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Published in:
Journal of oral biology and craniofacial research

DOI:
10.1016/j.jobcr.2021.09.009

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2022

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):
Reddy, R. R., Reddy, S. G., Pandey, A., Banala, B., Bronkhorst, E. M., & Kuijpers-Jagtman, A. M. (2022). Effect of antibiotic pack on hard palate after fistula closure on nasal airflow and reoccurrence rate. *Journal of oral biology and craniofacial research*, *12*(1), 27-32. https://doi.org/10.1016/j.jobcr.2021.09.009

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Journal of Oral Biology and Craniofacial Research 12 (2022) 27–32

Contents lists available at ScienceDirect

Journal of Oral Biology and Craniofacial Research

journal homepage: www.elsevier.com/locate/jobcr

Research Paper

Effect of antibiotic pack on hard palate after fistula closure on nasal airflow and reoccurrence rate

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ARTICLE INFO

Keywords:
Cleft palate
Surgical procedures
Operative
Oral fistula
Treatment outcome

ABSTRACT

This parallel blocked randomized controlled trial was done in two groups of 30 patients each to determine if placement of an antibiotic oral pack on the hard palate after hard palatal fistula repair reduces nasal air emission and fistula re-occurrence. Group A had an oral pack on the hard palate for 5 days post-operatively while group B did not. In group A, percentage of nasal air emission was tested using nasometry with and without pack. Paired t-tests were performed to compare nasal emissions for patients with and without pack. Recurrence of fistulas after 6 months between group A and B was tested using odds ratio. Effect of nasal air emission on fistula rates was tested using paired t-tests. There was a significant increase ($p < 0.0001$) in nasal emission after removal of the pack in group A. Fistula re-occurrence tended to be higher in group B (no pack) than group A but this was not significant ($p = 0.242$). There was no correlation between nasal air emission and fistula rates. In patients with recurrent fistulae, placement of an oral pack after fistula repair diminishes nasal air emission. Whether this has an impact on re-occurrence of fistulae needs to be investigated further.

1. Introduction

One of the aims of primary cleft palate repair techniques is to reduce oro-nasal fistula development to minimal levels without affecting maxillofacial growth.[1]Fistulas occur between 0 and 77.8% of patients after primary palatoplasty.[2] Recurrent fistula formation after fistula repair occurs in16–50% of patients.[3,4] Depending on size, number rand location, oronasal fistulae may pose a challenge both for the patient and the surgeon. Nasal air emission, fluid and food escape and resultant social distress, speech distortion or velopharyngeal insufficiency, mucosal inflammation, malodor, nasal catarrh, hearing loss, affected eating habits, maxillary growth retardation are all examples of findings and complaints.[3,4]

Since a repaired hard palate is an open surgical site and open to food debris, there is an infection risk in the area during the healing phase. Mechanical trauma from the tongue, foreign objects or food could cause surgical wound breakdown. Furthermore, anatomically, a cleft palate has a communication between the mouth and the nose because there is a congenital cleft in the bony portion of the hard palate. When a cleft palate is repaired, only mucosal closure is performed. Therefore, the passage of air through the nose when the patient breathes, speaks or cries might exert pressure on the mucosal repair, which is devoid of bony support. This pressure and the resultant movement of the healing tissues could cause a mechanical breakdown.

Placing an oral pack made out of a folded piece of sterile gauze soaked in antibiotic cream on the hard palate post operatively could address any injury to the healing tissue caused by localized infection, mechanical trauma or movement of palatal mucosa during speech and breathing until the onset of primary healing. The aim of this randomized controlled trial was to investigate whether placement of an antibiotic oral pack on the hard palate after fistula repair reduces fistula re-occurrence and volume of air that passes through the nose while phonating. This study also investigated if change in the volume of air through the nose had an effect on the re-occurrence of fistulas.

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https://doi.org/10.1016/j.jobcr.2021.09.009
Received 27 May 2021; Received in revised form 31 July 2021; Accepted 11 September 2021
Available online 30 September 2021
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2. Materials and methods

2.1. Trial design

This study was conducted to determine if placement of a post-operative oral pack affects nasal air emissions and also reduces fistula rates in patients that have had fistula repairs. This study was conducted as parallel blocked randomized trial. As this is a surgical trial the surgeon and patients could not be blinded for the treatment.

The study was conducted from June 1, 2017 to August 31, 2018 at the high volume cleft center where 1400 cleft surgeries are performed every year. The local Ethical Committee approved the research protocol based on the guidelines declared by the Government of India. All participants and parents, if the participants were minors, were informed about the study and signed a written informed consent. Reporting of these trials in this paper follows the CONSORT (Consolidated Standards of Reporting Trials) statement.[5]

2.2. Eligibility and randomization

This study included a set of sixty non-syndromic patients with a complete unilateral cleft lip, alveolus and palate. All patients included in this study had longitudinal fistulae in the hard palate after primary palatoplasty with a maximum length and width of 10 and 5 mm, respectively. To measure the length of the fistula a blunt periodontal probe was passed through the oral end of the fistula at its widest point so as be seen nasally. The probe was then moved anteriorly and posteriorly till the ends of the fistula. These points were marked and measured with calipers. The widest point of the visible fistula was measured for the width.

All patients with bilateral cleft lip and/or palate, isolated cleft palate, incomplete cleft lip and palate and patients with associated syndromes were excluded from the study.

Eligible patients were randomly divided into two groups A and B of 30 patients in each group. Blocked randomization was done using a computer program (Sealed envelope™, Sealed Envelope Ltd, London, UK) in block sizes of 10. Within each block participants were assigned by computerized random numbers to one of the 2 treatment groups. The randomization was performed by one speech therapist (BB). The surgeon was blinded to the randomization process. After assigning the treatment method, each patient or their parents were informed of the treatment plan by the speech therapist (BB). If the patient/parent did not agree to the treatment plan assigned randomly to them, the patient was excluded from the study.

2.3. Interventions

In all patients, the fistula closure was performed in two layers, i.e. nasal and oral, with local mucoperiosteal flaps. One experienced surgeon (RRR) performed all surgeries. The patients in group A had an oral pack made of sterile cotton gauze soaked in Framycetin antibiotic cream and sutured in such a way that it was closely adherent to the hard palate. The pack was placed immediately postoperatively and was kept in place for 5 days after which it was removed. The patients in group B did not have the pack placed post operatively.

2.4. Outcomes

For the patients in groups A, the volume of nasal and oral air emission was tested using a Nasometeron the fifth postoperative day. Nasalance was measured with the Nasometer-II, model 6450 (Kay Elemetrics Corp. USA). The testing stimulus used was the revised Simplified Nasometric Assessment Procedures Test (SNAP Test-R).The SNAP Test-R was performed with three subtests: a)The Syllable Repetition/Prolonged Sounds Subtest; b)The Picture-Cued Subtest; and c) The Reading Subtest. The mean nasalance was calculated between the onset and offset of the data displayed for each speech sample separately, using the nasometer software. The severity of nasalance was measured based on the SNAP test-R normative data. The data were delivered as a percentage of the nasal emission. The SNAP Test-R was performed by a single speech therapist (BB) on the patients in group A. The first test was performed with the pack in place. Retest was done after 1 h. The third test was done with the pack removed. Retest was done after 1 h.

Patients in group A and B were recalled after 6 months to clinically examine them for presence or re-occurrence of fistulae. A single examiner (RRR) performed the examination to elicit the presence or absence of fistulae. The examiner was blinded to whether the patient had a pack placed postoperatively or not. Fistula occurrence was tested visually as the first stage. If there was no visual sign of a fistula, history of nasal regurgitation was elicited. If the patient and/or parent gave a history of nasal regurgitation, a blunt periodontal probe was used to confirm a fistula in the hard palate. Additionally, all patients underwent a nasal endoscopy to reconfirm the presence or absence of a fistula.

2.5. Statistical methods

The statistical analysis was performed with SPSS version 22 (Chicago, IL, USA). To test for test-retest reliability of the SNAP Test-R the reliability coefficients between the two measurements were calculated as Pearson's correlation coefficients. Paired sample t-tests were applied to identify systematic differences between the first and second measurement. The duplicate measurement error (DME) was calculated as the SD of the difference between two observations divided by $\sqrt{2}$.

Comparisons of the nasalance scores with and without the pack were performed using the paired sample *t*-test. Occurrence of fistulae was compared using odds ratios.

The effect of nasal air emissions on re-occurrence of fistulas was estimated using paired t-tests (see Fig. 1).

3. Results

The flow of participants through each stage of the study is detailed in Fig. 2 (see Fig. 3).

The mean age of the patients in group A was 12.4 years (SD = 5.1; range 7–22 years) and of those in group B was12.9 years (SD = 4.7, range 7–20 years).

Six months after fistula repair the rate of fistula re-occurrence in

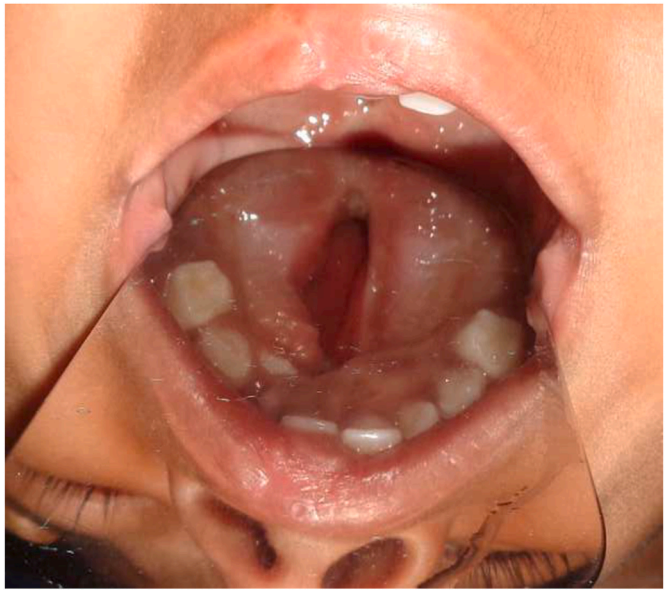

Figure 1. Pre operative picture of Palatal Fistula

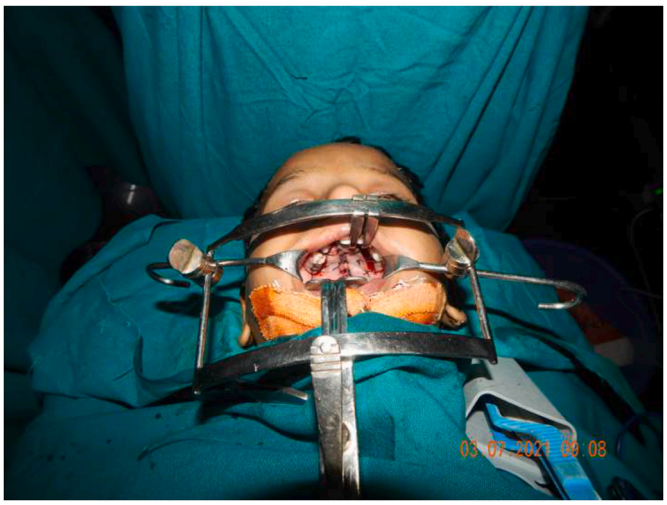

Figure 2. Immediate post operative picture of Palatal fistula

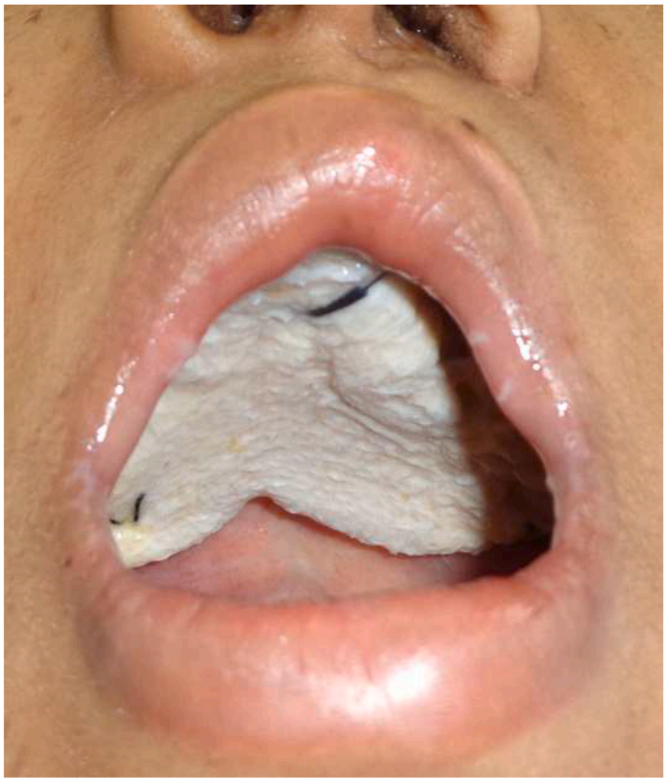

Figure 3. Oral antibiotic pack over palatal fistula

group B(no oral pack) was higher than in group A (with oral pack) though the difference was statistically not significant (OR = 2.80, CI = 0.48…16.3,p = 0.242) (Table 1). In group A (with oral pack) 6.66% (n = 2) had a fistula 6 months after fistula repair, while 16.66% (n = 5) of the patients in group B (without oral pack) showed a re-occurrence of the fistula.

The results for the test-retest reliability for the SNAP Test-R in group A with pack and after removal of the pack are shown in Tables 2 and 3, respectively. A reliability coefficient of more than 0.8, a low duplicate measurement error (DME) and a p-value above 0.05 meant that the testing protocol was reliable. Though, incidentally, there were variable outcomes that did not meet all these criteria, the test was found to be fairly reliable.

Table 1
Odds ratio of fistula formation in primary palatoplasty group.

Primary palatoplasty group			
		Group B: Without pack	Group A: With pack
Fistula	Yes	21	2
	No	79	98
	Total	100	100
	Odds Ratio	0.0768	
	95% CI	**[0.02 … 0.34]**	
	p	**0.0007**	

Table 2
Odds ratio of fistula reoccurrence in recurrent fistula group.

Recurrent fistula group			
		Group D Without pack	Group C: With pack
Fistula	Yes	5	2
	No	25	28
	Total	30	30
	Odds Ratio	**2.80**	
	95% CI	**[0.48 … 16.3]**	
	p	**0.242**	

Paired *t*-test was used to compare the nasalance scores for patients in group A with oral pack and after removal of the pack. This test showed a statistically significant ($p \leq 0.001$) increase of air passage through the nose after removal of the pack for 18 of the 22 sounds tested sounds (Table 4) (see Table 5).

Paired *t*-test was used to evaluate nasal air emissions in group A (with oral pack) between patients with and without fistula re-occurrence (table not shown). Only one test of the 25 phonation tests revealed a significant result (speech variable Prolonged_i, $p = 0.031$).

4. Discussion

Effective fistula management has to be practiced by cleft team to ensure that occurrence or re-occurrence of palatal fistulae is minimized. Literature reports show that secondary fistula recurrence in previously repaired cleft palate fistulas ranged from 16 up to 50%.[3,4] Amaratunga[6] reported about successful closure of fistulae in only 56% of the 73 patients in his sample, while Abyholm et al.[7] were successful in closing 84% of fistulae in their series of 113 patients. All these studies make cleft surgeons aware that there is a high percentage of failures after surgeries that attempted to repair fistulae after primary palate surgery.

Several studies have searched for an association between the severity of the palatal cleft and the rate of fistula formation.[3,4] Some authors have attempted to isolate factors that would cause fistulae. We feel that local factors such as infection, mechanical trauma or movement of palatal tissue due to volume of airflow through the nose could cause reoccurrence of fistulae. This study was performed to test possible reduction of volume of nasal airflow and fistula rates by placing a temporary barrier between the hard palate and the oral environment.

The study was designed as a parallel blocked randomized controlled trial. Patients that did not agree with the treatment plan randomly assigned to them were excluded. This happened more often in the group that was randomized to have surgery without an oral pack. We continued randomization until both groups had the same number of patients (N = 30). This is a deviation of the 'intention to treat principle' of randomized controlled trials. Actually, we performed a per protocol analysis. Theoretically, this may have affected the results as it might be possible that the comparability of baseline characteristics for both groups has been violated.[8] Many randomized clinical trials use modified

Table 3
Test-retest reliability of Group C patients with the oral pack.

	Reliability	DME	Diff.	p	95% CI
papapa	0.922	3.56	0.47	0.616	[-1.41 … 2.35]
tatata	0.594	5.4	−1.77	0.215	[-4.62 … 1.09]
kakaka	0.854	3.7	0.8	0.409	[-1.15 … 2.75]
sasasa	0.867	3.64	1.07	0.266	[-0.86 … 2.99]
fafafa	0.599	5.37	1.37	0.333	[-1.47 … 4.2]
pipipi	0.8	5.42	0.43	0.759	[-2.43 … 3.3]
tititi	0.764	6.5	−3.03	0.081	[-6.47 … 0.4]
kikiki	0.76	5.87	−0.4	0.794	[-3.5 … 2.7]
sisisi	0.74	6	−1.7	0.282	[-4.87 … 1.47]
fififi	0.722	6.53	−1.5	0.381	[-4.95 … 1.95]
mamama	0.872	4.36	0.07	0.953	[-2.24 … 2.37]
nanana	0.791	5.11	−1.17	0.383	[-3.86 … 1.53]
mimimi	0.538	5.43	2.2	0.128	[-0.67 … 5.07]
ninini	0.911	2.97	−2.07	0.012	[-3.64 … -0.5]
Prolonged a	0.888	4.42	−0.67	0.564	[-3 … 1.67]
Prolonged i	0.865	6.53	−0.87	0.611	[-4.32 … 2.58]
Prolonged s	0.914	7.09	1.9	0.308	[-1.84 … 5.64]
Prolonged m	0.807	3.12	1.37	0.101	[-0.28 … 3.01]
Bilabial Plosives	0.819	3.79	0.33	0.736	[-1.67 … 2.33]
Lingual Plosives	0.785	4.16	−1.23	0.26	[-3.43 … 0.96]
Velar Plosives	0.764	5.06	0.8	0.545	[-1.87 … 3.47]
Sibilant Fricatives	0.753	4.37	−0.03	0.977	[-2.34 … 2.28]
Nasals	0.889	3.66	0.67	0.486	[-1.27 … 2.6]
Bilabial Plosives	0.709	4.9	−2.9	0.029	[-5.49 … -0.31]
Sibilant_Fricatives_without_nasals	0.839	3.24	−0.77	0.367	[-2.48 … 0.95]

Table 4
Test-retest reliability of Group C patients without the oral pack.

	Reliability	DME	Diff.	p	95% CI
papapa	0.936	3.09	0.13	0.868	[-1.5 … 1.76]
tatata	0.776	3.59	0.17	0.859	[-1.73 … 2.06]
kakaka	0.77	4.25	1.2	0.283	[-1.05 … 3.45]
sasasa	0.617	5.11	1.63	0.225	[-1.06 … 4.33]
fafafa	0.655	3.87	−0.33	0.741	[-2.37 … 1.71]
pipipi	0.934	2.26	−1.2	0.049	[-2.39 … -0.01]
tititi	0.941	2.63	−1.9	0.009	[-3.29 … -0.51]
kikiki	0.93	3.02	−0.83	0.295	[-2.43 … 0.76]
sisisi	0.882	3.85	−1.2	0.237	[-3.23 … 0.83]
fififi	0.759	4.27	−1.87	0.101	[-4.12 … 0.39]
mamama	0.767	5.06	−1.7	0.204	[-4.37 … 0.97]
nanana	0.797	3.96	−1.23	0.237	[-3.32 … 0.86]
mimimi	0.599	5.79	−2.8	0.071	[-5.86 … 0.26]
ninini	0.843	4.36	−2.1	0.073	[-4.4 … 0.2]
Prolonged a	0.902	3.31	−0.63	0.464	[-2.38 … 1.11]
Prolonged i	0.978	2.73	2.13	0.005	[0.69 … 3.58]
Prolonged s	0.977	3.05	0.5	0.53	[-1.11 … 2.11]
Prolonged m	0.797	5.41	−0.8	0.571	[-3.66 … 2.06]
Bilabial Plosives	0.843	3.4	0.9	0.313	[-0.89 … 2.69]
Lingual Plosives	0.943	2.24	−1.4	0.022	[-2.58 … -0.22]
Velar Plosives	0.78	4.97	2.77	0.04	[0.14 … 5.39]
Sibilant Fricatives	0.849	3.28	2.2	0.015	[0.47 … 3.93]
Nasals	0.902	3.52	2.07	0.03	[0.21 … 3.92]
Bilabial Plosives	0.872	2.4	0.23	0.709	[-1.03 … 1.5]
Sibilant_Fricatives_without_nasals	0.757	3.22	−0.8	0.344	[-2.5 … 0.9]

intention to treat principles or per protocol analysis of trial data. This is done in circumstances where trial authors have to deal with missing data or deviations from the trial protocol after randomization. In an extensive meta-epidemiological study on data from 50 meta-analyses and 322 randomized controlled trials it was shown that trials that deviated from the standard intention to treat analysis showed larger intervention effects than trials that reported the standard approach.[9] In our study we found no significant effect on fistula rate of our intervention, so an overestimation of the treatment effect seems to be unlikely.

To decide the pack to use on the hard palate a review of literature was done to identify various appendages such as palatal splints, bandages and other devices in order to reduce the reoccurrence of palatal fistulae. The most common appendage used was the acellular dermal grafting.[10–17] Other packs that were used to protect the hard palate after closure were acrylic splints or celluloid acetone dressings.[18,19] We did not use an acellular dermal matrix or acrylic splint for a number of reasons. An antibiotic soaked sterile gauze pack is readily available at the time of surgery and it is cost-effective, it does not need to be manipulated into shape and once placed it takes the natural shape of the palate due to the pressure exerted by the tongue. Acellular dermal matrix and iodoform gauze were not used due to their higher costs and difficulty to procure in India. Acrylic splints were not used due to the time taken for preparing a splint and the possibility of an adverse reaction of the palatal mucosa to acrylic. The antibiotic pack was kept in place for 5 days at which stage the proliferative phase leads to the maturation phase of healing by primary intention.[20] The antibiotic used was oil based and thus could be placed in the oral cavity for 72+ hours. Since the antibiotic was thoroughly squeezed, the chances of ingestion

Table 5
Effect of pack to reduce audible airflow through the nose.

Passage	Diff.	p	95% CI
papapa	−6.2	<0.001	[-8.04 … -4.36]
tatata	−7.17	<0.001	[-9.41 … -4.92]
kakaka	−5.9	<0.001	[-7.62 … -4.18]
sasasa	−6.97	<0.001	[-9.18 … -4.76]
fafafa	−4.33	0.001	[-6.8 … -1.87]
pipipi	−8.7	<0.001	[-12.02 … -5.38]
tititi	−4.17	0.035	[-8.01 … -0.32]
kikiki	−6.37	<0.001	[-9.88 … -2.86]
sisisi	−5.8	<0.001	[-8.83 … -2.77]
fififi	−5.63	0.003	[-9.24 … -2.03]
mamama	−2.57	0.092	[-5.57 … 0.44]
nanana	−7.67	0.001	[-12.06 … -3.28]
mimimi	−6.17	0.003	[-10.03 … -2.3]
ninini	−8.27	<0.001	[-11.19 … -5.34]
Prolonged_a	−12.77	<0.001	[-17.21 … -8.32]
Prolonged_i	−14.2	<0.001	[-19.03 … -9.37]
Prolonged_s	−10.3	<0.001	[-14.31 … -6.29]
Prolonged_m	−11.53	<0.001	[-16.21 … -6.86]
Bil_Plosives	−8.37	<0.001	[-10.35 … -6.38]
Ling_Plosives	−7.53	<0.001	[-9.89 … -5.18]
Velar_Plosives	−8.13	<0.001	[-10.07 … -6.2]
Sibilant_Fricatives	−10.27	<0.001	[-12.92 … -7.61]
Nasals	−7.4	<0.001	[-8.91 … -5.89]
BilabialPlosives	−7.57	<0.001	[-9.65 … -5.49]
Sibilant_Fricatives_wo_nasals	−6.87	<0.001	[-8.2 … -5.53]

of antibiotic is also minimized. Moreover the pack is stabilised well with 5 sutures, thus it adapts well to the palate leading to no or little discomfort to the patients. Care should be taken about the length of the pack as it should not touch the soft palate or else patient will have severe gag reflex.

Different surgical techniques like local mucoperiosteal flaps, turnover flaps from the palate, tongue flaps, pharyngeal flaps, buccal myomucosal flaps, facial artery musculo-mucosal flaps, free grafts of bone, cartilage or dermal fat, free tissue transfer for large or recalcitrant fistulae and acellular dermal matrix as well as cultured mucosal epithelium have been used to treat recurring fistulae.[21–34] In the present study local mucoperiosteal flaps were used in both groups to repair the hard palate. All operations were performed by one experienced surgeon to eliminate surgical experience as a confounder.[35,36] Because phonation was necessary to measure air volume, this study was performed in older individuals with recurrent fistulae. The clinical picture in older patients with recurrent fistulae remains the same as those operated primarily because there is still no bony bridge between the cleft palate shelves. This means that the palatal tissue is still prone to be affected by volume of air passing through the nose during phonation.

The nasometric testing stimulus using the Nasometer II measures the air flow between the nose and mouth. This method was chosen because it is a non-invasive method that is patient compliant and accurate.[37] The nasometer does not test the exact volume of air-flow through the nose and mouth. It measures the percentage of airflow between nose and mouth. This test showed that percentage of airflow expressed through the nose during speech decreased significantly when the oral pack was in place. This could be attributed to the presence of the pack ensuring the mucosal flaps of the repaired hard palate not being displaced as much as the flaps when the pack was removed. The reliability of the test-retest of nasometric values was found to be reliable though the reliability of the testing with the pack was found to be slightly better than the testing without the pack. It might be that the patient with a pack in place for 5 days, is used to that intra-oral environment and when measured with the pack removed and re-tested after 1 h, the patient is still adapting to the new intra-oral situation when speaking, which may have led to variability in the measurements.

In this study only patients with longitudinal fistulae were included. This was done to obtain a standardized pre-operative situation so that there was an even distribution of one particular type of fistula. The odds ratio of recurrent fistula formation between groups A and B showed that patients in group B (no pack group) were more prone to fistula formation when compared to those in group A (pack group), but this difference was not statistically significant. Nasal air emission in group A (pack group) patients with and without recurrent fistula was also found to be comparable.

There are limitations to this study. The number of patients in each group (N = 30) was rather small. The highly significant difference between pack and no pack for nasal air emission shows that the study is not underpowered regarding measuring nasal air emission during speech. A post hoc power analysis regarding fistula rate revealed achieving significance for fistula re-occurrence would have required more than 90 patients in each group. Taking into consideration the low number of fistulae that presented for treatment in this high volume center during the trial period of 15 months, the study would have taken approximately 5 years to complete. This time period was considered too long. Second, only patients with longitudinal fistulae not measuring more than 10 mm long and 5 mm wide were included in this study. Since these fistulae are small in size their repair does not require extensive movement of adjacent tissues. This study should be repeated in a sample with large palatal defects after primary surgery. Third, further research needs to be performed to test the efficacy of the oral pack used in this study against the efficacy of various other materials used to provide a local barrier. Fourth, the precise volume of air expressed through the nose during speech, feeding and breathing could not be determined. However, there was a significant reduction in the flow of air, which would evidently lead to reduction in the volume of air present in the nose during speech. This can be safely extrapolated to infer that there was reduction of air volume during crying and breathing.

There is 3–10% fistula rates even among experienced surgeons although fistula rates ranging from 0% to 60% have been reported (Hardwicke et al., 2014; Jodeh et al., 2019; Stein et al., 2019).[38] The recurrence of fistula even become more challenging to operate. Fistula occurrence is related to different reasons, including type and severity of cleft, surgeon's experience, and operative technique (Antonelli et al., 2011; Hardwicke et al., 2014; Bykowski et al., 2015; Jodeh et al., 2019; Saralaya et al., 2019; Stein et al., 2019).[39] The problem arises as once a fistula forms, the rate and risk of recurrence post surgery also becomes more (Schultz, 1986; Losee et al., 2008; Bykowski et al., 2015). Thus every possible measures should be taken for a successful surgery. Our method of antibiotic pack needs to be investigated more but the preliminary results are satisfying enough for further exploration.

5. Conclusions

Fistula correction is one of the most challenging and technique sensitive surgeries in cleft surgeries. Despite handled by best surgeons, the success of surgery is highly unpredictable. Antibiotic soaked gauze pack can be easily made and is highly economic. Care to be taken to squeeze the ointment completely from the pack before placing to minimise the ingestion of antibiotic in high doses. It acts as a dressing over the hard palate and aid in the healing.

Moreover placement of pack reduces the collection of food debris in the initial phase of healing which further decreases the chances of wound dehiscence and infection. In patients with recurrent fistulae, antibiotic oral pack after fistula repair diminishes nasal air emission. the exact volume of air present through the nose at the time of speech, feeding and breathing could not be determined. But, it is evident from our study that significant reduction in the flow of air was there. This would surely reduce the volume of air present in the nose during speech. Thus we can safely conclude that there was reduction of air volume during crying and breathing as well. It is also evident from our nasometric tests. Whether this has an impact on re-occurrence of fistulae needs to be investigated further.

Conflict of interest and authorship conformation form

Please check the following as appropriate:

○All authors have participated in (a) conception and design, or analysis and interpretation of the data; (b) drafting the article or revising it critically for important intellectual content; and (c) approval of the final version.
○ This manuscript has not been submitted to, nor is under review at, another journal or other publishing venue.
○ The authors have no affiliation with any organization with a direct or indirect financial interest in the subject matter discussed in the manuscript
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Acknowledgment

This study was partly funded by the former World Health Organization Collaborating Center for Oral Health Care Planning and Future Scenarios of the Radboud university medical center in Nijmegen, the Netherlands.

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