Efficacy of Sucralfate in Improving Post Operative Outcomes in Palatoplasty Patients: A Prospective Study

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Palatoplasty, Wound Healing, Sucralfate, Mucosal Coverage, Pain Relief

ABSTRACT
Background: Palatoplasty is a commonly performed procedure in paediatric population. Adequate wound healing and sufficient pain relief post surgery are the main concerns. Sucralfate has been used as an effective medium to restore the damaged epithelial barrier in cases of tonsillectomy, uvuloplasty and similar surgical procedures.
Materials and methods: Forty patients who underwent palatoplasty in our unit were randomised into 2 groups- sucralfate group and control group. Sucralfate suspension was administered orally for a period of 7 days post operatively and the pain scores, mucosal coverage and the general degree of wellness were measured on each of these days.
Results: Oral pain severity was reduced in the study group and this reduction was statistically significant (p=0.04) between both the groups POD 1 onwards. Mucosal coverage at the surgical site was accelerated and more effective in the sucralfate group. The difference between both the groups was significant POD 2 (0=0.022) onwards. The general degree of wellness between the participants was also statistically significant POD 2 onwards (p=0.04)
Conclusion: Sucralfate is a potent and safe adjunct in improving and accelerating post operative outcomes in paediatric palatoplasty patients.

1. Introduction:

Cleft palate is one of the most common congenital anomalies, affecting approximately 1 in 700 live births globally [1]. Palatoplasty or cleft palate repair, is performed to enhance the patient's physical and psychological well-being [2 3 4]. As with all surgeries, the postoperative period is critical to minimise complications and achieve the best results. Pain, resulting from nerve irritation, swelling, and muscle spasms, is a frequent complication of palatoplasty and continues until the mucosa fully heals.

Peptic ulcers have traditionally been treated with sucralfate, an aluminum salt of sulfated sucrose. By linking itself to the exposed proteins of injured cells, it is thought to create a protective barrier. The drug's affinity for injured mucosa is explained by its viscous adhesiveness and the formation of polyvalent bridges between positively charged proteins in mucosal lesions and negatively charged sucralfate polyanions. There is evidence that sucralfate increases the formation of local prostaglandin E2, which in turn increases blood flow, mucus production, cell activity, and surface cell migration. Additionally, sucralfate promotes mucosal healing and the prompt return to regular activities by binding with growth factors and demonstrating angiogenic effects.(5)

Sucralfate has been used to provide pain relief and better healing post adenotonsillectomy and uvulopalatopharyngoplasty with promising results (5)(6). Sucralfate can similarly protect the exposed surfaces of the palatine muscles, preventing muscle spasms and nerve irritation and facilitate a comfortable post operative period(6).

The purpose of this study was to evaluate the efficacy of sucralfate in the reduction of the severity of oral pain, in the improvement of the general degree of wellness and mucosal healing between a control group and a sucralfate treated group in paediatric patients undergoing palatoplasty. The hypothesis was that making a protective barrier like the one made for peptic ulcers around the palatoplasty injury would minimise postoperative complications.

What would make this study particularly valuable is its focus on pediatric patients, who may

experience different pain management challenges compared to adults. By comparing the control group with the sucralfate-treated group, the study could provide insights into whether this use of sucralfate leads to a significant difference in pain reduction and recovery quality.

2. Materials and methods

Forty patients who underwent palatoplasty in our unit were randomised into 2 groups- sucralfate group (n=20) and control group(n=20). Female and male paediatric patients in the age group of 4 to 12 years of age who were indicated for palatoplasty were selected.

Inclusion criteria were patients between 4 to 12 years of age, patients planned for primary or secondary palatoplasty procedures, systemically healthy patients and non syndromic patients, those fit for surgery under general anaesthesia and those with no known history of allergy to sucralfate.

Exclusion criteria were patients with known comorbidities, patients not fit for surgery under general anaesthesia and patients with a history of sensitivity to sucralfate.

The study was approved by the institutional ethics committee (IHEC/SDC/OMFS-2302/24/113). Patient parents gave informed consent for the procedure before surgery.

The randomisation was computer generated and the random allocation sequence was implemented using sealed envelopes. The random number allocation, surgery and data collection were each performed by a different person to reduce the chances of bias. There were no withdrawals or dropouts.

Cleft repair was performed using Bardach's palatoplasty and von Langenback palatoplasty for complete and incomplete cleft palate respectively. Dissection of the layers was carried out and the nasal layer, muscular layer and oral mucosal layers were closed using 3-0 polygalactin sequentially. Any lateral raw areas post closure were loosely approximated and packed with Surgicel (oxidised cellulose). Stay sutures were placed to secure the oxidised cellulose.

Post operative instructions included liquid diet during the first 7 days after surgery, strict oral hygiene maintenance and adherence to the prescribed drug protocol. Both the sucralfate group and the control group were given standard post operative medications-Injection Amoxicillin+clavulanic acid Intravenously twice a day, Syrup Paracetamol thrice a day, Injection Dexamethasone IV twice a day and Syrup Ondansetron BD according to their weight.

Sucralfate was administered as an oral suspension- 2 ml of a 100 g suspension to the study group. Patients enrolled in the sucralfate group were instructed to gargle the sucralfate suspension gently and then to swallow. Two ml of the suspension was administered every 12 hourly after the operation during the next 7 days. Patients enrolled in the control group were instructed to use placebo suspension, which was similar in appearance to the sucralfate suspension and was given at the same doses and schedule.

Patients were examined and scored clinically, once a day for the first 7 post operative days. Oral pain, the percentage of mucosal coverage and general degree of wellness were the clinical parameters evaluated . Oral pain was estimated by the patients themselves using the Wong Baker FACES scale based on a linear scale from 0 to 10, with 0 representing an absence of pain and 10 representing worst pain. The patient was familiarised with the scale prior to the surgery in order to to accustom him/her to the evaluation method. The extent of mucosal coverage and the degree of wellness were evaluated and recorded daily according to a numerical scoring system developed by Prakash Zodpe et al(5) (Figure 1). Patients in the sucralfate group were questioned regarding the possible adverse effects of sucralfate, and any adverse effect, if present, was noted.

Statistical analysis was performed and a p value <0.05 was considered statistically significant.

Degree of strength
1—Patient felt well
2—Patient felt moderately well
3—Patient felt weakness
Mucosal coverage
0—Complete healing
1—1%-25% bare mucosa
2—26%-50% bare mucosa
3—51%-75% bare mucosa
4—76%-100% bare mucosa

Figure 1- scoring criteria

3. Results

A total of 40 patients , 20 in each group received the planned treatment and completed the prescribed protocol. There were no dropouts in the study. The overall toleration of sucralfate was good .

Graph 1: Mean age of study participants

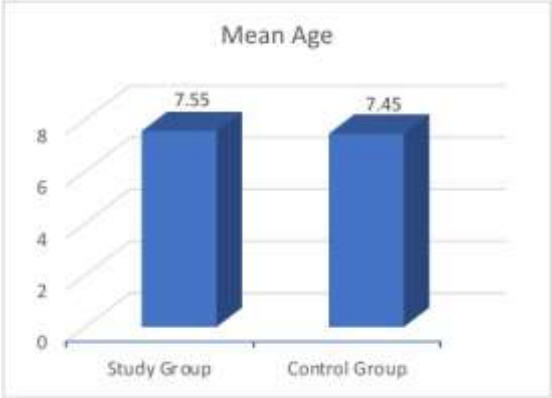

Table 1: Comparison of mean age of study participants

	Number	Mean	SD	t	P value
Study Group	20	7.55	2.4	0.133	P = 0.89
Control Group	20	7.45	2.3		NS

SD-standard deviation; NS-not significant using unpaired t-test

It was found that mean age of participants in study group was similar to mean age of participants in the control groups. The mean difference between the groups was not statistically significant (P = 0.89).

Graph 2: Distribution of participants according to gender

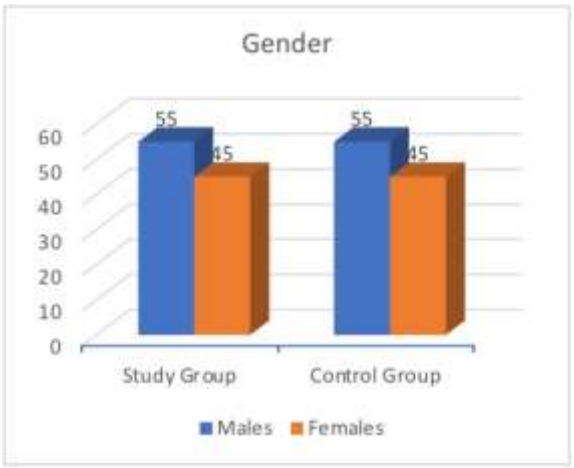

Table 2: Distribution of participants according to gender

	Study Group	**Control Group**	**Total**	**P value**
	N (%)	**N (%)**		
Males	11 (55)	11 (55)	22	P = 0.99
Females	9 (45)	9 (45)	18	NS
Total	20 (100)	20 (100)	40	

N-number; %-percentage; NS-not significant using Chi-square test

It was found that the distribution of males and females between the groups was comparable (P = 0.99).

Graph 3: Mean pain scores at different time intervals between the groups

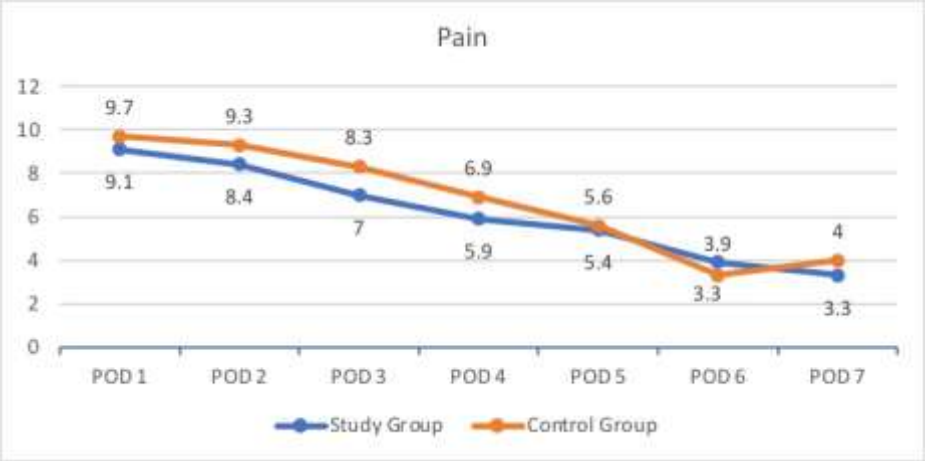

Table 3: Comparison of mean pain scores at different time intervals between the groups

		Number	Mean	SD	t	P value
POD 1	Study Group	20	9.1	1.02	-2.16	***P = 0.04****
	Control Group	20	9.7	0.73		
POD 2	Study Group	20	8.4	0.89	-2.7	***P = 0.01****
	Control Group	20	9.3	0.98		
POD 3	Study Group	20	7	1.02	-4.6	***P = 0.001***
	Control Group	20	8.3	0.73		
POD 4	Study Group	20	5.9	0.78	-3.46	***P = 0.001***
	Control Group	20	6.9	1.02		
POD 5	Study Group	20	5.4	1.14	-0.63	P = 0.53 NS
	Control Group	20	5.6	0.82		
POD 6	Study Group	20	3.9	1.02	0.375	P = 0.71 NS
	Control Group	20	3.3	0.61		
POD 7	Study Group	20	3.3	1.17	-2.66	***P = 0.01****
	Control Group	20	4	0		

POD 1

It was found that participants in study group had lesser pain scores when compared to participants in the control group. The difference was found to be statistically significant (P = 0.04).

POD 2

It was found that participants in study group had lesser pain scores when compared to participants in the control group. The difference was found to be statistically significant (P = 0.01).

POD 3

It was found that participants in study group had lesser pain scores when compared to participants in

the control group. The difference was found to be statistically significant (P = 0.001).

POD 4

It was found that participants in study group had lesser pain scores when compared to participants in the control group. The difference was found to be statistically significant (P = 0.001).

POD 5

It was found that participants in both the study and the control group had similar pain scores The difference was not statistically significant (P = 0.53).

POD 6

It was found that participants in study group had higher pain scores when compared to participants in the control group. The difference was not statistically significant (P = 0.71).

POD 7

It was found that participants in study group had lesser pain scores when compared to participants in the control group. The difference was found to be statistically significant (P = 0.001).

Graph 4: Mean mucosal coverage scores at different time intervals between the groups

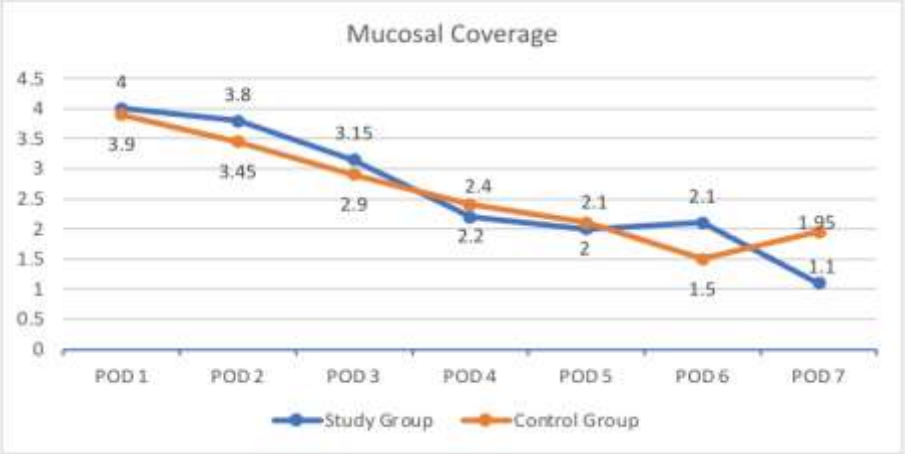

Table 4: Comparison of mean mucosal coverage at different time intervals between groups

		Number	Mean	SD	t	P value
POD 1	Study Group	20	4	0	1.4	P = 0.15
	Control Group	20	3.9	0.3		NS
POD 2	Study Group	20	3.8	0.4	2.4	***P = 0.022****
	Control Group	20	3.45	0.51		
POD 3	Study Group	20	3.15	0.36	2.3	***P = 0.025****
	Control Group	20	2.9	0.3		
POD 4	Study Group	20	2.2	0.4	-1.37	P = 0.17
	Control Group	20	2.4	0.5		NS
POD 5	Study Group	20	2	0	-1.45	P = 0.16
	Control Group	20	2.1	0.3		NS
POD 6	Study Group	20	1.5	0.5	-3.6	***P = 0.001****
	Control Group	20	1.95	0.22		
POD 7	Study Group	20	1.1	0.3	-9.9	***P = 0.001****
	Control Group	20	1.95	0.22		

SD-standard deviation;
NS-not significant; statistically significant at *P < 0.05, **P < 0.01 using unpaired t-test

POD 1

It was found that the mucosal coverage was more among study group when compared to participants in control group. However, the mean difference was not statistically significant (P = 0.15).

POD 2

It was found that the mucosal coverage was more among study group when compared to participants in control group. The mean difference was statistically significant (P = 0.022).

POD 3

It was found that the mucosal coverage was more among study group when compared to participants in control group. The mean difference was statistically significant (P = 0.025).

POD 4

It was found that the mucosal coverage was more among control group when compared to participants in study group. However, the mean difference was not statistically significant (P = 0.17).

POD 5

It was found that the mucosal coverage was more among control group when compared to participants in study group. However, the mean difference was not statistically significant (P = 0.16).

POD 6

It was found that the mucosal coverage was more among control group when compared to participants in study group. The mean difference was statistically significant (P = 0.001).

POD 7

It was found that the mucosal coverage was more among control group when compared to participants in study group. The mean difference was statistically significant (P = 0.001).

Graph 5: Mean general wellness among participants at different time intervals between groups

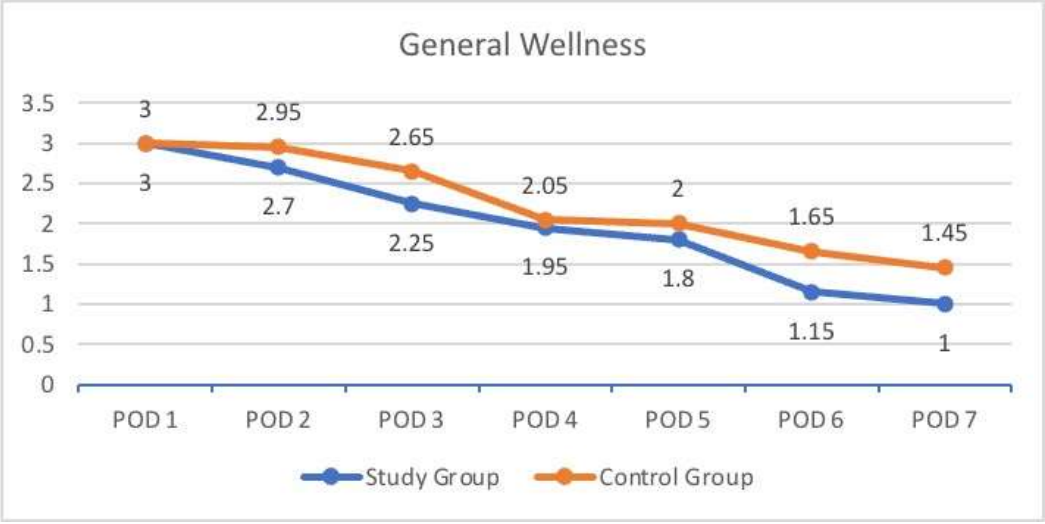

Table 5: Comparison of mean general wellness among participants at different time intervals between groups

		Number	Mean	SD	t	P value
POD 1	Study Group	20	3	0	-	-
	Control Group	20	3	0		
POD 2	Study Group	20	2.7	0.4	-2.1	**P = 0.04***
	Control Group	20	2.95	0.22		
POD 3	Study Group	20	2.25	0.44	-2.7	**P = 0.01***
	Control Group	20	2.65	0.49		
POD 4	Study Group	20	1.95	0.22	-1.4	P = 0.16
	Control Group	20	2.05	0.22		NS
POD 5	Study Group	20	1.8	0.4	-2.18	**P = 0.04***
	Control Group	20	2	0		
POD 6	Study Group	20	1.15	0.36	-3.6	**P = 0.001****
	Control Group	20	1.65	0.49		
POD 7	Study Group	20	1	0	-3.9	**P = 0.001***
	Control Group	20	1.45	0.5		

SD-standard deviation;
NS-not significant; statistically significant at *P < 0.05, **P < 0.01 using unpaired t-test.

POD 1

Participants in both groups had similar scores (felt weak)

POD 2

It was found that participants in the study groups felt more better than participants in the control group. The difference between the means was statistically significant (P = 0.04).

POD 3

It was found that participants in the study groups felt more better than participants in the control group. The difference between the means was statistically significant (P = 0.01).

POD 4

It was found that participants in the study groups felt more better than

participants in the control group. However, the difference between the means was not statistically significant (P = 0.16).

POD 5

It was found that participants in the study groups felt more better than participants in the control group. However, the difference between the means was not statistically significant (P = 0.04).

POD 6

It was found that participants in the study groups felt more better than participants in the control group. However, the difference between the means was not statistically significant (P = 0.001).

POD 7

It was found that participants in the study groups felt more better than participants in the control group. However, the difference between the means was not statistically significant (P = 0.001).

Oral pain severity was reduced in the study group and this reduction was statistically significant (p=0.04) between both the groups POD 1 onwards. Mucosal coverage at the surgical site was accelerated and more effective in the sucralfate group. The difference between both the groups was

significant POD 2 (0=0.022) onwards. The general degree of wellness between the participants was also statistically significant POD 2 onwards (p=0.04)

4. Discussion

Cleft palate is a frequently observed condition with multi factorial etiology [7]. Palatoplasty is a crucial intervention in paediatric patients. It aids in reconstruction of the palatal muscle sling, establishment of a proper anatomical structure for sufficient palatal movement and clear speech, separation of the oral cavity from the nasal cavity and closure of the palatal defect and in minimisation of maxillary growth disturbances and dento-alveolar deformities. The success of the surgery is not solely dependent on the surgical technique but also on the post operative care which includes pain management and promotion of wound healing.[7 8]

Sucralfate, a drug that is chiefly used as a gastrointestinal anti ulcer agent, has emerged as a promising treatment adjunct. Apart from the treatment of ulcers, it is also used in reducing pain after tonsillectomy, treating recurrent aphthous stomatitis and chronic venous stasis ulcer, and preventing stomatitis induced by cancer chemotherapy. The outcomes have been ranging from limited to positive[9]

In this regard, Kyrmizakis et al [10] undertook a block randomised, single-blind clinical study of twenty eight patients who underwent laser-assisted uvulopalatoplasty and reported that fourteen patients in the sucralfate group experienced significantly less postoperative pain than the other fourteen patients who received placebo. It has also been shown to considerably reduce the need for analgesic consumption along with the duration it took to reach their pre operative state.

Analgesic activity of sucralfate during the postoperative period promotes recovery, eventually making oral intake in the post operative period less difficult. The mucosal coverage was also improved and occurred at an accelerated rate in the study group unlike that in the placebo group.

A significant symptom of postoperative morbidity is pain after palatoplasty. However, the pain is severe and subsides when the mucosa heals. It occurs due to irritation of the nerve endings that have been exposed as well as spasms in the muscles of pharynx and palate, and edema. Pain during fluid intake or swallowing is an obstacle for more oral intake which may result in reduced intake causing muscle spasms to continue. The increased bacterial load in the mouth leads to inflammation and infections making pain worse.

Analgesics should be used carefully after palatoplasty. Anaesthetic and narcotic agents can increase the risk of upper airway collapse, which can be particularly dangerous for paediatric patients. Steroids, due to their strong anti-inflammatory properties, can help reduce postoperative swelling and pain. Topical anaesthetic sprays like lignocaine hydrochloride provide temporary pain relief and have been used to manage post-tonsillectomy pain in adults. Non steroidal anti-inflammatory drugs (NSAIDs) have also been effective in reducing postoperative pain; however, despite their positive safety profile, anti-platelet effects of aspirin and other NSAIDs could potentially lead to bleeding or gastrointestinal irritation.

Sucralfate has emerged as a valuable adjunct in management of post operative pain in adults and paediatric patients alike. Its potential benefits are wound protection and healing at the surgical site which is vulnerable to mechanical stress and microbial invasion. Sucralfate can create a protective coating over the wound, reducing the risk of mechanical disruption and promoting an optimal environment for mucosal healing. This protective layer may minimise the incidence of fistula formation, a common postoperative complication. This barrier can also help reduce postoperative pain by shielding the exposed nerve endings from irritants. This may result in reduced need for systemic analgesics, which can have side effects in paediatric patients.

5. Conclusion

The use of sucralfate has a beneficial effect in management of oral pain in post operative palatoplasty cases. As the study has demonstrated, topical sucralfate has a potent effect as an analgesic and can be used as an adjuvant to achieve pain relief. Because it is simple, safe, tolerated, and of low cost, it is our opinion that topical sucralfate is an important tool in adjuvant treatment of post- palatoplasty pain.

Additional information:

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