Indian Survey on Practice Patterns of Lacrimal and Eyelid Disorders (iSUPPLE) Report 2: Mitomycin-C and Lacrimal Stents in Dacryocystorhinostomy

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Purpose: The aim of the study was to assess practice patterns on the use of intraoperative Mitomycin-C (MMC) and lacrimal stents (intubation) in dacryocystorhinostomy (DCR) for nasolacrimal duct obstruction (NLDO) among oculoplastic surgeons in India. The survey was aimed at obtaining data on the duration of stent placement and specifics regarding MMC usage namely, concentration and duration of application.

Methods: A survey that included questions on the management of lacrimal disorders was sent in April 2015 to members of the Oculoplastic Association of India, through an email communication. The results were tabulated and analyzed.

Results: External DCR is the preferred surgery of choice to treat NLDO for most oculoplastic surgeons (86%) surveyed. A majority (58%) of the respondents do not place stents during DCR routinely in their practice. Lesser experienced oculoplastic surgeons (<10 years of experience) when compared with more experienced surgeons were more likely to place stents routinely in their DCRs (59% versus 19%; $P = 0.0002$). Of the special situations that the respondents would consider stent placement, the most common scenarios were the presence of coexisting canalicular pathology followed by cases of previously failed DCRs. The preferred duration for stent removal was 3 months (48%). Intraoperative MMC was used routinely by only 36% of the respondents. The most common condition where they would consider intraoperative MMC was previously failed DCRs. Three minutes (25%) and 0.2 mg/mL (30%) were the preferred duration of application and concentration of MMC, respectively.

Conclusions: External DCR is the most preferred surgery for NLDO; in comparison, endoscopic DCR enjoys less popularity as the surgical procedure of choice in NLDO. Adjunctive procedures, namely intraoperative MMC and stenting of the lacrimal passages, are not routinely performed; however, previously failed DCRs are common indications when the respondents may use MMC and/or lacrimal stents. Three months is the preferred duration for stent removal. The trends regarding the concentration of MMC and the application show considerable variation, underscoring the need for evidence-based guidelines to assist oculoplastic surgeons.

Key Words: Dacryocystorhinostomy, intubation, lacrimal sac, Mitomycin-C, nasal endoscope, nasolacrimal duct, nasolacrimal duct obstruction, stents

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Dacryocystorhinostomy (DCR) is the preferred surgical procedure in patients with epiphora arising from primary acquired nasolacrimal duct obstruction (PANDO). Toti and Caldwell[1,2] were the first to describe endonasal and external DCR, respectively. The surgical techniques as well as the use of newer instrumentation such as endoscopes, ultrasonic bone aspirators, and powered drills have evolved making DCR a safer and quicker procedure.[3,4] Over the past few decades, adjunctive techniques such as intraoperative application of Mitomycin-C (MMC) and intubation of the lacrimal passages have also gained popularity.[5,6]

Mitomycin-C is a systemic chemotherapeutic agent derived from *Streptomyces caespitosus* that inhibits the synthesis of DNA, cellular RNA, and protein by inhibiting the synthesis of collagen by fibroblasts. The rationale behind using MMC is to increase the longevity of the success of a DCR by inhibiting circum-ostial fibrous tissue growth and scarring.[7] Silicone intubation on the contrary is practiced with the idea that placing stents within the ostium could prevent postoperative obstructions by securing an open pathway during the healing process as fibrosis occurs. Upon removal of the stents at a later date, a patent passage would be maintained.[8] Both adjunctive techniques—the use of MMC and intubation of the nasolacrimal passage—have become almost routine despite the lack of consensus regarding the various variables involving duration and concentration of MMC and the ideal time for stent removal.[7,9] This communication presents the results of the survey which was conceptualized and undertaken to assess current practice patterns regarding intubation and intraoperative MMC usage during DCR among Indian oculoplastic surgeons.

METHODS

A survey that included questions on the management of lacrimal disorders was sent in April 2015 to members of the Oculoplastic Association of India through an email communication. The email clearly explained the nature of the survey and its questions and contained a hyperlink to an electronic survey hosted by a third party website: www.surveymonkey.com. Subsequently, a reminder to take the survey was sent after 2 weeks. The survey contained 30 questions, most of which were multiple-choice questions. Respondents were also asked questions that included demographic information of the respondent regarding years of practice, age, and

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practice setting. Respondents were also allowed to skip questions in case they did not want to reply to any particular question. The survey was anonymized and did not contain any identifying information. Institutional Review Board approval was obtained before commencement of the study. Association between categorical variables was assessed using Fisher exact test or Chi-squared test. Continuous data were analyzed using nonparametric test, that is Mann-Whitney test. We considered a $P < 0.05$ as statistically significant. All statistical analysis was performed with GraphPad Prism 6 (GraphPad Inc, La Jolla, CA).

RESULTS

Respondents

The email with the invitation to participate in the survey was sent to the members of the Oculoplastic Association of India. Invites sent to all 267 members with valid or active email addresses (as on April 1, 2015; as per the official website www.opai.in). One of the first questions included the nature of the respondent's practice; all respondents who mentioned that they did not practice oculoplasty and referred all oculoplastic cases to a specialist were automatically directed to the end of the survey and their responses were excluded from analysis (Table 1 includes the list of questions relevant to the use of stents and MMC in DCR). The survey saw a response rate of 46% with 124 responses, but only 103 responses were considered valid as the rest indicated that they did not practice oculoplastic disorders and therefore chose not to continue with the survey. However, the total number of responses obtained to each question varied, given that respondents were allowed to skip questions; therefore in the analysis, results have been calculated depending on the number of responses received for each question. The average age of the respondents was 39 years (range: 27–80; median 38 years). The average experience of the respondents was 10.5 years in practice.

Surgical Treatment of Nasolacrimal Duct Obstruction

Although 24% (21/86) of the respondents said they were trained in and could perform endoscopic DCRs, it was the surgery of choice for nasolacrimal duct obstruction (NLDO) for only 10% (9/88), with 86% (76/88) citing external DCR as their preferred surgical treatment in NLDO. Nonendoscopic endonasal DCR and transcanalicular laser-assisted DCR were least favored by respondents. When the group was split into 2 groups depending on the years in practice, one group comprising members with <10 years of experience and the other group with ≥10 years in practice, the results were comparable with no significant difference ($P = 0.9$).

Intubation/Stenting

Forty-two percent (36/50) of the respondents indicated that they regularly (≥50% of the cases they perform) perform intubation during primary DCR (Fig. 1). The proportion of surgeons placing stents among those who primarily perform external DCRs was similar to those who primarily perform endoscopic DCRs. However, on comparing the 2 groups on the basis of experience, 59% (29/49) of the respondents with <10 years of experience place stents as compared with 19% (7/37) of those with ≥10 years of practice experience. The difference was statistically significant ($P = 0.0002$). Among those who used stents (Fig. 2), the most common indications for placing lacrimal stents were associated canalicular stenosis (81%), revision DCR (71%), pediatric DCR (36%), and resolved acute dacryocystitis (36%). However, 10% of the respondents indicated that they use stents in *all* cases. When

TABLE 1. List of Questions in the Questionnaire Pertaining to the Use of MMC and Intubation/Stents in DCR

1. How old are you? (in y)
2. How many years of oculoplasty practice do you have?
3. In your practice, which of the following do you perform most frequently for primary nasolacrimal duct obstruction?
   a. External DCR
   b. Endoscopic endonasal DCR
   c. Nonendoscopic endonasal DCR
   d. Laser DCR
4. Do you perform endonasal DCR?
   a. Yes
   b. No
5. Do you place a lacrimal stent in the DCRs that you perform?
   a. Yes
   b. No
6. In which cases would you place a lacrimal stent? (You may choose more than one option)
   a. All cases
   b. Pediatric DCR
   c. Postacute dacryocystitis
   d. Repeat DCR
   e. Intraoperative canalicular pathology noted
   f. Small lacrimal sac flaps
   g. Small nasal mucosal flaps
   h. Long surgical duration (>1 h)
   i. Severe intraoperative bleeding
7. How long do you usually keep a lacrimal stent in place before removal?
   a. 2 wk
   b. 4 wk
   c. 8 wk
   d. ≥3 mo
8. Do you use intraoperative MMC in DCRs?
   a. Yes
   b. No
9. In which scenarios would you use MMC in a DCR? (You may choose more than one option)
   a. All cases
   b. Pediatric DCR
   c. Postacute dacryocystitis
   d. Repeat DCR
   e. Intraoperative canalicular pathology noted
   f. Small lacrimal sac flaps
   g. Small nasal mucosal flaps
   h. Long surgical duration (>1 h)
   i. Severe intraoperative bleeding
10. In cases that you use MMC intraoperatively while performing DCR, what is your preferred duration for application?
    a. 1 min
    b. 2 min
    c. 3 min
    d. 4 min
    e. 5 min
11. In cases that you use MMC intraoperatively while performing DCR, what is the preferred concentration?
    a. 0.1 mg/mL
    b. 0.2 mg/mL
    c. 0.3 mg/mL
    d. 0.4 mg/mL
    e. 0.5 mg/mL

DCR, dacryocystorhinostomy; MMC, Mitomycin-C.

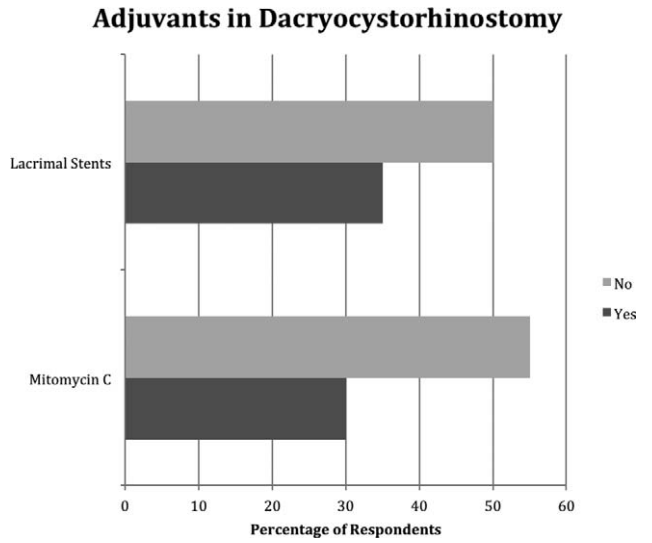

FIGURE 1. Graph depicting the practice patterns among respondents when it came to using adjuvants in dacryocystorhinostomy surgeries, namely MMC and the use of lacrimal stents. MMC, Mitomycin-C.

asked the preferred time period for removing the stents, 3 months was the commonest response (48%) (Fig. 3) followed by 4 weeks (31%).

Mitomycin-C

Of the 86 respondents who replied, 36% (31/86) reported using MMC routinely (≥50% of the cases they perform) in their practice during primary DCR (Fig. 1). However, only 14% (12/86) used MMC in all the DCRs they performed and 41% (36/86) did not use MMC at all in *any* of their DCRs. Among those using intraoperative MMC (Fig. 4), the most common indication for using MMC was previously failed DCR (78%). This was followed by DCR status postacute dacryocystitis (24%) and pediatric DCR (22%). Regarding the duration of application of MMC, among those using MMC, 3 minutes was the most common response (43%), followed by 2 minutes (29%) and 1 minute (16%). However, there was a more even distribution seen when the respondents were asked about the concentration of MMC used: 50% of the respondents indicated 0.2 mg/mL and 48% mentioned their preferred concentration to be 0.4 mg/mL.

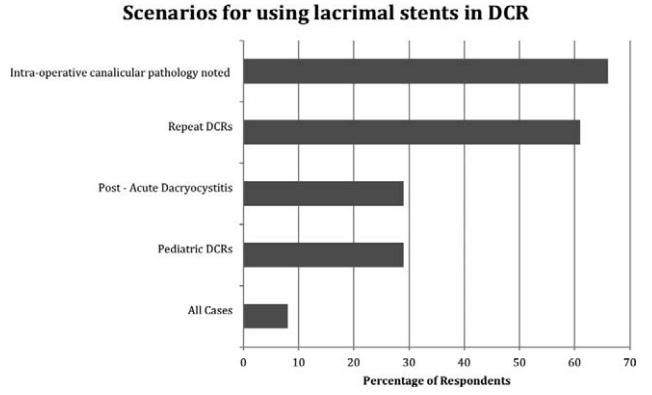

FIGURE 2. Graph depicting the scenarios where respondents prefer to place lacrimal stents while performing DCR surgery. DCR, dacryocystorhinostomy.

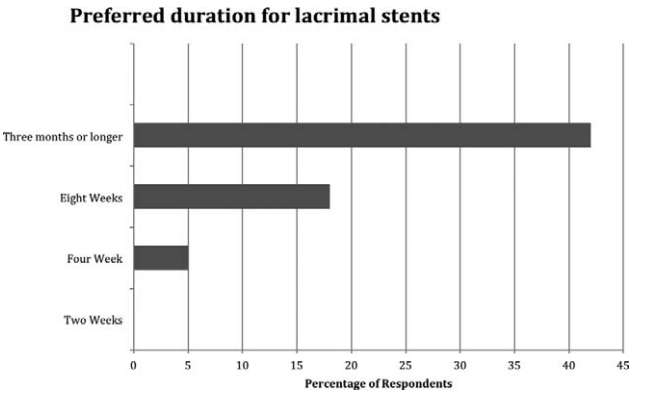

FIGURE 3. Graph depicting the practice patterns among respondents with regards to duration of stent retention before removal following DCR surgery. DCR, dacryocystorhinostomy.

DISCUSSION

Our results show that oculoplastic surgeons in India have a clear, overwhelming preference for external DCR as their preferred choice of surgery in NLDO in adults. A survey of the members of the American Society of Ophthalmic Plastic and Reconstructive Surgeons (ASOPRS) in 2010 showed a comparable trend: 83% of the respondents preferred external approach for performing a DCR in majority of their patients and there was no statistically significant difference between physicians of different years in practice.[10] Barmettler et al[11] reported in a similar survey of ASOPRS members in 2012 that a significantly higher proportion of surgeons offered external DCR as opposed to those who offered endonasal DCR. However, they reported that as number of years since fellowship increased, the proportion of surgeons offering endonasal DCR declined. The above-mentioned surveys, however, may not report current trends in surgery as they were conducted a few years ago.

The results of our survey indicate a similar pattern—preference of external over endonasal DCR. The number of years in practice, however, had no bearing on the choice of surgery in our study. There can be many factors that could be attributed to this. By and large, most ophthalmologists in India do not receive training to perform endoscopic endonasal surgeries. Fellowship training at most centers in India do incorporate the endoscope as a part of the lacrimal practice; however, the use is largely restricted to diagnostic procedures and surgically—only in the management of congenital nasolacrimal duct obstruction. Therefore, being

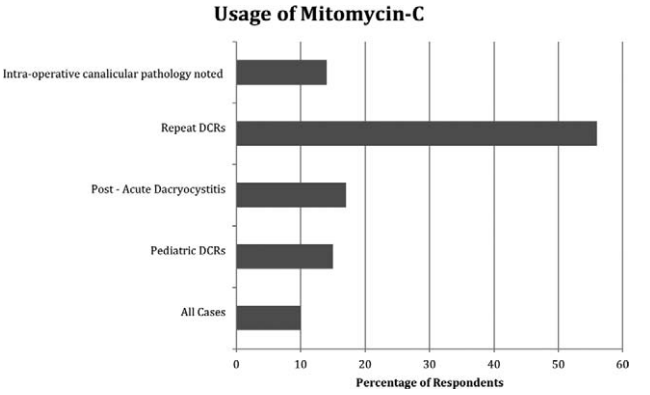

FIGURE 4. Graph depicting the scenarios where the respondents prefer to use MMC intraoperatively during DCR surgery. DCR, dacryocystorhinostomy; MMC, Mitomycin-C.

primarily trained as ophthalmologists and with the limited exposure to endoscopic DCRs, most oculoplastic surgeons fall short in terms of the exposure and expertise required for endoscopic endonasal DCR to be their procedure of choice. Although ENT specialists who are familiar with the sinus anatomy and instruments are often relied upon by oculoplastic surgeons to assist in their endoscopic DCRs, it is interesting to note that the curriculum of fellowship training in ophthalmic plastic surgery now includes endonasal endoscopic DCR.[12] However, as of now, unfamiliar anatomy, expensive instrumentation, non-availability of ENT back-up, lack of expertise with equipment, longer operative times, and the need for general anesthesia might contribute to the preference of oculoplastic surgeons for external DCRs over endoscopic DCRs.[11,13,14] Although over the past few years, fellowship training at many centers in India have consciously incorporated endoscopic surgery as a part of the structured curriculum; we believe it will take a few years for this to reflect in a visible shift in practice patterns. Barmettler et al[11] hypothesized that endonasal training in recent years has led the younger surgeons offering endonasal DCR compared with their more experienced colleagues.

The 2012 survey of ASOPRS members showed that all surgeons preferred to place stents after DCR with bicanalicular Crawford tubes being the most popular.[11] In stark contrast, 58% of the respondents in our survey did not regularly use lacrimal intubation in their surgeries and only 10% of the surgeons preferred to use stents in *all* their cases. Surgeons with <10 years of experience were more likely to use stents than those in practice for ≥10 years ($P = 0.0002$). The most common time period for removal of the lacrimal stent in our study was 3 months which was comparable with the ASOPRS survey. The glaring contrast in the usage of lacrimal stents across the 2 surveyed populations could partly be explained by the lack of class I evidence that favors the practice of lacrimal intubation during DCR. It would be worthwhile to look at the evidence in current literature. In the past decade, there has been evidence that has questioned the rationale behind intubation in the first place. Madge and Selva[9] in their concise review have mentioned that the role of intubation in routine DCR surgery is unclear, with no conclusive evidence supporting the practice. Although treating any coexistent canalicular pathology, it would be considered prudent to place stents; it is not clear what role stents play in maintaining the anatomic patency especially when large ostoetomy with adequate flaps are made. Choung and Khwarg conducted a prospective study of selective nonintubation in external DCR where canalicular pathology was excluded. Here both anterior and posterior flaps were sutured; intubation was performed only if the lacrimal sac, when opened, was <10 mm in height or if the decongested nasal cavity measured <3 mm wide during surgery. Their results showed that anatomic patency was achieved in 100% of the nonintubation cases versus 97.5% in the intubated group. This indicates a possible role of selective nonintubation while performing DCR in uncomplicated cases.[9,15] Cannon et al[16] reported a high success rate in their series of 129 consecutive cases of endoscopic DCR without intubation, 127 (98.5%) had endoscopic evidence of a both patent ostium and positive endoscopic dye test at the 12-month follow-up. They concluded that routine intubation for the purpose of maintaining canalicular patency is not necessary when performing endonasal DCR in PANDO. Similarly, Smirnov et al[17] reported a higher success rate in endoscopic DCRs without intubation than those with intubation. Furthermore, Feng et al[18] in their meta-analysis of 5 randomized clinical trials and 4 cohort studies reported no significant difference between the success rates of external or endoscopic DCR surgery with versus without silicone intubation. Vicinanzo et al[19] studied the effect of premature stent loss after external DCR. They reported that of the 233 DCRs included in their study, 42 stents extruded or had to be removed before the planned 2-month period. The overall success rate was 94.9%, whereas it was 90.5% among those who had early extrusion and 95.8% for those who did not ($P = 0.24$). With randomized studies showing that there is no significant advantage of using stents in DCR as opposed to not using them, Vicinanzo et al raise a pertinent issue: if early extrusion of the silicone stent does not decrease the success of the DCR, are they a useful augmentation to the surgery in the first place?[19,20,21] Furthermore, there is also lack of evidence-based guidelines regarding the ideal duration for which a stent should be left in place before removal. Ali et al[22] in their study to assess the shrinkage of DCR ostium beyond 4 weeks reported that the ostia achieved using the powered endoscopic DCR technique that involved mucosa-to-mucosa apposition following osteotomy remains stable in size from 4 weeks to 2 years postsurgery. Chan and Selva[23] have found that maximum ostial shrinkage occurs during the first 4 postoperative weeks and a lesser degree of shrinkage between 1 and 12 months postoperatively. With majority of ostial shrinkage and circumosteal scarring taking place within 4 weeks, are we then justified in retaining stent for longer periods?[24]

With regard to MMC in DCR, there is a lack of consensus regarding multiple variables, namely the dosage, the route of delivery/application, the time of exposure, and subsequently what role each of these variables plays in the final outcome of the surgery.[7] There are many studies that have shown the beneficial effect of MMC, Nair and Ali mention that there remains no study till date, which has reported a worse success rate for DCR with MMC than DCRs without the use of MMC.[7,25–27] Although intraoperative MMC did not seem to be very popular among the surgeons we surveyed, our survey threw up a variety of responses with regard to the concentration and duration of application of MMC. The most preferred concentration was 0.2 mg/mL for 3 minutes. There seems to be early evidence suggesting that this might be the appropriate concentration and duration to help maximize outcomes. Ali et al[28] reported the effect of varying concentrations of MMC and treatment durations on cellular proliferation and viability of the fibroblasts in the nasal mucosa. Normal nasal mucosa that was harvested from patients undergoing DCR was used to establish primary cultures. Subsequently, these cells were exposed to different concentrations of MMC (0.1–0.5 mg/mL) for varying time periods (3, 5, and 10 min). The parameters that were studied included cell viability, cellular proliferation, and the actin cytoskeletons of fibroblasts. The relevant outcomes that were noted were that the doubling time of cultured nasal mucosal fibroblasts was found to be approximately 24 hours. Furthermore, MMC at 0.4 mg/mL beyond 5 minutes and 0.5 mg/mL concentration at all time points were lethal and caused extensive cell death when compared with controls. The minimum effective concentration seemed be 0.2 mg/mL for 3 minutes as it prevented cell proliferation of the fibroblasts by inducing cell cycle arrest, without causing extensive apoptosis.[7,28] In spite of the potential benefits of using MMC in DCR, it is not used frequently by Indian oculoplastic surgeons. Both lacrimal intubation and intraoperative MMC add to the cost of each surgery, which we hypothesize is one of the most significant reasons for their low usage in India.

CONCLUSIONS

Our survey highlights the distinct preference for external DCR over endonasal DCR among Indian oculoplastic surgeons. The open nature of the survey, the limitations and context of our study, the inherent drawbacks that any survey has, namely recall bias and selection bias, and the limited applicability of our findings are acknowledged. We also did not address the reasons for preference of external over endonasal DCRs. Although there seems to be a definite growing popularity of endonasal DCRs, external DCRs as

of now is the preferred surgery for NLDO in adults, globally. Use of intraoperative MMC and lacrimal stents is not common among Indian oculoplastic surgeons. The lack of unanimity over the situations that warrant the use of stents, the ideal timing for stent removal, concentration of MMC, and the duration of application underscore the need for large multicentric, double blinded, randomized controlled trials to formulate guidelines what will help oculoplastic surgeons in taking well-informed decisions.

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