Original Article

Outcome of External Dacryocystorhinostomy Operation with and without Posterior Nasal Mucosal Flap Suturing Technique in Combined Military Hospitals of Bangladesh

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Abstract

Introduction: External Dacryocystorhinostomy is an anastomosing operation which creates a fistula between the medial wall of lacrimal sac and lateral wall of nasal cavity.

Objective: To compare the success rate by suturing both the anterior and posterior nasal mucosal flaps and without suturing the posterior nasal mucosal flap in External DCR surgery of 50 cases in different Combined Military Hospitals (CMH) of Bangladesh.

Methods: The study included 50 cases of Chronic Dacryocystitis patients with symptoms of epiphora and blocked Sac Patency Test (SPT). External Dacryocysto-rhinostomy (DCR) surgery was done by same surgeon in different CMH over the period of 02 years extending from January 2016 to December 2017. Total 50 patients were divided into equal 02 groups. Group A underwent External DCR with silicone tube intubation and both anterior and posterior nasal mucosal flaps were sutured. Group B underwent similar DCR surgery where only anterior nasal mucosal flaps were sutured with lacrimal sac flap and posterior mucosal flap was excised completely.

Results: External DCR surgery success rate was evaluated by a patent SPT at 03 months, 06 months and 12 months post operatively in both groups. SPT was successful in 92% cases in group A and 96% in group B at 3 months follow up after silicone tube removal. At 6 months reduction of epiphora occurred in 90% cases in Group A and 96% cases in Group B with unchanged SPT percentage. At 12 months follow up result remained unchanged as found at 6 months. There was significant difference in success rate of two different surgical technique. Quality of surgery improved with less intraoperative complications with shorter surgical time when only anterior nasal mucosal flap was sutured with excision of posterior nasal flap.

Conclusion: This study suggested that comparing both the techniques of with and without suturing anterior and posterior nasal mucosal flaps in external DCR surgery, the later one makes considerable improvement in success rate of DCR. Excising the posterior nasal mucosal flaps can reduce operation time, improve operation technique and reduced epiphora post surgically.

Key words: Dacryocystorhinostomy (DCR), Sac Patency Test (SPT), Anterior and posterior nasal mucosal flaps, Silicone tube, Epiphora.

Introduction

External Dacryocystorhinostomy is an anastomosing operation which creates a fistula between the medial wall of lacrimal sac and lateral wall of nasal cavity. In 1904, Toti[1] was the first to describe the external DCR procedure. Dacryocystorhinostomy is a surgical procedure in which a lacrimal sac is drained into the nose. Toti's[1] classic transcutaneous technique has undergone many minor modifications, but the basic operation has withstood the test of time and has a high success rate of 93-95%. In 1921, Dupuy-Dutemps and Bourguet[2] described the technique of external DCR. They incised the posterior nasal mucosal flaps and approximated flaps of lacrimal sac and anterior nasal mucosal flaps. Use of silicone tube in later period is a useful adjunct to external DCR and improve success rate in removing any blockage in lacrimal passage to 95%.

Materials and Methods

The study included 50 patients with chronic dacryocystitis. Their sac patency test (SPT) showed total and partial obstruction before surgery. Among the study group, we took group A (25 patients) and performed DCR with silicone tube intubation and followed the technique of suturing both anterior and posterior nasal mucosal flaps. In the other group B (25 patients) we performed DCR with silicone tube intubation with suturing of only anterior nasal mucosal flap with lacrimal sac flap where posterior nasal mucosal flap was excised totally. Patients with history of failed DCR, gross nasal pathology, lacrimal fistula, punctal abnormality were excluded from the study. Out of 50 patients, 45 patients were operated under local anaesthesia with mild sedation. Only 5 patients were given general anaesthesia considering anxiety and difficulty in lying down for operation period.

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Skin incision was a curved one along the tear trough in all cases. This type of incision helps better cosmetic outcome postoperatively and also helps in locating and dissecting out lacrimal sac easily. Incision started from 2mm above the medial canthal tendon extending downword for about 20mm. After careful superficial dissection of orbicularis muscle, an incision given along anterior lacrimal crest and periosteum was elevated by blunt dissection Lacrimal Sac fossa is then exposed. A bony ostium is then created with bone punch and lateral wall of nasal mucosa exposed by removing frontal part of maxillary bone. Ostium size 12-15mm is created along the anterior lacrimal crest. Inferior extent of ostium is from lacrimal sac to inferior nasolacrimal duct (NLD) junction at inferior meatus. Superior extent of ostium is made above the medial canthal tendon. Blanching the nasal mucosa with lignocaine and adrenaline injection helped in reducing hemorrhage and gives clear operating field. Probing the sac with metal probe confirmed correct positioning for silicone tube intubation. A longitudinal incision created the lacrimal sac flaps, anterior and posterior one. Then nasal mucosal flaps were made by longitudinal incision. Silicone tube was introduced thru upper and lower puncta into opened lacrimal sac area. In Group A, anterior and posterior nasal mucosal flaps were sutured with 5"0 vicryl. Silicone tube passed thru ostium into nasal cavity and tied with 3"0 silk. In Group B, posterior nasal mucosal flap was excised totally and only anterior nasal mucosal flap and lacrimal sac flap was sutured with 5"0 vicryl. Silicone tube passed to nasal cavity and both ends of tube tied with 3'0 silk suture. Orbicularis muscle layer then sutured. Skin incision closed by subcuticular suture with 6'0 vicryl. Silicone tube left in situ in nasal cavity for 3 months and removed at 3 months follow up.

Results

Among the 50 cases, 30 were female and 20 were male. In the study groups, age of the patients was between 20 to 55 years. In both groups the age difference was not significantly different to mention. Group A included suturing of both anterior and posterior nasal mucosal flaps. Group B included excision of posterior nasal mucosal flap and suturing only anterior nasal mucosal flap with lacrimal sac flap. Intraoperative complications like bleeding and laceration of nasal mucosa was 7.6% and 4.7% respectively in Group A and 5% and 2% in Group B. The total operative time was also reduced in Group B about 5 to 7 minutes in average compared to Group A. Follow up of both groups of patients were at 3 months, 6 months and at 12 months post operatively. All patients had silicone tube intubation which was removed at 3 months follow up time and Sac Patency Test (SPT) was done in all 50 cases. Success of removing lacrimal drainage passage obstruction was assessed by patency of test at 3 months, 6 months and 12 months follow up and patients satisfaction of reduced epiphora and discharge at follow ups. At 3 months follow up, SPT was patent in 92% cases in Group A and 96% cases in Group B which is higher. At 6 months follow up in Group A, recurrence of epiphora symptom occurred in 3 cases and 1 case in Group B and SPT result remain same as found at 3 months in both group. At 12 months result of SPT and symptom of epiphora remained unchanged in both the groups.

Table-I: Distribution of patients according to age and sex

		Group A	Group B
Age in years	20-35	9	7
	35-50	14	14
	>50	2	4
Male		15	12
Female		10	13

Table-II: Intraoperative Complication

	Group A	Group B
Uneventful	87.7%	92%
Hemorrhage	7.6%	5%
Laceration of nasal mucosa	4.7%	2%

Table-III: Approximate duration of surgery in 2 groups

Group	Duration
Group A	42-47 min
Group B	35-40 min

Table-IV: SPT result at 3 months follow up

	Group A	Group B
Patent Sac Patency Test	92%	98%
Blocked Sac Patency Test	8%	2%

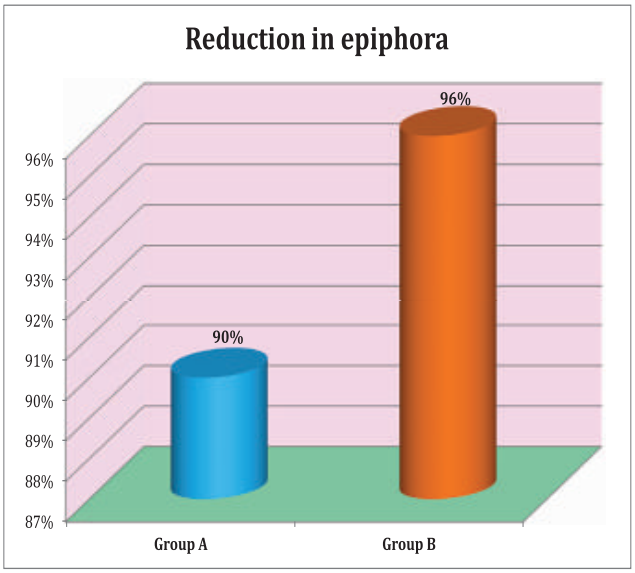

Figure-1: Reduction in epiphora at 6 and 12 months follow up.

Discussion

In treatment of chronic dacryocystitis, surgical options are multiple and has evolved with time. In worldwide practice External DCR surgery has stood the preferable method with or without silicone tube intubation. Recently Endolaser DCR, Endoscopic DCR is practiced by many surgeons. Different studies suggested that the success rate in removing the obstruction in lacrimal passage, External DCR has been reported of higher success rate. The success rate of external DCR has been reported between 90% and 100% depending on the surgeon's experience.[3-7] Dareshani et al[8] compared the success rate in which they sutured anterior and posterior flaps in one group and left the posterior flaps un-sutured in the second group. The success rate in sutured group was 97.6% and 94.2% in the un-sutured group. Talpur et al[9] reported success rate of 98.14% out of 54 procedures of conventional external DCR. Baldeschi et al[10] anastomosed large and mobile anterior flaps of the lacrimal sac and nasal mucosa and passed sutures through the orbicularis muscle to elevate the flaps forward and did not suture posterior flaps with a success rate of 100%. Elwan[11] reported a success rate of 90% with excision of posterior flaps and 85% with suturing. Serin et al[12] reported that with posterior flap anastomosis success rate was 93.75% and with resection it was 96.67%. Khan et al[13] reported success rate of 97.1% in DCR with suturing of the posterior flaps and 94.3% in DCR with excision of the posterior flaps. Gazmend Kaçaniku and Ilir Begolli[14] in their study mentioned that the success rate which was evaluated by lacrimal patency to irrigation and relief of epiphora, patency achieved in groups A and B was 94.4% and 96.2% respectively. There was no statistically significant difference in success rate between the groups.

External DCR is cheap, reliable but difficult surgical technique which requires more operative time than endolaser or endoscopic laser. To improve surgical technique in DCR, not compromising success rate different surgical techniques were advocated. As such, suturing only the anterior nasal mucosal flap with lacrimal sac flap and excising posterior nasal mucosal flap method was tried. Adopting this technique has considerably made surgical steps easier and improved quality of surgery and less operative time is required. In the Ophthalmology department, number of chronic dacryocystiis patients is large and we need to perform surgeries with easier and time conserving techniques. This anastomosing flaps and bypass surgery, when we excised the posterior flap of nasal mucosa, it was easier to follow the subsequent steps of surgery with suturing only anterior nasal mucosal flap. Total time of surgery was reduced and cost also reduced as we could save use of 5”0 vicryl suture for the mentioned step. Compared to this technique, the other technique of making anastomosis of posterior flap with suturing posterior nasal mucosa with lacrimal sac flap was difficult and consumed more time. It is very common in DCR surgery to experience bleeding due to different reasons in many steps of surgery in hands of most experienced surgeons also. In such cases of bleeding during surgery, though in very small amount, making a modification in this step of surgery by excising the posterior mucosal flap and suturing only anterior flap and lacrimal mucosal flaps saved time of surgery and ensured better outcome. It is considerably appreciated to make an wide open ostium than a poorly constructed posterior mucosal flap suturing which may actually block the ostium partially. The nasal opening becomes compromised, leading to reduced success rate and increased chances of failed DCR surgery.

Conclusion

This study have shown suturing the anterior nasal mucosal flap with lacrimal sac flap and excising posterior nasal mucosal flap in external DCR surgery technique has multiple advantage and improved surgical quality with reduced time of surgery. It also showed higher success rate in overcoming epiphora and higher number of patent lacrimal sac patency test in chronic dacryocystitis patients undergoing external DCR surgery.

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Original Article

Side Effects of COVID-19 Vaccination among the Pregnant Women: A Cross-Sectional Study in a Tertiary Hospital of Bangladesh

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Abstract

Introduction: Pregnancy is a very special time for a woman and her family, although being pregnant is a stressful condition for every woman. The COVID-19 pandemic has made that condition more stressful. Clinical trials prove that COVID-19 vaccines are safe for pregnant women and also for lactating mothers. So WHO has approved vaccines for both above-mentioned groups. Hence, Bangladesh Government has taken the decision to vaccinate every pregnant woman against COVID-19 infection.

Objective: To assess the side effects of COVID-19 vaccination on pregnant women in a tertiary care hospital in Bangladesh Army.

Methods: This cross sectional single-centered observational study was conducted in Combined Military Hospital (CMH) Dhaka from August 2021 to November 2021. Total 50 pregnant nullipara and multipara women with double dose vaccination were included. Relevant data were recorded in a preformed data collection sheet and analyzed by SPSS version 20.

Results: Mean age of the participants was 19.2±10.8 years. The most commonly observed symptoms were pain in injection site, fatigue, swelling in injection site and myalgia. The most prevalent affected age group were 25-35 years. Among 48 participants, 20(41.6%) had co-morbidites. Two participants were found to have COVID-19 infection (4%) after vaccination.

Conclusion: Side effects profile obtained from pregnant women in this study were non-life threatening. A recognized vaccine programme can be a relieving factor for pregnant women from increased stress and anxiety caused by COVID-19.

Key words: COVID-19, Vaccination, Pregnancy, World Health Organization, Nullipara, Multipara.

Introduction

Without any biological variations, the reproductive period of a woman begins at menarche and ends in menopause. It usually extends from 13 to 51 years, a short time of a woman's life.[1] For the last two years, the COVID-19 pandemic has caused a major impact on the global health system which has also affected pregnant women and lactating mothers. Similar to other pathogens like 2009 H1N1 influenza, pregnant women are at risk of serious morbidities from COVID-19, albeit with less intensity.[2] These heightened morbidities are due to increased need of intensive care, ventilatory support and death of symptomatic pregnant women as well as increased rates of preterm birth (<37 weeks) and caesarean delivery.[3,4]

The need for intensive care support among patients with COVID-19 is of particular concern for pregnant women who used to live in low-income and middle-income countries.[5] In women suffering from coronavirus infection, the use of effective drugs should also be restricted considering the scarcity of data on most drugs in pregnancy.[5] These factors suggest that pregnant women should be considered as candidates for preventive measures and for this purpose vaccination is the gold standard for reducing morbidity and mortality.[5]

The challenges of vaccine development procedures against COVID-19 infection are to ensure safe vaccines for all which includes also pregnant and lactating group population. Pregnant women and lactating mothers deserve particular attention, because the potential benefits and risks of vaccination not only affect the health of the women themselves, but also the health of their offspring.[1] So after several nonclinical studies such as study on developmental and perinatal/postnatal reproductive toxicities (DART) in which pregnant mammals were vaccinated (in early and late gestational age) and no vaccine-related adverse effects on female fertility, embryo- fetal or postnatal development were observed.

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Then clinical trials of different vaccines include participation of pregnant women in COVID-19 vaccination program.[6] These clinical trials reveal that the vaccines against COVID-19 infection have acceptable safety level. WHO-approved suitable vaccines for pregnant women are as follows:

- Pfizer/BioNTech
- Moderna
- AstraZeneca/Oxford
- Johnson & Johnson
- Sinopharm
- Sinovac

COVID-19-vaccinated pregnant women have no negative impact on their unborn babies. If one gets vaccinated against COVID-19, there is no increased risk of miscarriage.[7] No harm detected in breastfeeding after vaccination.[8] In a study, a total of 94 pregnant women affected by COVID-19 admitted in the Combined Military Hospital, Dhaka, Bangladesh, a five maternal death was recorded and ten were severely ill.[9] Most of the hospitals all around Bangladesh have experienced similar type of incidence. After WHO recommended vaccines for pregnant women, Bangladesh Government began to enroll pregnant women for COVID-19 vaccination from July 2021. This was followed by Bangladesh Army as well.

In this study, pregnant women warrant particular consideration, because the potential benefits and risks of vaccination apply not only to the health of the women themselves but also to the health of their offspring. This study has a few limitations which we could not address. These included a small sample size and a short follow-up interval. Moreover, most of our participants were of young age and had less associated comorbidities. Therefore, the results of this study may not be applicable to the elderly populations.

Materials and Methods

This cross-sectional single-centered study was conducted in CMH Dhaka Cantonment, a tertiary level hospital in Bangladesh, from August 2021 to November 2021. We selected 50 (fifty) pregnant women of all trimesters, aged between 19 to 37 years, who were vaccinated with mRNA vaccine (AstraZeneca). The pregnant women who were having comorbidities (hypertension, diabetes, obesity, hypothyroidism) were included in the study along with both primipara and multipara. Those who had been diagnosed as COVID-19-positive and were hospitalized for COVID-19 infections were excluded.

The participants were cautioned about development of following symptoms: Injection site pain, redness, chills or mild fever, tiredness, headache, joint pain or muscle pain. They were advised to apply cool, clean and wet wash cloth over the vaccinated area for 1-2 days, taking plenty of fluid, drinks. If fever was sustained for one week, then consultation of health worker was advised. They were also briefed about the rare side effects of the vaccines and were assured about the treatment of the above-mentioned effects. Data were collected from them through semi-structured questionnaire. The participants had given informed written consent before hand. The clinical parameters including age, duration of pregnancy, comorbidities (systemic hypertension, diabetes, obesity etc.) were collected and recorded in structured forms and later compiled and analyzed using SPSS version 20. The study protocol was approved by the ethical review committee of CMH Dhaka.

Results

In this study, the participants were aged between 19 and 37 years. The mean age was 19.2±10.8 years. Among them, highest (66%) participants were in the 25-35 years age group (Table-I).

Table-I: Age, parity, comorbidities and trimester distribution of participants (n=50)

Distribution of participants		n(%)
Age in years	19-24 years	14(28%)
	25-35 years	33(66%)
	36-37 years	3(6%)
Parity	Nullipara	20(40%)
	Multipara	30(60%)
	Total (n)	50
Comorbidities	HTN	8(16%)
	DM	6(12%)
	Obesity	4(8%)
	Hypothyroidism	2(4%)
	Total (n)	50
Timing at first vaccine dose	1st trimester (<14 weeks)	14(28%)
	2nd trimester (>14 and <28 weeks)	27(54%)
	3rd trimester (>28 weeks)	9(18%)
	Total (n)	50

Table-II: Frequency of local and systemic reactions reported on the day after mRNA COVID-19 vaccination in pregnant women from July 2021 to November 2021.

Reported reaction	Dose 1 (50)	%	Dose 2 (50)	%
Injection site pain	42	84	44	88
Fatigue	13	26	32	64
Headache	8	16	23	46
Myalgia	6	12	22	44
Chills	2	4	12	24
Fever or feeling feverish	2	4	12	24
Measured temperature ≥ 38°C	1	2	3	6
Nausea	2	4	10	20
Vomiting	0	0	1	2
Injection site swelling	2	4	3	6
Joint pain	2	4	10	20
Abdominal pain	0	0	0	0
Diarrhoea	1	2	2	4
Injection site itching	1	2	0	0
Rash	1	2	1	2
Injection site redness	4	8	5	10

Table-I also showed that among enrolled pregnant patients 40%(20) were nullipara and 60%(30) were multipara and of the participants 8(16%) had hypertension, 6(12%) had diabetes mellitus, 4(8%) had obesity and 2(4%) had hypothyroidism.

It should be noted that out of 50 patients, 20(40%) had co-morbidities which were already shown in Table-I. Among them 2 (two) were diagnosed as COVID-19 positive based on results of RT-PCR from nasopharyngeal swab samples, so they were excluded from the study. Both were multipara and belonged in the age group of 25-35 years.

Among the 50 pregnant women, 14(28%) had been vaccinated in the 1st trimester, 27(54%) in the 2nd and 9(18%) in the 3rd respectively (Table-I). Reports of injection site pain (84% for first dose, 88% for second dose), fatigue (26% for first dose and 64% for second dose), headache (16% for first dose and 46% for second dose) and myalgia (12% for first dose and 44% for second dose) and were the most frequent local and systemic reactions after either dose (Table-II). These were reported more frequently after dose 2. More local and systemic reactions are tabulated in Table-II.

Discussion

Evidence suggests that pregnant women with COVID-19 are at higher risk of developing severe disease compared with non-pregnant women. According to data, 97% of COVID-19-positive pregnant women were hospitalized either for illness or labor and delivery.[10] Hence, the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP), in collaboration with the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, have instructed to provide COVID-19 vaccines to pregnant women.[11] Pregnant women who are requiring hospitalization are older (≥35 years), have high BMI and pre-existing medical conditions such as diabetes and high blood pressure. Pregnant women who frequent places with high COVID-19 transmission, or have co-morbidities causing greater risk of getting severely ill from the virus, should be vaccinated.[12]

A clinical study in approximately 4,000 healthy pregnant women 18 years of age or older vaccinated (mRNA) during 24 to 34 weeks of gestation, to see safety, tolerability and immunogenicity of two doses administrated 21 days apart. Adverse reactions included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%) and lymphadenopathy (0.3%).[13] This study shows similar results as these (as mentioned in Table-II). These were reported more frequently after dose 2 for all vaccines.[14]

The National Immunization Technical Advisory Group (NITAG), Bangladesh said it recommended COVID-19 vaccine for pregnant and breast feeding women by the end of July 2021. All side effect profiles obtained from pregnant women were non-life threatening.[15]

We found only 02 (two) positive COVID-19 cases. Diagnosis was based on result of RT-PCR nasopharyngeal swab samples. But presented with no fever, breathlessness, cough, dysgeusia, anosmia, parosmia, chest pain, diarrhea and sore throat. Kadali et al showed a study on 38 pregnant women who received one dose and 31 who received both dozes of mRNA vaccine having sore arm/pain (37), fatigue (22), headache (19), chills (18), myalgia (3), fever (6), swelling (3) but one participant reported seizure having a known history of seizure, one had a miscarriage, one had a premature delivery and one had gestational hypertention.[16] In this study, we did not find any participant with reported seizure, no miscarriage and no premature delivery. According to real world data from the USA, 160,000 pregnant women were vaccinated mainly with mRNA vaccines have not raised any safety concerns.[17]

Six studies in four countries, involving more than 40,000 pregnant women, shows having the vaccine does not increase the risk of miscarriage, preterm birth, still birth, nor does it increase the risk of a small for gestational age baby or the risk of congenital abnormalities.[18] But MHRA reported miscarriage is estimated to occur in about 20 to 25 in 100 pregnancies and most occur in 1st trimester. Still births are sadly estimated to occur in about 1 in 200 pregnancies.[18] Most of our patients were young and having less associated comorbidities. Therefore the results of this study may not be applicable to the elderly populations.

Conclusion

Reluctance towards vaccination hinders COVID-19 preventative measures. Population immunity depends on the effectiveness of the vaccine and acceptance rate within the population. Public opinion on acceptance can be influenced by various factors, including their awareness of the risk of infection, vaccine safety and reliability of relevant channels of communication. Preliminary findings did not show any serious side effects among pregnant persons who received mRNA COVID-19 vaccines. Research on larger groups vaccinated earlier in pregnancy, is necessary to reliably forecast mother, pregnancy and infant outcome.

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