success rates were similar. Hartikainen et al¹² demonstrated that the thickness of the lacrimal bone at the lacrimal sac fossa was mostly less than 100 μm , which could be easily penetrated with most surgical instruments without the need for excessive bone burring. In addition, the use of burrs and drills can be associated with thermal damage that can cause scarring and increases the chances of DCR failure. Linberg et al¹³ used intranasal endoscopes to assess the size of the healed intranasal ostium in a successful external DCR. No statistically significant correlation between the size of the bony opening and the final healed intranasal ostium was noted. The average diameter of the healed intranasal ostium was only 1.8 mm, but excellent functional results were obtained. The investigators showed that patients with small ostia obtained the same clinical relief as those with large ostia. The authors questioned the need for the extensive bony dissection and proposed the advantages of a smaller ostium made in a more direct manner. Silbert and Matta⁷ retrospectively studied 97 endoscopic DCR procedures using a 9-mm endonasal balloon and reported a 92% success rate.

Endocanalicular balloon catheter endoscopic DCR provided a better safety profile and more toleration under local anesthesia with minimal sedation than did conventional endoscopic DCR. The former showed a significant decrease in the operative time with a 23.5% shorter mean operative time than conventional endoscopic DCR. It also had fewer adverse events such as bleeding and synechia. The patient acceptance for the new technique to be done under local anesthesia with minimal sedation was significantly higher than that for conventional endoscopic DCR. The fact that the new procedure can be conducted under local anesthesia with minimal sedation increases its safety profile over conventional endoscopic DCR through avoidance of general anesthesia. Silbert and Matta⁷ noted no complications among a cohort of 97 patients

who underwent endonasal balloon catheter endoscopic DCR. In our study, the only adverse events resulting from conventional endoscopic DCR were bleeding and synechia. Conventional endoscopic DCR has been reported to be associated with some adverse events such as bleeding, synechia, orbital injury, and CSF rhinorrhoea.⁹⁻¹¹ The source of bleeding is usually the nasal mucosa, the ethmoids, and the nutrient vessels of the anterior lacrimal crest. Synechia can occur attributable to rough manipulations or thermal injury of bone drilling. Orbital injury was demonstrated to occur especially with posterior bone removal or drilling. CSF rhinorrhoea can occur following inadvertent trauma to the ethmoid roof during drilling or with fracture of the ethmoid bone extending superiorly to the cribriform plate secondary to torsion motion on bone removal with rongeurs.

The success of the endocanalicular, high-pressure, balloon catheter, endoscopic DCR in this study has initiated our enthusiasm to test whether the high success rate is reduced after 2 or 3 years, so a further follow-up point of 3 years after stent removal will be assessed and the results will be published in a long-term follow-up study.

Conclusion

The endocanalicular balloon catheter endoscopic DCR shares the advantages and success rate of conventional endoscopic DCR. In addition, the former is simpler, requires less manipulation, entails a shorter operative time, has a better safety profile, and can be conducted totally under local anesthesia with minimal sedation.

Author Contributions

Sameh M. Ragab, substantial contributions to conception, design, writing, acquisition, analysis and interpretation of data, and surgery conduct; **Mona S. El-Koddousy**, ophthalmologist who shared in writing, analysis, and interpretation of data; **Mohammed Badr**, ophthalmologist who participated in surgery, following up the patients, interpretation of results, and writing the paper.

Disclosures

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