ORIGINAL RESEARCH

Efficacy of a Biodegradable Dressing Containing Tranexamic Acid for Prevention of Alveolar Osteitis: A Randomized Clinical Trial

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Abstract

Aim: This study aimed to evaluate the efficacy of a biodegradable dressing containing tranexamic acid in preventing alveolar osteitis (AO) following mandibular third molar extraction and to investigate the impact of various risk factors on its occurrence, including smoking, the use of oral contraceptives, a history of pericoronitis, and the difficulty level of the procedure.

Materials and methods: This double-blind, randomized, controlled clinical trial was conducted on 182 patients requiring mandibular third molar extraction. The patients were randomly assigned to two groups and standardized in terms of gender, age, level of difficulty of surgery, smoking status, and intake of oral contraceptives. After the surgical extraction of the third molars, the control group received a biodegradable dressing without any loaded medication. The experimental group received a biodegradable dressing loaded with tranexamic acid in the extraction socket. The patients were recalled after 3 and 7 days, and the presence/absence of blood clots, detritus, empty sockets, halitosis, and pain using a visual analog scale (VAS) was assessed. Data were analyzed using the Chi-squared test, independent *t*-test, exact logistic regression, and repeated measures ANOVA ($\alpha = 0.05$).

Results: The incidence of AO was not significantly different between the two groups (7.6% in the experimental group and 8.9% in the control group, $p = 0.744$). The odds of AO development in patients with level II or III difficulty were 9.169 times the odds of AO in patients with level I difficulty ($p = 0.015$). The experimental group had significantly lower pain than the control group ($p < 0.001$). The interaction effect of time and AO was significant on pain ($p < 0.001$).

Conclusion: A biodegradable dressing loaded with tranexamic acid was ineffective in preventing AO after third molar extraction but significantly decreased postoperative pain.

Clinical significance: There is a critical need to explore effective strategies for reducing postoperative complications such as pain and AO following mandibular third molar extractions. The findings of this study highlight the potential clinical application of biodegradable dressings containing tranexamic acid for pain management, offering a translational benefit in improving patient comfort and recovery experiences.

Keywords: Bandages, Dry socket, Third molar surgery, Tooth extraction, Tranexamic acid.

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Introduction

Alveolar osteitis (AO), or dry socket, is a common complication after tooth extraction, hindering socket healing.[1] It is characterized by acute inflammation of the alveolar bone, severe pain, and the absence of a blood clot in the socket. Clinical features include gingival redness, slight swelling, halitosis, bone exposure, and severe tenderness. While pain generally decreases within three days after extraction, persistent and worsening pain in the first week and poor socket healing indicate AO.[2] This complication most commonly occurs after surgical extraction of impacted mandibular third molars, with a lower incidence after extraction of other teeth.[3] Alveolar osteitis commonly occurs in patients aged 40–45 years, with an incidence ranging from 0.9 to 30% after mandibular third molar extraction and less than 1–4% after extraction of other teeth.[4–8] Although the exact cause is unclear, fibrinolysis and bacterial infection are proposed as potential factors.[9] Typically, a blood clot forms in the extraction socket to protect the bone; however, in AO, failure to form, premature elimination, or early resorption of the clot exposes bone and nerve endings, causing severe pain.[10]

Risk factors for AO include mandibular and molar teeth, female gender, surgical extraction, multiple extractions, traumatic extraction, poor oral hygiene, hormonal changes, and oral contraceptive use, with higher incidence mid-menstrual cycle.[7,11–14] Additional contributing factors include smoking, insufficient

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clinician experience, and difficult extractions, particularly of impacted mandibular third molars, which also increase the risk.[14–16] Since the etiology of AO has not yet been identified, its treatment primarily focuses on pain control through analgesics, anti-inflammatory drugs, and antibiotics.[17] Although AO is self-limited and typically resolves within 5–10 days without treatment, prevention is preferred due to the severe and prolonged pain associated with it.[5,18]

Various preventive measures have been shown to reduce the incidence of AO, including antibiotics like clindamycin, regular irrigation with warm salt water, rinsing or applying 0.12 and 0.2% chlorhexidine in the extraction socket, azithromycin intake, laser therapy, and platelet-rich fibrin application.[3,5,19–22] Additionally, studies have demonstrated the efficacy of tranexamic acid, an antifibrinolytic medication, in reducing AO after mandibular third molar surgery.[6,23] Tranexamic acid prevents proteolytic fibrin degradation by inhibiting the attachment of plasminogen and plasmin, thereby preventing blood clot lysis. However, there is controversy regarding its efficacy in reducing the incidence of AO.[6,24] Additionally, the impact of tranexamic acid-loaded chitosan-tripolyphosphate polymer biodegradable membranes on the occurrence of AO has not been investigated. Thus, this study aimed to assess the efficacy of a biodegradable dressing containing tranexamic acid to prevent AO following mandibular third molar extraction and evaluate the role of specific risk factors, including smoking, oral contraceptive use, history of pericoronitis, and difficulty level of procedure, in the occurrence of AO.

Materials and Methods

This study was conducted from July to September 2017 at the Oral and Maxillofacial Surgery Department of the School of Dentistry of Kermanshah University of Medical Sciences. The University's Ethics Committee (IR.KUMS.REC.1396.570) approved the study protocol and registered in the Iranian Registry of Clinical Trials (IRCT20140503017537N5).

Trial Design

A randomized double-blind controlled clinical trial was designed in which the experimental group received a biodegradable dressing containing tranexamic acid (Cyklokapron) after mandibular third molar extraction surgery. In contrast, the control group received the dressing with no loaded medication. The results were reported by the Consolidated Standards of Reporting Trials.

Sample Size Calculation

The sample size was calculated to be 180 patients ($n = 90$ in each group) according to a previous study by Hita-Iglesias et al.[25] assuming the incidence of AO to be 25% in the control group and 7.5% in the experimental group, effect size of 0.2417, $\alpha = 0.05$, and study power of 90% using PASS 11.

Participants, Eligibility Criteria, and Settings

The sample included patients presenting to the School of Dentistry of Kermanshah University of Medical Sciences for mandibular third molar extraction surgery. The inclusion criteria were (i) patients requiring mandibular third molar extraction surgery, (ii) age ≥ 18 years, and (iii) possession of risk factors for AO (history of pericoronitis, smoking, intake of oral contraceptives, or previous history of AO).

The exclusion criteria were (i) allergy to tranexamic acid or contraindications for its use, (ii) intraoperative complexities, (iii) current antibiotic therapy, and (iv) poor cooperation and not showing up for the recall sessions.

Interventions

The biodegradable dressing was synthesized at the Pharmaceutics Department of the School of Pharmacy. A biodegradable polymer synthesized the biodegradable scaffold loaded with tranexamic acid, chitosan, and tri-polyphosphate. After synthesis, the dressing was dried, sterilized, and packed. Finally, it underwent sterilization testing. Both dressing types had the same packages in terms of appearance and weight.

Randomization

Each patient was randomly assigned a dressing pack with a 4-digit code using the sealed envelope technique. The 4-digit codes were generated by the random command of a calculator (FX-991ES; Casio, China) for each dressing package. A pharmacist not involved in the study tabulated the allocated codes to the two groups and kept them in a sealed envelope until the end of the experiment.

Blinding

Neither the clinician nor the patients were informed about the type of dressing allocated to each patient; thus, the study had a double-blind design. A blind examiner collected data, and the group allocations were only disclosed for statistical analysis to ensure allocation concealment.

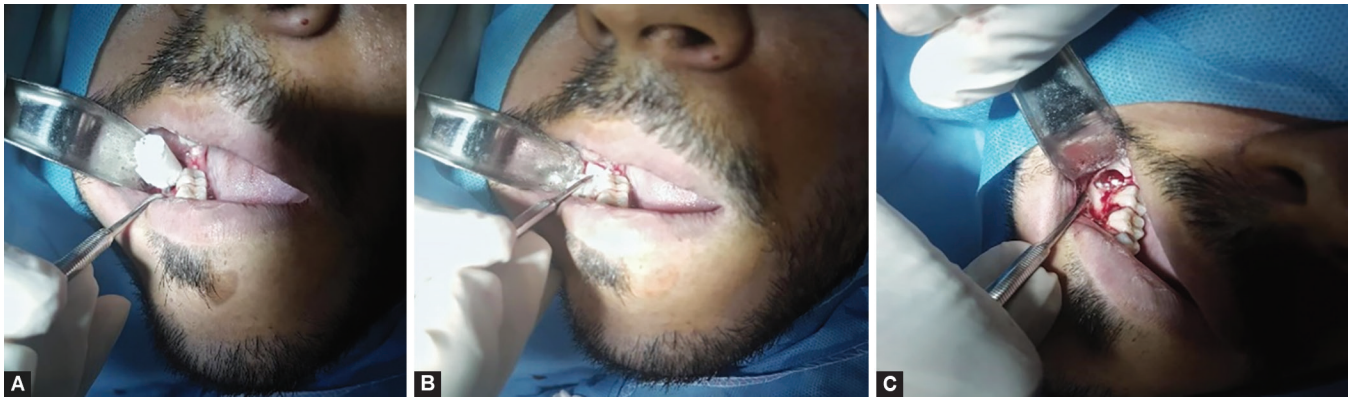
Surgical Procedure

After the patients were selected, they were briefed about the study, and written informed consent was obtained. Age, gender, intake of oral contraceptives, smoking, tooth impaction, and radiographic tooth position were also collected. The surgeon requested panoramic radiographs of the impacted teeth to assess the level of difficulty of the procedure according to Eshghpour et al.[26] and based on the sum of scores of tooth orientation, depth of impaction, and its relationship with the ramus. These radiographs were not used as selection criteria for inclusion in the study but were employed to categorize the cases according to their difficulty level, ensuring standardization in the outcomes assessment. The patients were then randomly assigned to two groups:

Group I (Experimental): Received the biodegradable dressing loaded with tranexamic acid.

Group II (Control): Received the biodegradable membrane without medication.

In all patients, mandibular third molars were surgically extracted at the university's Oral and Maxillofacial Surgery Department using the standard technique. Perioral areas were disinfected by povidone-iodine. Inferior alveolar nerve block, lingual nerve block, and local infiltration anesthesia were administered using 2% lidocaine plus 1:80,000 epinephrine (manufactured by Darou Pakhsh, Tehran). A pocket mucoperiosteal flap was elevated without any releasing incision from the mesial papilla of the first molar at the gingival sulcus level of the first and second molars to the distobuccal line-angle of the second molar and then continued posteriorly, buccally, and superiorly at the anterior border of the ramus. Bone was removed from the occlusal, buccal, and distal areas relative to the cervical region of the impacted tooth. Next, the impacted tooth was sectioned into several pieces by a bur. The alveolar socket, surgical site, and base of the flap were rinsed with 100 mL of sterile saline.



Figs 1A to C: Clinical images of application of biodegradable scaffold in the extraction socket. (A) The scaffold is prepared and ready for placement; (B) Partial insertion of the scaffold into the socket; (C) The scaffold fully positioned within the socket

After tooth removal, the assigned dressing was placed directly into the extraction socket, ensuring complete coverage of the surgical area (Fig. 1). For patients in group I, the biodegradable dressing loaded with tranexamic acid was inserted, while group II received the non-medicated biodegradable membrane. The flap was sutured with 0–3 silk sutures (manufactured by Supa Medical Devices Co, Tehran). Finally, a gauze was placed over the surgical site and compressed for 30–45 minutes. At the time of discharge, recall sessions were scheduled for the patients after 3 and 5 days. At the recall sessions, the patients were examined for AO according to the criteria by Rubio-Palau et al.,[27] including severe pain uncontrollable by analgesics between 1 and 3 days to 1 week after extraction along with one or more of the following: complete or partial absence of blood clot in the socket, presence of an empty socket/exposed alveolar bone, and detritus with/without halitosis. During the postoperative period, the pain intensity experienced by patients was quantified using a 0–100 mm visual analog scale (VAS), with 0 indicating no pain and 100 indicating the most severe pain imaginable. Patients' pain scores were recorded at 3 and 7 days after surgery. The patient companions were instructed to record patients' pain scores and report them to the examiner responsible for data collection of patients blinded to their group allocation. Occurrence/no occurrence of AO and its time of occurrence were recorded for each patient.

Statistical Analysis

Due to the low frequency of the class III difficulty levels, the class II and III difficulty levels were merged. This increased the statistical power by ensuring enough data points for meaningful comparisons across difficulty categories. The normal data distribution was analyzed using the Kolmogorov-Smirnov test, which showed that age and pain 3 and 7 days after surgery had a normal distribution ($p > 0.05$). Thus, the Chi-squared test assessed the correlation between qualitative variables and the group. Independent *t*-test was used to compare the mean age between the two groups. Exact logistic regression was applied to analyze the correlation of variables with AO due to no occurrence of AO in smokers and those with difficulty level I, and its generally low incidence rate. Repeated measures ANOVA was applied to analyze the effect of study variables on pain scores. All statistical analyses were done using SPSS version 18 (SPSS Inc., IL, USA) and STATA version 12 at 0.05 significance level.

Results

The sample consisted of 182 patients, including 92 patients (50.5%) in the intervention group. Of all, 75 (41.2%) were males and 107 (58.8%) were females. The mean age of the participants was 27.14 ± 6.85 years. Figure 2 shows the CONSORT flow diagram of patient selection and allocation. Table 1 presents the demographic information of the participants. The two groups had no significant difference in gender distribution ($p = 0.139$), mean age ($p = 0.251$), smoking status ($p = 0.637$), intake of oral contraceptives ($p = 0.207$), or level of difficulty of the procedure ($p = 0.375$).

Table 2 presents the frequency percentage of AO based on the assessed variables. As shown, the incidence of AO was 7.6% in the experimental group and 8.9% in the control group. The incidence of AO was not significantly different between the two groups ($p = 0.744$). It had a higher incidence in patients over 30 years. None of the smokers and none of those with level I difficulty had AO. Table 3 presents the correlation of AO with the assessed variables. Use of loaded biodegradable membrane, gender, age, smoking status, and intake of oral contraceptives had no significant correlation with AO. Difficulty of surgery significantly correlated with AO, such that the odds of AO development in patients with level II or III difficulty were 9.169 times the rate in patients with level I difficulty ($p = 0.015$).

Table 4 shows the mean VAS pain score 3 and 7 days after surgery. As indicated, the pain score was lower in the experimental group than in the control group. Also, except for patients with AO, pain after 7 days was lower than that at 3 days. Repeated measures ANOVA showed that time (4-day interval) had no significant effect on VAS pain score ($p = 0.100$). However, the interaction effect of time and AO was significant on pain ($p < 0.001$) such that those who developed AO had significantly greater pain at 7 days compared to 3 days. Still, those without AO had lower pain at 7 days compared to 3 days (Table 5). The experimental group had a significantly lower pain score than the control group ($p < 0.001$). Males had a significantly lower pain score than females ($p = 0.036$). Also, the level of difficulty had a significant effect on pain, and those with level I difficulty had significantly lower pain than those with difficulty levels II and III ($p < 0.001$). Additionally, patients with AO had a significantly greater pain score than those without it ($p < 0.001$).

The incidence of AO was similar between the experimental and control groups. However, the experimental group reported

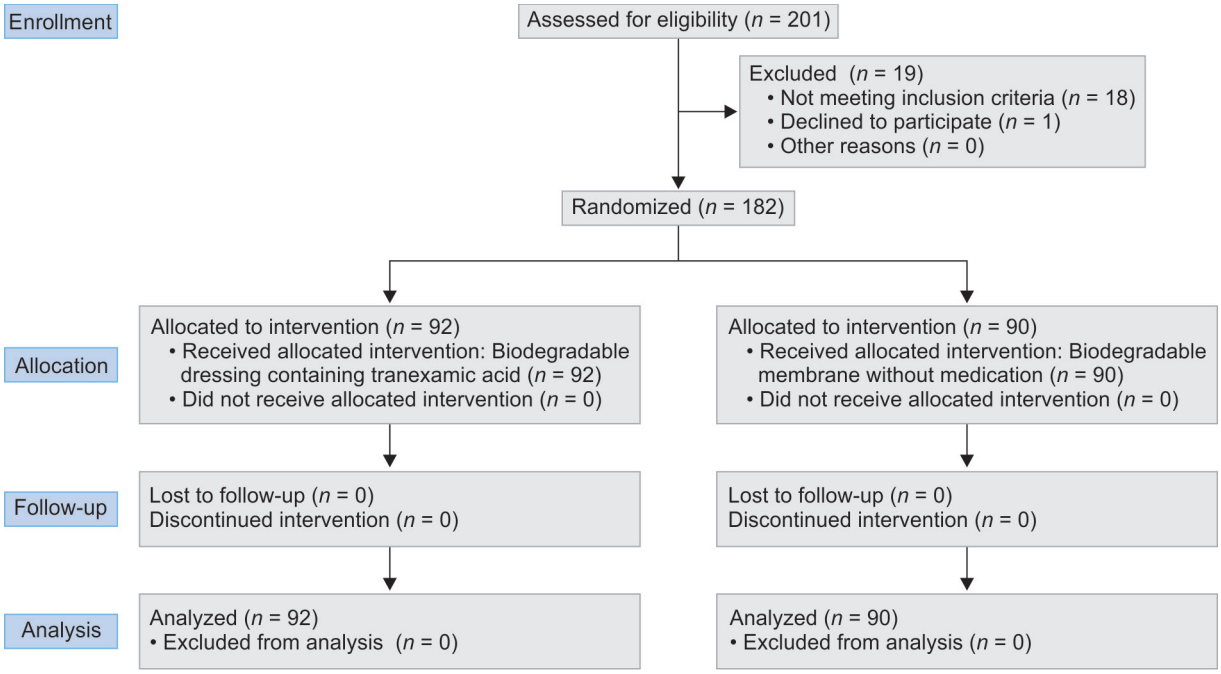


Fig. 2: CONSORT flow diagram of patient selection and allocation

Table 1: Demographic information of the participants

Category	*Treatment*	*Control*	*Total*	*p-value*
Sex				0.139[a]
Male	33 (35.9%)	42 (46.7%)	75 (41.2%)	
Female	59 (64.1%)	48 (53.3%)	107 (58.8%)	
Age (mean ± SD)		27.14 ± 6.85		0.251[b]
Smoking				0.673[a]
No	81 (88.0%)	81 (90.0%)	162 (89.0%)	
Yes	11 (12.0%)	9 (10.0%)	20 (11.0%)	
Oral contraceptive				0.207[a]
No	85 (92.4%)	80 (88.9%)	165 (90.7%)	
Yes	7 (7.6%)	10 (11.1%)	17 (9.3%)	
Difficulty level				0.375[a]
Level I	29 (31.5%)	25 (27.8%)	54 (29.7%)	
Levels II and III	63 (68.5%)	65 (72.2%)	128 (70.3%)	

Mean ± standard deviation and percentage (%) are presented for parametric and categorical data, respectively; [a]Chi-squared; [b]Independent samples *t*-test

Table 2: Frequency percentage of AO based on the assessed variables

	Alveolar osteitis			
	No		*Yes*	
Assessed variables	*Count*	*Row N (%)*	*Count*	*Row N (%)*
Group				
Treatment	85	92.4	7	7.6
Control	82	91.1	8	8.9
Sex				
Male	71	94.7	4	5.3
Female	96	89.7	11	10.3
Age				
≤30	132	94.3	8	5.7
>30	35	83.3	7	16.7
Smoking				
No	147	90.7	15	9.3
Yes	20	100.0	0	0.0
Oral contraceptives				
No	153	93.9	10	6.1
Yes	14	73.7	5	26.3
Difficulty level of procedure				
Level I	63	100.0	0	0.0
Levels II and III	104	87.4	15	12.6

significantly lower pain scores at both 3 and 7 days post-surgery. The occurrence of AO was significantly correlated with the difficulty level of the surgery, with higher difficulty levels increasing the likelihood of AO. Additionally, patients with AO experienced greater pain, which was most evident at the 7-day mark.

Discussion

Alveolar osteitis is a common postoperative complication following dental extractions. It is characterized by persistent pain within and around the extraction site.[3] Tranexamic acid is an antifibrinolytic agent that prevents fibrin breakdown, effectively reducing bleeding with minimal systemic absorption when used in a 4.8% solution.[6] This study assessed the efficacy of a biodegradable dressing containing tranexamic acid for preventing AO following mandibular third molar extraction surgery and evaluated the role of some risk factors in this respect.

The results showed no significant difference in the incidence of AO between males and females, although it occurred more commonly in females. Younis and Ra'ed,[12] and Bonine,[28] reported a higher risk of AO in females than males. Also, Kadkhodaie and Asadi[29] reported that the incidence of AO was 2.7% in males and

3.2% in females. Different incidence rates in males and females may be due to the effects of hormones, menstrual cycle, or intake of oral contraceptives by females.[25] Nonetheless, others reported equal involvement of males and females.[30,31]

In the present study, AO had no significant correlation with age, although it more commonly occurred in those over 30. A higher incidence of AO in those older than 30 may be due to a small number of patients in this age-group in the present study since approximately 73% of patients were under 30. Oginni et al.[31] reported that 18–25 years was the most common age range for the occurrence of AO, which was in line with the present results and may be explained by the fact that this age range corresponds to the time of eruption of the third molars and increased demand for their extraction, which can lead to AO.[31]

The prevalence of AO was 8.2% in the present study, which was higher than the rates reported by Nosrati et al.[32] (2.6%) and Kadkhodaie and Asadi[29] (2.9%). This finding may be because the present study was only conducted on patients requiring mandibular third molar extraction surgery, and suspected cases were also recorded as AO. Variations in study populations can also explain the difference in the reported incidence rates. Ghavimi et al.[33] reported an incidence rate of 7.9% for AO in their study, close to the rate reported in the present study.

In the current study, the two groups had no significant difference in the incidence of AO. Since the two groups were standardized in terms of confounders (i.e., age, gender, smoking status, intake of oral contraceptives, and level of difficulty of the procedure), it may be stated that the tested intervention was not effective. However, the VAS pain score was significantly lower in the intervention group than in the control group at 3 and 7 days after the procedure. Also, the reduction in pain scores over time was significantly greater in the intervention group than in the control group. Anand et al.[6] assessed the efficacy of one dose of tranexamic acid orally (500 mg) one hour before tooth extraction and the application of its gel foam (160 mg) in the extraction socket postoperatively. Their results supported using tranexamic acid both locally and systemically following tooth extraction to decrease the incidence of AO. Consistent with the present results, they reported a lower incidence of AO symptoms in the experimental group; however, only the difference in pain scores reached statistical significance. Gersel-Pedersen[23] reported that tranexamic acid failed to control the incidence of AO, which agreed with the present results. Blinder et al.[34] showed that the prevalence of AO was 8% in those who received an anti-fibrinolytic

Table 3: Correlation of AO with the assessed variables

	95% confidence interval			
	OR		p-value	
Assessed variables	*Lower*		*Upper*	
Group (reference)				
Treatment	1	–	–	–
Control	1.457	0.744	0.380	5.914
Sex (reference)				
Male	1	–	–	–
Female	1.496	0.799	0.336	7.913
Age (reference)				
≤30 yrs	1	–	–	–
≥30 yrs	3.963	0.052	0.988	17.301
Smoking (reference)				
No	1	–	–	–
Yes	0.580	0.647	0	4.519
Oral contraceptives (reference)				
No	1	–	–	–
Yes	3.960	0.105	0.781	20.448
Difficulty level (reference)				
Level I	1	–	–	–
Levels II and III	9.169	0.015	1.435	+Inf

Table 4: Mean VAS pain score at 3 and 7 days after surgery

	Pain VAS day 3		Pain VAS day 7	
Assessed variables	*Mean*	*SD*	*Mean*	*SD*
Group				
Treatment	29.46	17.72	17.07	17.75
Control	34.44	15.87	26.61	18.80
Sex				
Male	28.53	16.48	21.00	18.76
Female	34.30	16.98	22.34	18.96
Age (yrs)				
≤30	30.57	15.36	20.00	16.28
>30	36.43	21.08	27.74	24.92
Smoking				
No	32.65	17.28	22.35	19.68
Yes	26.00	13.14	17.25	8.66
Oral contraceptives				
No	31.04	16.82	20.34	17.38
Yes	39.47	16.82	34.21	25.83
Difficulty level				
Level I	21.90	14.01	12.86	8.22
Levels II and III	37.23	16.02	26.51	21.07
Alveolar osteitis				
No	29.28	14.61	17.22	11.31
Yes	61.33	13.56	72.67	7.04

Table 5: Effect of study variables on the mean pain score

Source	*Sum of squares*	*df*	*Mean square*	*F*	*p-value*	*Partial ETA squared*	*Observed power*
Group	5671.461	1	5671.461	29.003	<0.001	0.143	1.000
Sex	875.582	1	875.582	4.478	0.036	0.025	0.557
Age	247.403	1	247.403	1.265	0.262	0.007	0.201
Smoking	9.714	1	9.714	0.050	0.824	0.000	0.056
Oral contraceptive	71.465	1	71.465	0.365	0.546	0.002	0.092
Difficulty level	7959.570	1	7959.570	40.704	<0.001	0.190	1.000
Alveolar osteitis	36681.544	1	36681.544	187.583	<0.001	0.519	1.000

agent vs 26% in the control group. Poor et al.[35] found that tranexamic acid inhibits fibrin proteolysis by preventing the attachment of plasmin and plasminogen and can effectively decrease secondary bleeding due to clot fibrinolysis. Hamid et al.[36] assessed the efficacy of irrigation of the extraction socket with tranexamic acid on post-surgical bleeding after mandibular third molar extraction surgery. They showed that tranexamic acid caused a significantly greater reduction in postoperative bleeding compared with saline. Peymani Mojaver et al.[37] assessed the efficacy of tranexamic acid oral rinse for preventing bleeding after tooth extraction in patients taking warfarin. They concluded that 4.8% tranexamic acid oral rinse may be used for effective bleeding control in such patients as an alternative to discontinuation of warfarin. However, they added that it was ineffective in preventing blood clot lysis and AO. An earlier study discussed that inhibition of plasminogen activation by tranexamic acid is insufficient for preventing alveolitis sicca dolorosa.[23]

In the present study, no significant correlation was found between smoking and the occurrence of AO. In contrast, many previous studies reported a significant correlation between smoking and AO, such that smoking has been proposed as a major risk factor for AO occurrence.[12,38] The lack of a significant correlation in the present study may be due to the small number of smokers compared to non-smokers in the present study (20 vs 162 patients). In the current study, the odds of AO development in patients with level III or II difficulty were 9.169 times the odds of AO in patients with level I difficulty. None of the patients with level I difficulty developed AO. In the study by Kadkhodaie and Asadi,[29] the incidence of dry sockets was 2.5, 2.4, and 6.6% in cases with easy, slightly difficult, and complicated procedures, respectively. Also, Haraji et al.[39] proposed the procedure's difficulty level as a risk factor for AO. Sánchez et al.[40] discussed that an increased difficulty level is associated with a higher risk of AO. Some other studies reported that the incidence of AO development increased by prolonging the surgical procedure, level of difficulty, and tissue traumatization.[30,41]

The current results failed to find an association between the intake of oral contraceptives and AO. However, some other studies reported the intake of oral contraceptives as a predisposing factor to AO following mandibular third molar surgery.[27,42] The lack of a significant association in the present study may be due to the small number of patients taking oral contraceptives (n = 19) or demographic differences of the study populations. Nonetheless, Haraji et al.[39] also reported that the intake of progesterone was not associated with AO.

The main strengths of the present study were its double-blind design and standardization of the two groups' demographics.

To the best of the authors' knowledge, no previous study has assessed the efficacy of tranexamic acid in a dressing for prevention of AO to compare our results with, which was a limitation. The small number of patients over the age of 30 years, those taking oral contraceptives, and smokers were among other limitations that might be responsible for not finding a significant association between these variables and AO. Future studies with a larger sample size are required to address such associations. The lack of a no-dressing control group was another limitation. Also, the efficacy of tranexamic acid in combination with antibiotics loaded on biodegradable dressings should be investigated in future studies. Last but not least, the efficacy of tranexamic acid dressing should be assessed for reduction of dental implant and periodontal surgery complications and acceleration of healing.

Conclusion

The application of a biodegradable dressing loaded with tranexamic acid did not demonstrate a significant effect in preventing the occurrence of AO following the third molar extraction surgery. Despite this, the dressing showed a notable reduction in postoperative pain, suggesting a potential benefit in pain management during the recovery phase.

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