Biomedical and Biopharmaceutical Research
Abbreviation: Biomed. Biopharm. Res.
Volume: 22: Issue: 02 |Year: 2025
Page Number: 202-211

THE EFFICACY OF TOPICAL FERACRYLUM IN ACHIEVING HEMOSTASIS IN TONSILLECTOMY PATIENTS: A RANDOMISED CONTROLLED TRIAL

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Received: 21-05-2025

Accepted: 16-06-2025

Published: 14-07-2025

ABSTRACT

Background: Tonsillectomy is a common ENT surgical procedure in which palatine tonsils are removed. Haemorrhage due to tonsillectomy remains a major cause of morbidity and mortality associated with the procedure. The merit of feracrylum lies in its combination of haemostatic action with antimicrobial activity without toxicity or local-irritating action.

Methodology: 94 patients of 5 years and above are randomly divided into two groups with block randomization, with each block of 8 divided into 47 in each group. Group 1 & 2 received feracrylum-soaked gauze and saline-soaked gauze in tonsillectomy, respectively. Intraoperatively, blood loss was analysed by visual estimation, and postoperative healing of tonsillar fossae was assessed by percentage of unhealed raw area.

Results: The mean blood loss in Group 1 was estimated to be 49.15 ml, while in Group 2 it was 48.06 ml. Blood loss was higher among group 1 than group 2, with a p-value of 0.939, which is statistically insignificant. On comparing the rate of healing from the day of surgery to postoperative day 30, the patients in both groups had the same rate of healing, except on postoperative day 3, where there was more unhealed raw area in group 2 patients but with no significant differences (p value of 0.057). Both the groups took the same amount of time for complete healing.

Conclusion: Feracrylum is a solution with haemostatic action, antimicrobial action, and hygroscopic action. From our study, we conclude usage of feracrylum had no significant difference in intraoperative blood loss and healing when compared to the usual method of haemostasis.

KEYWORDS: Feracrylum, Haemostasis, Tonsillectomy.

INTRODUCTION

Tonsillectomy is one of the most common surgical procedures done in children worldwide, although tonsillectomy's prevalence rate is less often than before (1). Primary haemorrhage is the bleeding occurring intraoperatively; reactionary haemorrhage is the bleeding occurring within 24 hours of surgery, and secondary haemorrhage is bleeding occurring after 24 hours of surgery (2). Feracrylum is a water-soluble mixture of incomplete ferrous salt (II and III) of polyacrylic acid with 0.05%–0.5% of iron, and it contains a pharmaceutical solvent, which can be water or a physiologic solution of 0.85% of sodium chloride. It is odourless with a pH of 2.9 to 4. The main actions of feracrylum are haemostatic, antimicrobial, and hygroscopic with no toxicity or local irritation (3). There has not been much research done regarding its usage in tonsillectomies. Hence, this study aims to evaluate the efficacy of topical 1% feracrylum in achieving

haemostasis in tonsillectomies.

Aim: To evaluate the efficacy of topical 1% feracrylum in achieving haemostasis among the tonsillectomy patients.
Objectives: To assess intraoperative bleeding in tonsillectomy patients after the use of topical 1% feracrylum. Also, to assess the effectiveness of topical feracrylum in postoperative healing of tonsillar fossae.

REVIEW OF LITERATURE

Feracrylum with albumin forms a biodegradable synthetic complex that forms a large clot. This acts as a physical barrier on the wound surface, which in turn stops the capillary bleeding (4). The antimicrobial action of feracrylum is against gram-positive and gram-negative organisms and a few fungal species by cell wall lysis, which also decreases the chance of surgical wound infection. Feracrylum helps in quicker wound healing by the hygroscopic action of the solution by maintaining the moist environment at the wound site (5, 6). In a study by Sathyaki DC et al. (2017) (7), done among 40 patients with tonsillectomy to compare the efficacy of feracrylum in the treatment of primary haemorrhage to adrenaline in tonsillectomy. The results showed that the study participants in the feracrylum group did not have haemorrhage, whereas 6 participants in the adrenaline group had primary haemorrhage, and we have concluded that feracrylum in tonsillectomy reduces haemorrhage significantly more than adrenaline.

METHODOLOGY

This study was a randomized control trial done among patients undergoing tonsillectomy in the Department of Otorhinolaryngology, Mahatma Gandhi Medical College and Research Institute, within the period of January 2020-June 2021 after the approval from the ethical committee. The patients with signs & symptoms of chronic tonsillitis for more than 5 years undergoing tonsillectomy form the study population and were divided into two groups by block randomization with a block size of 8. The patients undergoing radio-frequency tonsillectomy, adenotonsillectomy, patients with a previous history of peritonsillar abscess, active infection, bleeding disorders, known allergy to feracrylum, and hypertensive patients were excluded. Estimated sample size of 94, grouped into 47 in each group. Group I with Feracrylum and Group II (control group) with normal saline.

Procedures:

After obtaining written consent from the parents of the participants in their language of understanding, all 94 study participants were given thorough history taking and clinical examinations, which were recorded in preformed pro forma. After basic pre-operative blood investigations and anaesthetic clearance for surgery, the patients were randomly allocated into 2 groups and taken up for conventional dissection and snare tonsillectomy. Under general anaesthesia by endotracheal intubation in the sister Rose position with a Boyle-Davis mouth gag in place, a throat pack and nasopharyngeal packs were placed. Then one side tonsil was held with vulsellum forceps and pulled medially, and an incision was placed on the mucosal reflection of the anterior pillar, and the incision was extended superiorly and inferiorly. Dissection began from the superior pole and was continued up to the inferior pole. The tonsil was then snared off with Eve's tonsillar snare. After snaring the tonsil, the tonsillar fossa was packed with gauzes soaked in 1% feracrylum solution. The same procedure was repeated on the opposite side. Intraoperatively, the amount of blood loss was evaluated by calculating the quantity of blood present in the suction jars and the number of gauze pieces used. Blood loss was calculated by visual estimation (8). The gauze piece size used for this study was 10 x 10 cm. Postoperatively, the time required for wound healing was noted by a grading system based on the percentage of raw area present in the tonsillar fossae. The patients were evaluated on postoperative days 0, 1, 2, and 3, and then the patient was discharged on the 3rd postoperative day in the absence of any postoperative complications. The patient was followed up at the end of the 1st week, 2nd week, and 1 month post-

operatively. The privacy and confidentiality of patients and their data were maintained.

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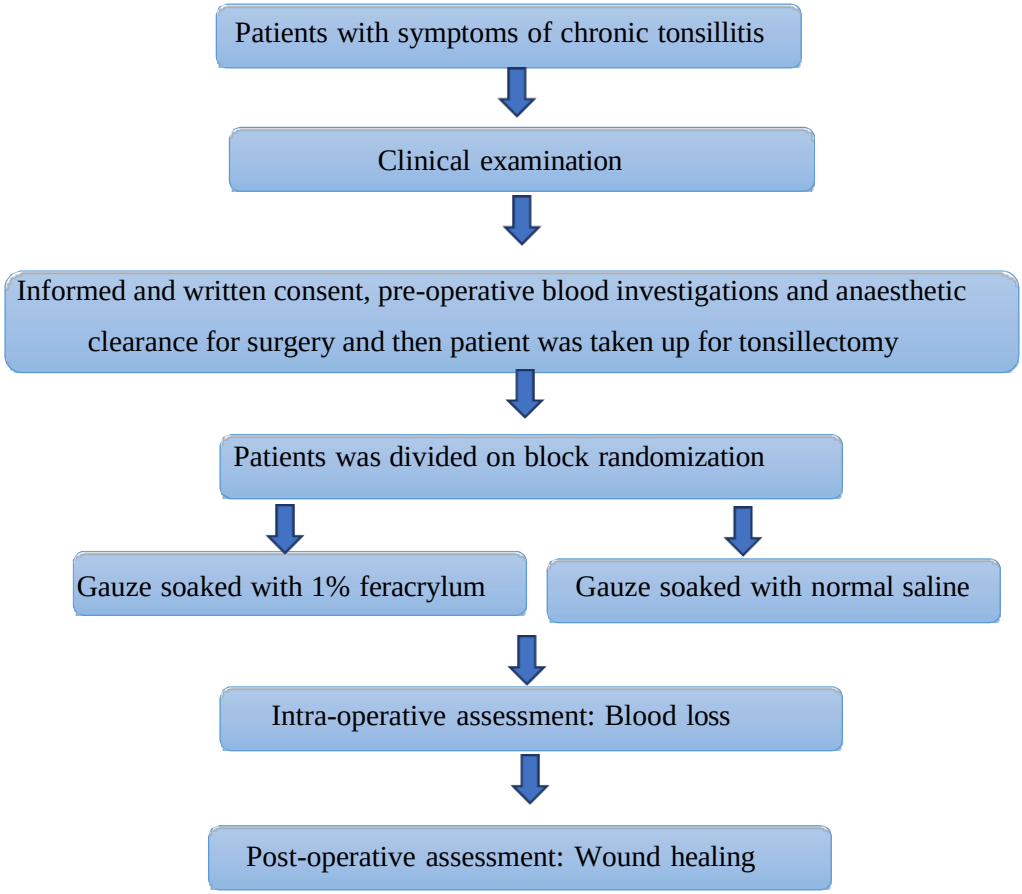
Table 1: Grading of raw area among study participants N = 47 in each group

Grade I	Raw area less than 25%
Grade II	Raw area 25 to 50%
Grade III	Raw area 50 to 75%
Grade IV	Raw area > 75%

FLOW-CHART TO SUMMARIZE THE SEQUENCE OF EVENTS



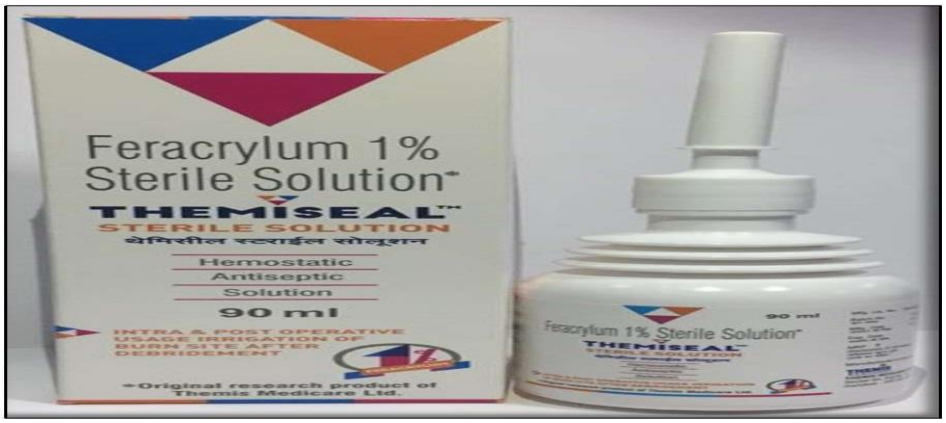


Figure 1: Feracrylum

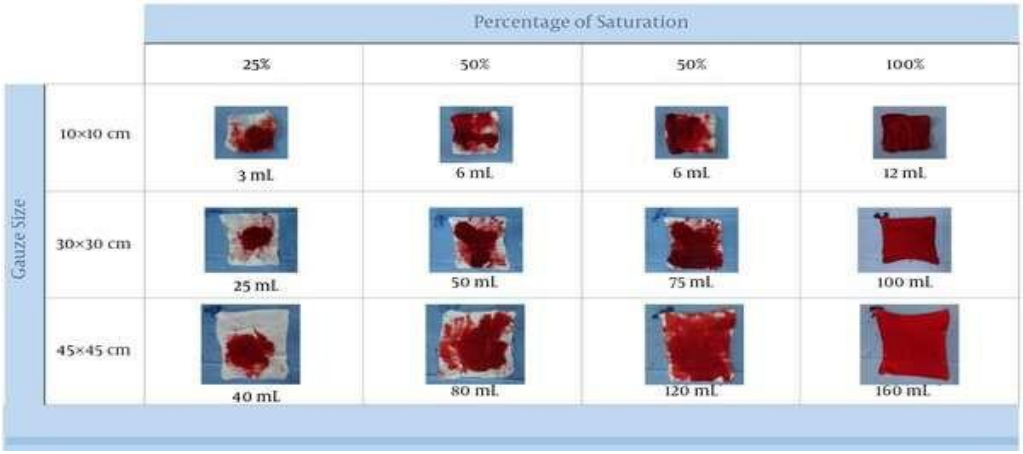


Figure 2: Calculation of blood loss by visual estimation

Figure 3: Healing on Post-operative Day : 0

Figure 4: Healing on Post-operative day 1

Figure 5: Healing on Post-operative day 2

Figure 6: Healing on Post-operative day 3

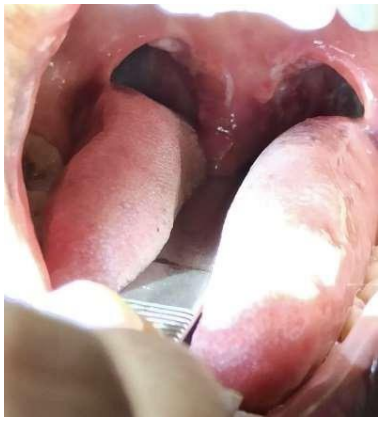


Figure 7: Healing on Post-operative day 7

Figure 8: Healing on Post-operative day 14

Figure 9: Healing on Post-operative day 30

Data Analysis:

All the data collected using Performa were entered into an Excel sheet (MS Excel 2021). The continuous data (e.g., age, blood loss) were given in mean and SD. The categorical variables (e.g., sex, grading of wound healing) are given in proportion. The independent t-test was used to compare the mean, and the chi-square was used to compare the proportion between the two groups, with a p-value < 0.05 as statistically significant.

RESULTS

The mean age of patients in both groups was 15.34, with the youngest age being 5 and the oldest 46 years of age. In group I, the mean age was 14.15 ± 9, and in group II, the mean age was 16.19 ± 9.5, with no statistically significant (p-value 0.224) differences. In Group I, 51.1% were males and 48.9% were females. In Ingroup II, 53.2% were males and 46.8% were females**.** There was no statistically significant difference (p-

value 0.836) between the two groups in sex distribution. In group 1, 83% and in group 2, 91.5% had grade 3 tonsillar enlargement, respectively. There was no statistically significant difference (p-value 0.428) between both groups in grading before surgery. The mean blood loss in Group 1 was 49.15 ml, while in Group 2 it was 48.06 ml, with no statistically insignificant difference between the two groups (p value of 0.939). All patients in the study population had either grade 2, grade 3, or grade 4 of healing on day 0, i.e., on the day of surgery (i.e., 25-50% of unhealed raw area, 50-75% of unhealed raw area, and >75% of unhealed raw area, respectively). On post-op day 3, 42.6% in Group 1 and 25.5% in Group 2 had grade 1 healing with no statistically significant differences (p-value 0.057). On day 7, 89.4% in Group 1 and 83% in Group 2 had grade 1 healing. There were only grades 1 & 2 present among the study participants in both the groups. On days 14 & 30, all the study participants in both groups had only grade 1 healing, i.e., were completely healed. There were no statistically significant differences between two groups (p-value > 0.05) in grading of healing on days 0, 1, 2, 3, 7, 14, and 30 post-surgeries. The mean blood loss in Group 1 among paediatric and adult patients was 45.16 ± 7.5 and 66 ± 9.6, with statistical significance (p-value was <0.001). In Group 2, blood loss in paediatric and adult patients was 44.5 ± 9.3 and 54.35 ± 8.5, respectively, with statistical significance (p-value was < 0.001).

Table 2: Characteristics of the study participants

Variables	**Group 1**		**Group 2**		**p value**
	Mean	**SD**	**Mean**	**SD**	
Age	14.15	9.005	16.19	9.543	0.224
	Frequency	**Percentage**	**Frequency**	**Percentage**	
Gender					
Male	24	51.1	25	53.2	0.836
Female	23	48.9	22	46.8	

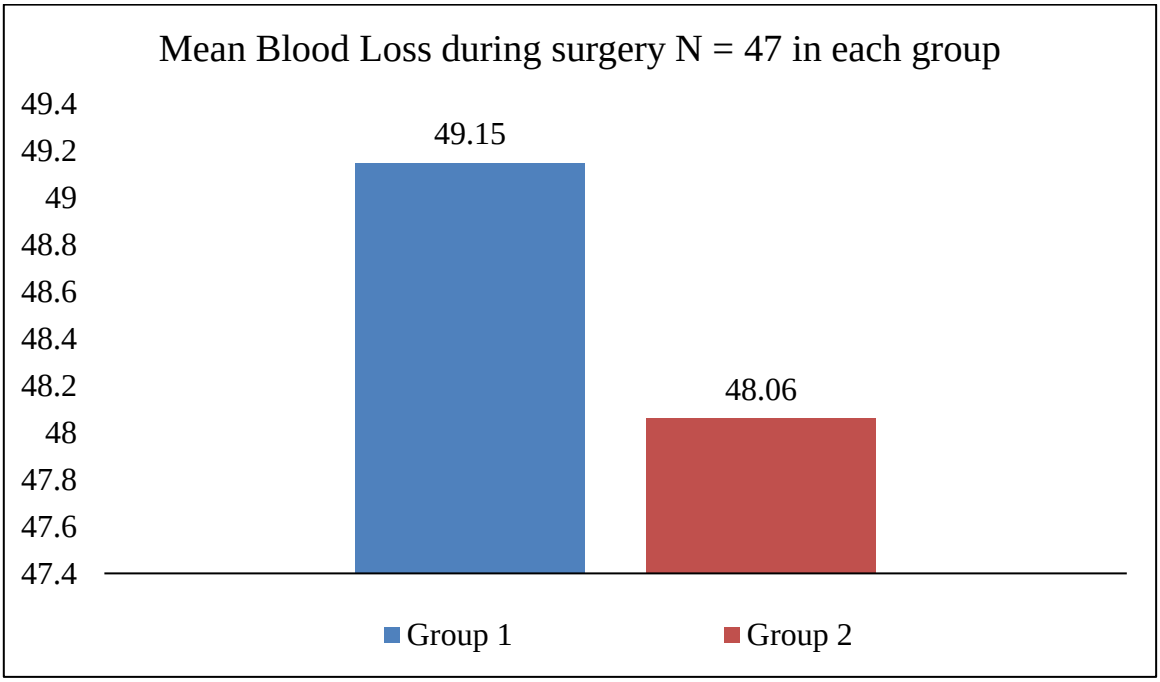


Figure 10: Blood loss during surgery

Table 3: Distribution of grade of healing on pre operative, day 0, 2, 3, 7, 14 & 30 (N = 47 in each group)

Day of Surgery	Grade	Group 1		Group 2		p value
		Frequency	Percentage	Frequency	Percentage	
Pre-Operative	2	5	10.6	3	6.4	0.428
	3	39	83	43	91.5	
	4	3	6.4	1	2.1	
Day 0	2	5	10.6	2	4.3	0.143
	3	19	40.4	13	27.6	
	4	23	49	32	68.1	
Day 1	2	7	14.9	5	10.6	0.768
	3	30	63.8	33	70.2	
	4	10	21.3	9	19.1	
Day 2	1	0	0	3	6.4	0.209
	2	27	57.4	22	46.8	
	3	20	42.6	21	44.7	
	4	0	0	1	2.1	
Day 3	1	20	42.6	12	25.5	0.057
	2	26	55.3	29	61.7	
	3	1	2.1	6	12.8	
Day 7	1	42	89.4	39	83	0.370
	2	5	10.6	8	17	
Day 14	1	47	100	47	100	1.0
Day 30	1	47	100	47	100	1.0

DISCUSSION

The mean age of patients in both groups was 15.34 years. The mean ages in group 1 and group 2 were 14.15 years and 16.19 years, respectively. The youngest is 5 years old and the oldest 46 years old in this study. Similarly, a study done by Sathyaki DC et al. (7) showed the mean age of the study was 26.95 ± 11.88 and 21.7 ± 12.26, respectively, in the adrenaline and feracrylum groups in tonsillectomy. In group 1, 24 males and 23 females were present; in group 2, 25 males and 22 females were present. In Sharma K et al.'s (9) study, 32% of the participants were aged between 11 and 20 years, 20% were aged 21 and 30 years, and 10% were between the ages of 31 and 40 years. Similarly, in a study done by Baumann et al. (10), it was shown that the majority of the study participants were males and there was no significant gender difference in the prevalence of tonsillitis.

In the prospective study by Valse D et al. (2021) (11)**,** among 60 patients with the objective to assess the role of feracrylum in intraoperative bleeding. The intraoperative blood loss in groups I (feracrylum) and II (normal saline) was 26.67 ± 4.81 ml and 44.70 ± 7.59 ml, respectively, which was contrary to our study result. In our study, the intraoperative mean blood loss was slightly higher among group 1 (49.15 ml) than group 2 (48.06 ml). The blood loss (p-value 0.939) had no statistically significant difference between both groups. No postoperative haemorrhage was reported in either group.

The study by Davidoss et al. (12) done on the wound healing in post-tonsillectomy patients showed that the wound healing occurs in three stages: early, intermediate, and late stages. In the early stage (24 to 48 hours), the wound shows oedema of soft tissue, oral commensal bacteria with inflammatory exudate causing fibrinous clot, and oedema of the uvula. The intermediate proliferative stage (Day 5 to 14) results in epithelialization. By day 5, the tonsillar fossa is filled with slough, and by day 7, peripheral epithelial edges grow inwards with pink mucosa. By day 9, the pink epithelial edges cover larger areas, and by day 12, they cover the entire

wound bed. After day 14, complete epithelialization occurs. No studies have been done to evaluate the wound healing in patients who underwent tonsillectomy after feracrylum usage. In our study, the wound healing was monitored on postoperative days 0, 1, 2, 3, 7, 14, and 30 in both groups. Our study has shown that the majority of study participants in both groups had grade 4 on day 0. On day 1, 70.2% and 63.8% had grade 3 among groups 1 and 2, respectively. Among the study participants in group 1, 57.4% had grade 2 on day 2, and the study participants in group 2 had grade 2 in 46.8%. On day 3, 42.6% and 25.5% had grade 1, respectively, among groups 1 and 2. On day 7, 89.4% and 83% in groups 1 and 2, respectively, had grade 1. All the study participants in both groups had grade 1 on day 14 and day 30. In addition to this, 4 patients in group 1 developed swelling of the cheek on day 1 of surgery. When the rate of healing was compared from the day of surgery to postoperative day 30, it was seen that both groups of patients had the same rate of healing except on postoperative day 3, where there was more unhealed raw area in group 2 patients with a p-value of 0.057. But thereafter both the groups took the same amount of time for complete healing. Hence, it was concluded that the difference between both the groups in terms of healing was statistically insignificant.

LIMITATIONS

Single-centre study with a smaller estimated sample size. A multicentric study with a larger sample size could yield better findings and results for generalization.

CONCLUSION

There is very little literature to support the effect of the usage of feracrylum in the post-operative tonsillectomy scenario. In our study, the usage of feracrylum on patients had neither a significant difference in the reduction of intraoperative blood loss nor contributed to faster wound healing when compared to the usual methods of haemostasis.

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