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Effectivness of Tranexamic Acid Mouthrinse on Extraction Socket in Patients Undergoing Anticoagulant and Anti Platelet Therapy

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KEYWORDS
Antiplatelet, Anticoagulant, Post Extraction Bleeding, Hemostasis, Tranexamic Acid.

ABSTRACT:
Background: The utilization of tranexamic acid mouthrinse has garnered significant attention in dental literature, particularly in the context of extraction sockets among patients undergoing anticoagulant and antiplatelet therapy. As individuals with such medical regimens face heightened risks of postoperative bleeding, exploring the effectiveness of tranexamic acid in this specific scenario becomes crucial.
Aim and objective: To evaluate the efficacy of tranexamic acid mouthwash on extraction socket in patient undergoing anticoagulant and anti-platelet therapy
Material and method: The study included 100 consecutive patients on antiplatelet and anticoagulant therapy, with INR levels between 1.9 and 3.5 on surgery day, requiring dental extractions. Following extractions, participants were instructed to use a 10% tranexamic acid mouth rinse, 5 ml four times daily for 7 days, documenting bleeding instances requiring pressure control and recording mouth rinse usage.
Result: In this study of 100 patients (60 males, 40 females; mean age 57.1 years), the duration of antiplatelet and anticoagulant prophylaxis ranged from 2 weeks to 20 years. Most patients (59%) were smokers. Antibiotics were used preoperatively and perioperatively. Seventeen patients reported bleeding on day 1, controlled by tranexamic acid; nine required local measures in the dental surgery. Statistical analysis identified significant risk factors for post-extraction bleeding.
Conclusion: Research and statistical analysis suggest that employing tranexamic acid mouth rinses post-operatively in patients with therapeutic INR levels following dental extraction is a secure, uncomplicated, efficient, and well-received approach to minimize post-extraction bleeding.

1. Introduction

Optimal management of patients on anti-platelet and anti-coagulant who require oral surgery procedure has been controversial. Historically the surgeons have to balance the risk of thromboembolism by reducing or stopping anti platelet and anticoagulant therapy, against the risk of triggering excessive post extraction bleeding if anticoagulation or anti platelet is maintained at therapeutic levels during surgery. (1-3) Patients on anti-platelet and anticoagulants have impaired fibrin formation that is more susceptible to normal fibrinolysis

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and is believed to be the major cause of post extraction bleeding. In this study the "Efficacy of tranexamic acid mouth rinse as a hemostatic agent after extraction in patients who are on anticoagulant and anti-platelet therapy" has been studied. (4-5)
The aim of this study is to verify that this technique is a safe, simple, effective and an acceptable method of patient management. The objective is to identify potential risk factors that may increase the likelihood of bleeding.

2. Materials and Methods

One hundred consecutive anti-platelet and anti-coagulant patients with an International Normalized Ratio (INR) ranges between 1.9 and 3.5 on the day of surgery and who required dental extractions were recruited to this study. Following dental extraction, patients were instructed to use 5 milliliters of 10% tranexamic acid mouth rinse 4 times a day for 7 days, to record bleeding that required pressure to control and their mouth rinse usage. The researcher collected demographic data, details of the state of anti-platelet and anticoagulation, details of the surgery and details of bleeding that required additional management. Descriptive statistics were produced for the sample demographics, the pre-extraction profile, the post extraction bleeding profile, mouth rinse acceptance and utilization. Identification of potential risks that might increase the likelihood of bleeding was carried out using the paired and unpaired t test appropriate.

3. Results

One hundred individual patients were recruited into this study. There were 60 males and 40 females. The mean age was 57.1 years with a standard deviation of 15.6 years (range 23- 87 years). The duration of anti-platelet and anti-coagulant prophylaxis varied between 2 weeks to 20 years. The median length of therapy was 2 years. The indications for anticoagulant / anti-platelet prophylaxis are shown Table 5.
The majority, (59 %) were smokers. Preoperative antibiotic therapy was involved in 12 of the 100 patient contacts for either intercurrent infection or long-term prophylaxis. The antibiotics used were amoxycillin, penicillin, augmentin and cephalosporin. Perioperative antibiotics were prescribed for 62 patient episodes (generally for infective endocarditis prophylaxis). Agents used were amoxycillin, cephalosporin and gentamicin. Amoxycillin was necessary to control postoperative infection in 75 patient episodes. Of these 100 patients treated, 17 reported bleeding at home on day 1 and 3 patients after day 1 that was controlled only by tranexamic acid pressure pack. A further 9 patients reported to the researcher's dental surgery where bleeding was controlled by local measures using gelatin sponge. No patients required hospital admission for systemic management of bleeding. Statistical analysis reveals significant risk factors for post-extraction bleeding were: those patients on age between 41-60; pre-extraction INR equal to greater than 2.5; smoking. Factors not statistically significant for an increased risk of bleeding included: The number of teeth removed; pre-extraction bleeding time; time on anti-platelets and anticoagulation.

Table-1: Distribution of patients based on age

Age (Years)	Number	Percentage (%)
20-40 years	10* (p=0.03)	10.00*
41-60 years	64	64.00
61-80 years	36* (p=0.04)	36.00*
Total	**100**	**100.00**

(*p<0.05 significant compared 41-60 years with others)

Table-2: Distribution of patients based on gender

Gender	Number	Percentage (%)
Male	60	60.00

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Female	40* (p=0.03)	40.00*
Total	**100**	**100.00**

(*p<0.05 significant compared male with female)

Table-3: Distribution of patients based on smoking

Smoking	Number	Percentage (%)
Yes	59	59.00
No	41* (p=0.05)	41.00*
Total	**100**	**100.00**

(*p<0.05 significant compared yes with no)

Table-4: Mean values of blood parameters pre-extraction

Blood parameters	MEAN±SD
INR	2.29±0.35
Platelet count	2.32±0.24
Bleeding time	3.54±0.32

Table-5: Distribution of patients based on reason for being on anti-coagulant medication

Reason for being on anti- coagulant medication	Number	Percentage (%)
CAD	72* (p=0.01)	72.00*
RHD	12	12.00
AVR	1	1.00
IHD	4	4.00
Atrial fibrillation	7	7.00

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TVD	1	1.00
ACHD	1	1.00
CAD+IHD	1	1.00
CHD/ASD	1	1.00
Total	**100**	**100.00**

(*p<0.05 significant CAD with others)

Table-6: Distribution of patients based on time on anti-coagulant medication

Time on anti-coagulant medication	Number	Percentage (%)
Days	2* (p=0.02)	2.00
Weeks	73	73.00
Months	19* (p=0.04)	19.00
Years	6* (p=0.04)	6.00
Total	**100**	**100.00**

(*p<0.05 significant compared weeks with others)

Table-7: Distribution of patients based on post extraction bleeding

Post extraction bleeding	Number	Percentage (%)
Yes	28	28.00
No	72* (p=0.03)	72.00
Total	**100**	**100.00**

(*p<0.05 significant compared yes with no)

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Table-8: Mean values of blood parameters

Blood parameters	MEAN±SD
INR	2.37±0.58

Table-9: Distribution of patients based on day of post operative bleeding

Day of post operative bleeding	Number	Percentage (%)
No	71* (p=0.03)	71.00
1st day	17#	17.00
2nd day	8	8.00
3rd day	3	3.00
4th day	1	1.00
Total	**100**	**100.00**

(*p<0.05 significant compared no with others,
#p<0.05 significant compare Nil with others)

Table-10: Distribution of patients based on event which caused bleeding

Event which caused bleeding	Number	Percentage (%)
No	71* (p=0.01)	71.00*
Spontaneous	26	26.00
Trauma	3	3.00
Total	**100**	**100.00**

(*p<0.05 significant compared no with others)

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Table-11: Distribution of patients based on degree of bleeding

Degree of bleeding	Number	Percentage (%)
No	71* (p=0.01)	71.00
Slight ooze	24	24.00
Frank ooze	5	5.00
Total	**100**	**100.00**

(*p<0.05 significant compared no with others)

Table-12: Distribution of patients based on post operative bleeding and INR

Degree of bleeding	Number	Percentage (%)
No	71* (p=0.01)	71.00
Present	29	29.00
Total	**100**	**100.00**
INR (MEAN±SD)	2.91±3.74	

(*p<0.05 significant compared no with others)

Table-13: Distribution of patients based on treatment to achieve hemostasis

Degree of bleeding	Number	Percentage (%)
No	71*(p=0.01)	71.00
Pressure	20	20.00
Hemostat	9	9.00
Total	**100**	**100.00**

(*p<0.05 significant compared no with others)

Table-14: Comparison of pre and post operative INR

Status	INR (MEAN±SD)	P value
Pre operative	2.29±0.35	**0.89**

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Post operative	2.37±0.58	

(p>0.05 no significant difference compared pre operative with post operative)

Table-15: Distribution of patients based on frequency of post extraction bleeding and its management

Type of bleed and management	Number	Percentage (%)
No bleeding	71	71.00
At home on day one, only	17	17.00
At home, after day one with pressure	3	3.00
At researcher's dental surgery with local treatment	9	9.00
At hospital by systemic treatment	0	0.00
Total	**100**	**100.00**

4. Discussion

This study was undertaken to verify that using tranexamic acid mouth rinse was a safe, effective and acceptable method of managing anticoagulation and anti-platelet patients in Sree Mookambika Institute of Dental Science. (7-10) A novel aspect of this investigation was the evaluation of potential risk factors associated with the removal of the teeth and the identification risk factors for bleeding. (10-13) This had not previously been reported in this group of patients. It must be recognized that because this study did not have a control group it does not provide a high level of evidence and does not more than enable the building of a hypothesis about the possible causes of post-operative bleeding in anti-coagulant and anti-platelet patients managed post-operatively with tranexamic acid mouthrinse. It is important that this limitation was borne in mind otherwise it was likely that observed associations could be misinterpreted or overstated. In addition, there was an inherent bias in the study design because it could not be double blinded. The possibility of information bias by both the researcher and patient may had influenced the results. This bias was minimized by collecting data on relevant variables in advance of the bleeding endpoint.

Compliance is an issue in any treatment study. This effect was offset because patients on anti-platelet and anti-coagulant requires a high level of compliance and regular monitoring to avoid serious complications. (14-16) The study population was perhaps more motivated to comply. Compliance was assessed by 2 methods. First, the patient was asked to record mouth rinse use on the patient data collection sheet. This relied on patient honesty not to record when they missed their mouth rinse and carefully to record when they did use it. Patients were encouraged to be honest, to only record definite mouthrinse use and not enter factitious data. There was also a problem with some patients who lived in a rest home. Language and old age were not a barrier to compliance as it was possible to recruit either a family member or a friend to take responsibility for informing and assisting the patient. (17-18)

All previous studies have used 10 ml of 4.8% tranexamic acid mouthrinse. This study used 5ml of 10% tranexamic acid mouthrinse. The reason for this decision was that 10mls of 4.8% tranexamic acid solution contains the same amount of active solution as 5mls of 10% solution.

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The main advantage of the larger volume used in other studies is that it may be easier to rinse around the mouth, especially the upper jaw. (19-21)

Defining bleeding had its problems. Two levels of bleeding were initially considered for analysis. First, bleeding managed either at home after day 1 or in the researcher's dental surgery and second, bleeding managed in the researcher's dental surgery only. Each of these levels had its advantages and disadvantages. The advantage of recording home bleeds after day 1 was that more bleeds were captured for endpoint analysis. However, there were several significant disadvantages. This relied on the patient accurately reporting and recording any bleeding that occurred at home. Different patients had different thresholds for reporting bleeding. This led either to under-reporting or to over-reporting depending on the individual patient's threshold. In an attempt to standardize home bleed reporting, patients were asked to only record bleeding that required a pressure swab to control. Bleeding requiring control at home is common following dental extractions, even in patients with normal coagulation. When multiple teeth were removed from the same region of the mouth it was impossible for the patient to identify and accurately record which tooth socket was bleeding. Therefore, when bleeding was recorded in a region by the patient, all tooth sockets in that region were recorded as having bleed. By this definition, 26 sockets were recorded as having bleeding although it was unlikely that all these sockets had actually bleed. This may have led to an over-estimation of the incidence of home bleeding. For statistical analysis, only "dental surgery bleeds" were used as these represented the most objective point. A further advantage of using dental surgery-managed bleeds was that the number and position of the bleeding sockets could be accurately recorded. A disadvantage of this approach was that relatively few endpoint bleeds were available for analysis. There was also variability in the threshold at which patients presented themselves to the dental surgery.

This study used 5ml of 10% tranexamic acid solution whereas other studies used 10 ml of 4.8% tranexamic acid. It is possible that the smaller volume of tranexamic acid did not effectively reach the upper sockets, where the majority of bleeds occurred and was therefore less effective at preventing fibrinolysis.

The present study with a bleeding rate of 8% requiring additional treatment, while slightly higher than other studies using a comparable technique, is considerably less than studies involving extraction of teeth at therapeutic INR without topical antifibrinolytic mouthrinses.

In the past, optimal management of patients on anti-coagulants / anti-platelets who require oral surgery had been controversial. However, the technique described by Sindet-Pedersen et al. (1989) and used in this study provides a method of management that was safe, simple, effective and acceptable. (22-26) The anticipated incidence of post-extraction bleeding requiring management by local measures of 21- 50% without the use of antifibrinolytic mouthrinses was reduced to 9% by using the antifibrinolytic mouthrinse tranexamic acid, 4 times a day for 7 days. Mouthrinse use was widely accepted with only 3% of patients strongly objecting to its use.

5. Conclusion

On the basis of research and statistical analysis, it can be concluded that the post-operative use of tranexamic acid mouth rinses in patients who underwent dental extraction at therapeutic INR levels is a safe, simple, effective and an acceptable method of reducing post extraction bleeding.

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