Research

Evaluation of Different Hemostatic Method in Achieving Hemostasis in Patient on Oral Anticoagulant Therapy

Akshay Kumar Rahmatker[1], Neha Jain[2*], Priyanka Sharma[3], Ajay Kumar Pillai[4], Hina Handa[5] and Rudra Joshi[6]

[1] Senior lecturer, Department of Oral and Maxillofacial Surgery, People Dental Academy, Bhopal.

[2] Professor, Department of Oral and Maxillofacial Surgery, People Dental Academy, Bhopal.

[3] Reader, Department of Oral and Maxillofacial Surgery, People Dental Academy, Bhopal.

[4] Professor and Head, Department of Oral and Maxillofacial Surgery, People Dental Academy, Bhopal.

[5] Professor, Department of Oral Medicine and Radiology, People Dental Academy, Bhopal.

[6] Senior lecturer, Department of Oral and Maxillofacial Surgery, People Dental Academy, Bhopal.

Corresponding Author: Neha Jain, Room No 101, Dept of Oral & Maxillofacial Surgery, People's Dental Academy, Bhopal.

Abstract

Patients receiving oral anticoagulant therapy are at an increased risk of bleeding complications, necessitating effective hemostatic interventions. This study aims to evaluate and compare the efficacy of four hemostatic agent (figure of eight suturing, Absorbable gelatin sponge (ABGEL), Topical application of hemocogulase, and pressure gauze pack) in achieving hemostasis among patients on oral anticoagulant therapy. The study was conducted on 100 patients which were randomly divided in four groups and we found that all methods of achieving hemostasis are equally beneficial.

Keywords: Oral Anticoagulant Therapy, International Normalised Ratio

Introduction

Patients receiving long-term oral anticoagulant therapy (OAT) pose a clinical challenge during invasive dental procedures by causing prolong and excessive haemorrhage.[1] As a maxillofacial surgeon it has been question is whether to continue, modify or interrupt OAT before dental treatment. Cessation or reduction of anticoagulant intake for several days prior to dental procedure may expose these patients to the risk of venous thromboembolism which is fatal.[2,3]

Tooth extraction in patients on OAT within the therapeutic International Normalized Ratio (INR) values (INR < 3.0) can be safely done without changing OAT regimen if proper local haemostatic measures are followed which stabilize or enhance clot formation at the surgical site. The commonly used haemostatic agents used are: oxidized cellulose, absorbable gelatin sponges, absorbable collagen sponges, fibrin glue, cyanoacrylate glue, platelet rich plasma gel and topical thrombin.[2] Figure of eight suturing (mechanical procedure) is effective method of haemostasis after tooth extraction patient on OAT.[2]

Absorbable gelatine sponge (ABGEL): Absorbable gelatine sponge is made from animal skin gelatine. Its bonding to surface is strong and works mechanically on low presser bleeder and if soaked in thrombin, it directly act on coagulation.[3/4]

Hemostatic dressings, including oxidized cellulose, gelatin-based, chitosan, and calcium-based dressings, provide localized hemostasis, reduce chair time, and improve patient outcomes.[8]

Topical Hemocoagulase: Hemocoagulase is fractional isolate of poisonous (bothrops or bothops atrox) and is a enzyme complex with coagulative and antihemorrhagic properties, also acts fast and atoxic. Hemocagulase action similar to thromboplastin and thrombin and promote rapid blood coagulation.[3]

Thus, we thought to conduct a study with an aim to compare 4 different local haemostatic agent which provides the better haemostasis on patient who are on OAT without interrupting their OAT regimen.

The objectives of the study were to:

1. To find out which local hemostatic method should be the choice of surgeon when patient is on OAT.
2. To assess whether the continuation of OAT regimen cause marked hemorrhage on patient undergo dental extraction.
3. To calculate the baseline INR value above which continuation of OAT may cause severe bleeding.
4. To assess the risk factors causing bleeding.

Material and Methods

A prospective double-blind study was conducted on patient who came to Department of Oral and Maxillofacial Surgery, Peoples Dental Academy Bhopal for extraction of tooth who were on OAT. Patient seeking extraction because of non-restorable tooth/orthodontic /prosthetic purpose who belong to ASA Grade I or II, who gave written inform consent, on oral anticoagulant therapy for more than 6 month and International Normalized Ratio (INR) ≤ 3.0 were included in the study. 100 Patients were randomly divided into 4 group and each group comprised of 25 patients.

1. **Group A:** Figure of eight suture with 3-0 silk suture.
2. **Group B:** Absorbable gelatine sponge (ABGEL) was placed on extraction socket.
3. **Group C:** Topical application of hemocogulase (Botroclot) into the extraction socket.
4. **Group D**: Only pressure gauze pack dipped in normal saline was placed in extraction socket.

Method

Under all aseptic condition, patients were anesthetized using Lidocaine hydrochloride 2% with 1:80,000 adrenalin as local anaesthetic agent. Extraction was done as atraumatic as possible.

After extraction patient according to its group was given local hemostatic, randomly selected one group hemostatic agent in all four group and above which the patient was asked to hold sterile gauze firmly. The patients were observed for next 2 hours, 4 hours, 24 hours and 48 hours later.

If severe bleeding was observed, it was planned to place ABGEL soaked with in topical hemocoagulase (botroclot) into the extraction socket and suture with figure of eight technique then apply pressure gauze.

If bleeding is still present, then oxidized regenerated cellulose or Vitamin K or Frozen plasma would be administered into the socket and physician would be consulted.

The data analysis was done using the statistical package of social sciences 25.0 software (SPSS Inc., Chicago IL). Results were statistically analyzed by ANOVA for continuous variables and Chi square test for categorical data. A 'p' value of 0.05 was considered for statistical significance.

Results

A total 100 patients were enrolled in the study. Enrolled patient were randomly assigned to the group (A, B, C, D) as mentioned in material and methods so that each group comprised of 25 patients.

There was no statistically significant difference in the demographic distribution of study subjects according to the age (p=0.585). **(Table 1)**

Table 2 depicts the demographic distribution of study subjects according to Gender. There was no statistically significant difference in the demographic distribution of study subjects according to the gender (p=0.229).**(Table 2)**

Table 1: Comparison of mean bleeding time between study groups.

Study groups	N (%)	Mean Bleeding Time	Standard Deviation	p-Value
Group A	25(25%)	2.18	0.262	
Group B	25(25%)	2.38	0.300	
Group C	25(25%)	2.28	0.291	
Group D	25(25%)	2.46	0.372	0.010
Total	100 (100%)	2.32	0.323	

Statistically significant *P<0.05

Table 2: Demographic distribution of study subject according to sex.

Groups	Male N (%)	Female N (%)	Total N (%)	p-Value
Group A	14 (56%)	11(44%)	25 (100%)	
Group B	14 (56%)	11(44%)	25 (100%)	
Group C	14 (56%)	11(44%)	25 (100%)	0.229
Group D	8 (32%)	17 (68%)	25 (100%)	
Total	50 (50.0%)	50 (50.0%)	100 (100.0%)	

In Group A 12.0 % patients reported with the history of deep vein thrombosis/ pulmonary embolus, 56.0% ischemic heart disease, 24.0% cerebro vascular accident and 8.0% reported other past medical history. In Group B, 28.0% patients reported the history of deep vein thrombosis/ pulmonary embolus, 44.0% ischemic heart disease, 16.0% cerebro vascular accident and 12.0% reported other past medical history. In Group C, 4.0% patients reported history of cardiac arrhythmia (atrial fibrillation), 20.0% deep vein thrombosis/ pulmonary embolus, 40.0% ischemic heart disease, 24.0% cerebro vascular accident and 12.0% reported other past medical history. In Group D, 4.0% patients reported the history of atrial fibrillation and valvular disease, 24.0% deep vein thrombosis/ pulmonary embolus, 32.0% ischemic heart disease, 24.0% cerebro vascular accident and 16.0% reported other past medical history. (**Table 3)**

Graph 1 is showing the mean bleeding time between the study groups. The mean bleeding time for group A was 2.18±0.26, mean bleeding time for Group B was 2.38+0.30, mean bleeding time for Group C was 2.28+0.29, mean bleeding time for Group D was 2.46+0.37. The overall mean bleeding time of the study subjects was 2.32+0.32. There was statistically significant difference between the groups (p= 0.010). **(Graph 1**)

On comparing the prothrombin time amongst different groups, we observed no statistically significant difference between the groups (p= 0.874). (**Graph 2)**

The overall mean clotting time of the study subjects was 4.11+0.30. There was statistically significant difference between the groups (p= 0.005) **(Table 4**.)

The mean International normalized ratio (INR) for group A was 1.20±0.413, mean International normalized ratio (INR) for Group B was 1.26+0.372, mean International normalized ratio (INR) for Group C was 1.25+0.42, mean International normalized ratio (INR) for Group D was 1.25+0.43. The overall mean International normalized Ratio (INR) of the study subjects was 1.24+0.40. There was no statistically significant difference between the groups (p= 0.967). **(Table 5)**

Study subjects according to drug history. In Group A 84.0% Patients were on Asprin (75mg), 4.0% patient were on Asprin(150mg), 8.0% patients were on combination of Clopidogrel and Aspirin (75mg) and 4.0 % patients were on Clopidogrel (75mg). In Group B 92.0% Patients were on Asprin(75mg), 4.0% patient were on Asprin(150mg), 4.0% patients were on combination of Clopidogrel and Aspirin (75mg). In Group C 76.0% Patients were on Asprin(75mg), 8.0% patient were on Asprin(150mg), 12.0% patients were on combination of Clopidogrel and Aspirin (75mg) and 4.0 % patients were on Clopidogrel (75mg). In Group D 76.0% Patients were on Asprin(75mg), 12.0% patient were on Asprin (150mg), 8.0% patients were on combination of Clopidogrel and Aspirin (75mg) and 4.0 % patients were on Clopidogrel (75mg). There was no statistically significant difference between the groups (p= 0.904). **(Table 6)**

Table 3: Distribution of study subjects according to past medical history.

Past Medical History	Group A N (%)	Group B N (%)	Group C N (%)	Group D N (%)	Total N (%)	p- Value
Prosthetic Valve Replacement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.779
Cardiac Arrhythmia (Atrial Fibrillation)	0 (0.0%)	0 (0.0%)	1 (4%)	0 (0.0%)	1 (1.0%)	
Atrial Fibrillation and Valvular Disease	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4%)	1 (1.0%)	
Atrial Fibrillation And cerebrovascular Accident	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Deep Vein Thrombosis/ Pulmonary Embolus	3 (12%)	7 (28%)	5 (20%)	6 (24%)	21 (21.0%)	
Ischemic Heart Disease	14 (56%)	11 (44%)	10 (40%)	8 (32%)	43 (43.0)%	
Cerebrovascular accident	6 (24%)	4 (16%)	6 (24%)	6 (24%)	22 (22.0%)	
Dilated cardiomyopathy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Other	2 (8%)	3 (12%)	3 (12%)	4 (16%)	12 (12.0%)	
Total	25 (100%)	25 (100%)	25 (100%)	25 (100%)	100 (100.0%)	
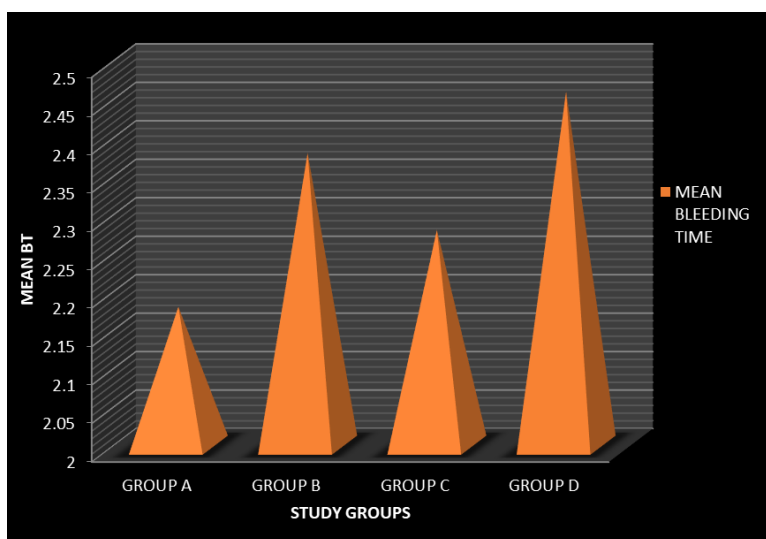
Graph 1: Comparison of mean bleeding time between study groups.
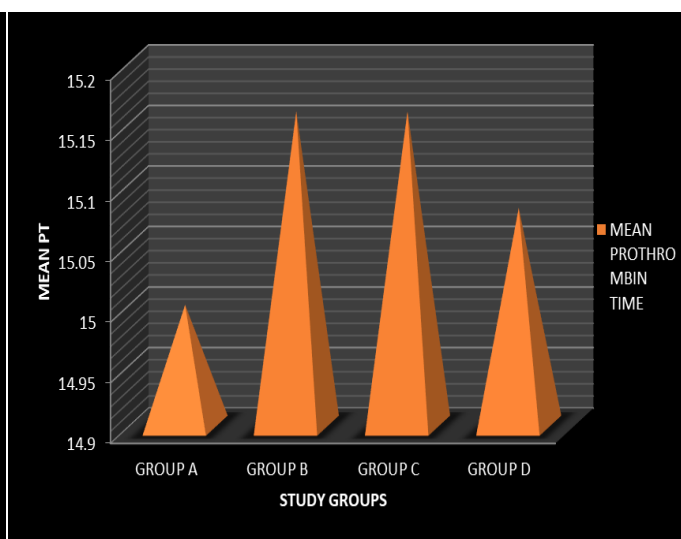
Graph 2: Comparison of mean prothrombin time between study groups

Table 4: Comparison of mean clotting time between study groups**.**

Study groups	N (%)	Mean Clotting Time	Standard Deviation	p-Value
Group A	25(25%)	4.19	0.276	
Group B	25(25%)	4.21	0.282	
Group C	25(25%)	3.94	0.364	0.005*
Group D	25(25%)	4.11	0.212	
Total	100 (100%)	4.11	0.304	

*Statistically significant *P<0.05*

Table 5: Comparison of mean international normalized ratio (INR) between study groups.

Study groups	N (%)	Mean INR	Standard Deviation	p-Value
Group A	25(25%)	1.20	0.413	
Group B	25(25%)	1.26	0.372	
Group C	25(25%)	1.25	0.429	0.967
Group D	25(25%)	1.25	0.434	
Total	100 (100%)	1.24	0.407	

Table 6: Distribution of study subject according to drug history.

Study groups	Drugs					p-Value
	Aspirin 75mg	Asprin150mg	Clopidogrel 75mg+Asprin 75mg	Clopidogrel 75mg	TOTAL	
Group A	21(84%)	1(4%)	2 (8%)	1(4%)	25 (100%)	
Group B	23(92%)	1(4%)	1(4%)	0(0%)	25(100%)	
Group C	19(76%)	2(8%)	3(12%)	1(4%)	25(100%)	0.904
Group D	19(76%)	3(12%)	2(8%)	1(4%)	25(100%)	
Total	82(82%)	7(7%)	8(8%)	3(3%)	100(100%)	

Status of the bleeding after 30 minutes,4.0 % patients of group A and 12% patient of group C reported bleeding. After 2 hours, 4.0 % patient of group A ,4% patient of group B ,12 % patient of group C reported bleeding. After 4 hours 4.0% patients of group A and 4.0% patient of group B and 12% patient of Group C reported bleeding. After 24 hours 4.0% patient of group A and 4.0% Patient of group B,12% patient of group C reported bleeding. After 48 Hours, 4.0% patient of Group B and 12% from group C reported bleeding. No bleeding was reported by Group D. There was no statistically significant difference between the groups at all the intervals. **(Table 7)**

Table 7: Distribution of study subjects according to bleeding status.

Study groups	Bleeding after 30 minutes		Bleeding after 2 hours		Bleeding after 4 hours		Bleeding after 24 hours		Bleeding after 48 hours	
	Stop N (%)	Continue N (%)	Stop N (%)	Continue N (%)	Stop N (%)	Continue N (%)	Stop N (%)	Continue N (%)	stop N (%)	Continue N (%)
Group A	24 (96%)	1 (4%)	24 (96%)	1 (4%)	24 (96%)	1 (4%)	24 (96%)	1 (4%)	25 (100%)	0 (0.0%)
Group B	25 (100%)	0 (0.0%)	24 (96%)	1 (4%)	24 (96%)	1 (4%)	24 (96%)	1 (4%)	24 (96%)	1 (4%)
Group C	22 (88%)	3 (12%)	22 (88%)	3 (12%)	22 (88%)	3 (12%)	22 (88%)	3 (12%)	22 (88%)	3 (12%)
Group D	25 (100%)	0 (0.0%)	25 (100%)	0 (0.0%)	25 (100%)	0 (0.0%)	25 (100%)	0 (0.0%)	25 (100%)	0 (0.0%)
Total N (%)	96 (96.0%)	4 (4.0%)	95 (95.0%)	5 (5.0%)	95 (95.0%)	5 (5.0%)	95 (95.0%)	5 (5.0%)	96 (96.0%)	4 (4.0%)
P- Value	0.100		0.261		0.261		0.261		0.100	

Discussion

Dental procedure in patient on OAT is very common. Many physicians are opinion to temporary discontinue the OAT before any dental procedure, but this may increase the risk of thromboembolic event so in order to prevent any thromboembolic event recent studies have emphasized on continuing OAT on patient undergoing oral surgical procedure. But need of local hemostasis is important. [5]

Thus, we conducted a prospective randomized controlled study to compare best local hemostatic method on patient who are on OAT who undergo dental extraction.

In our study, the mean INR for group A was 1.20±0.413, group B =1.26±0.372, group C =1.25±0.42 and group D =1.24±0.40. The overall mean INR of the study subject was 1.24±0.40. There was no statically significant difference between the groups (p=0.967). The result of the study is in consistent with   Bajkin B V et al and Shin-Yu Lu et al.[1,2] The reason may be because operative procedure being atraumatic, without retraction of periosteum and not more the 2 teeth were extracted at a time. So post-operative bleeding encountered was less resulting in non-significant results.

Post-operative bleeding encountered after 30 minutes,1 patient (4%) of group A and 3patient (12%) of group C reported bleeding. After 2 hours, 1patient (4.0 %) of group A,1patient (4%) of group B ,3 patients (12%) of group C reported bleeding. After 4 hours 1 patient (4%) of group A and 1patient (4%) of group B and 3 patient (4%) of Group C reported bleeding. After 24 hours 1 patient (4%) of group A and 1 Patient (4%) of group B,3 patient (12%) of group C reported bleeding. After 48 Hours, 1 patient (4%) of Group B and 3patient (12%) from group C reported bleeding. No bleeding was reported by Group D. Although statically non-significant which goes hand in hand with observation found by Dinkova A S et al. The reason may be due to non-compliance of the patient being not following postoperative instruction.[5]

Conclusion

- OAT regime need not to be stopped when INR $\leq$3.

- All methods of achieving hemostasis are equally beneficial in achieving hemostasis.

- It is important for dental professionals to stay updated with the latest advancements in hemostatic dressings and understand their appropriate application techniques.

Conflict of Interest

The authors declare there is no conflict of interest.

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