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Comparison of efficacy of local hemostatic modalities in anticoagulated patients undergoing tooth extractions

Poređenje efikasnosti različitih metoda lokalne hemostaze kod pacijenata na oralnoj antikoagulantnoj terapiji posle ekstrakcije zuba

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Abstract

Background/Aim. Patients receiving long-term oral anticoagulant therapy pose a clinical challenge during invasive dental procedures. The goal of this study was to compare different local hemostatic modalities after tooth extraction in patients receiving chronic Vitamin-K antagonist therapy. Methods. Totally 90 patients with International Normalized Ratio (INR) ≤ 3.0 requiring simple extraction of one or two teeth were randomized into three groups, 30 patients in each group. The patients with the mean INR value of 2.35 \pm 0.37, in whom extraction wound was sutured comprised the group A. In the group B with the mean INR of 2.43 \pm 0.4, local hemostasis was achieved by placing absorbable gelatin sponges into the wound without suturing. The group C consisted of the patients with the mean INR of 2.36 \pm 0.34 in whom neither gelatin sponge nor suturing were used for providing local hemostasis. Bleeding was registered as an event if other than initial hemostatic measure was needed or additional oral surgeon intervention required. Results. The obtainded results show that 1 (3.3%) patient in the group A, 2 (6.7%) patients in the groups B and C manifested post-extraction bleeding. All cases of hemorrhage were easily solved with local hemostatic measures and all, except one case, were registered in the first two hours after the procedure until the dismissal. A difference between the groups was not statistically significant ($\chi^2 = .42, p > 0.05$). Conclusion. In therapeutically anticoagulated patients tooth extractions can be safely performed without altering the dose of anticoagulant medication if efficient local hemostasis is provided. In most cases, in patients with INR \leq 3.0 after extraction of one or two teeth postoperative bleeding can be controlled with local pressure, without any additional local hemostatic measures.

Key words:

tooth extraction; antiacoagulants; administration, oral; drug therapy; hemostasis.

Apstrakt

Uvod/Cilj. Pacijenti koji duže vremena primaju antikoagulantnu terapiju predstavljaju poseban izazov prilikom invazivnih dentalnih procedura. Cilj rada bio je da se uporede različite metode lokalne hemostaze kod pacijenata na oralnoj antikoagulatnoj terapiji nakon ekstrakcije zuba. Metode. Ukupno 90 pacijenata na oralnoj antikoagulantnoj terapiji sa International Normalized Ratio (INR) vrednostima ≤ 3,0 kojima je bila potrebna ekstrakcija jednog ili dva zuba, bilo je podeljeno u tri grupe, po 30 ispitanika u svakoj grupi, zavisno od primenjenog metoda lokalne hemostaze. Grupu A činili su pacijenti čija je ekstrakciona rana ušivena, a zabeležena prosečna INR vrednost u ovoj grupi iznosila je 2,35 \pm 0,37. U grupi B za postizanje lokalne hemostaze u ekstrakcionu ranu su postavljani resorptivni želatinski sunđeri, bez ušivanja. Prosečna INR vrednost u ovoj grupi iznosila je $2,43 \pm 0,4$. U grupi C (pacijenti sa prosečnom INR vrednošću $2,36 \pm 0,34$) posle ekstrakcije zuba nisu korišteni ni lokalni hemostatici, niti je rana ušivana. Produženo postekstrakcijsko krvarenje definisano je kao događaj u slučaju da početne mere hemostaze nisu bile dovoljne ili je bila potrebna dodatna oralnohirurška intervencija. Rezultati. Kod 1 (3,3%) pacijenta u grupi A i po 2 (6,7%) pacijenta u grupi B i grupi C javilo se produženo postekstrakcijsko krvarenje. Nije utvrđeno postojanje statistički značajne razlike u učestalosti krvarenja po grupama $(\chi^2 = .42; p > 0.05)$. Svi pacijenti sa produženim krvarenjem bez poteškoća zbrinuti su merama lokalne hemostaze i svi su, izuzev jednog, registrovani u prva dva časa nakon intervencije. Zaključak. Kod pacijenata na oralnoj antikoagulantnoj terapiji moguće je bezbedno izvršiti ekstrakciju zuba bez izmene terapijskog režima uz primenu adekvatnih mera lokalne hemostaze. Kod pacijenata sa INR \leq 3,0 nakon jednostavnih ekstrakcija zuba kompresija rane gazom u većini slučajeva dovoljna je mera za postizanje lokalne hemostaze.

Ključne reči:

zub, ekstrakcija; antikoagulansi; oralna primena; lečenje lekovima; hemostaza.

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Introduction

Patients receiving long-term oral anticoagulant therapy (OAT) pose a clinical challenge during invasive dental procedures. The important 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 thromboembolism¹, especially in high risk patients, i.e. those with artificial heart valves and atrial fibrillation with related risk factors. An increasing number of authors state that tooth extraction in anticoagulated patients within the therapeutic International Normalized Ratio (INR) values (INR \leq 4.0) can be safely done without changing OAT regimen if using local hemostatic measures which stabilize or enhance clot formation at the surgical site 2-19. Hemostatic agents used for bleeding control in patients on OAT are: oxidized cellulose ^{2–7}, absorbable gelatin sponges ^{5–8}, absorbable collagen sponges ^{9, 19}, fibrin glue ¹⁰, cyanoacrylate glue ¹¹, platelet rich plasma gel ¹² and topical thrombin ¹⁷. The importance of antifibrinolytic solutions for mouthwash in postextractional bleeding prevention has also been noted in several articles 4, 20. None of these hemostatic agents has been proved to be superior compared to others ^{21–23}.

The aim of this study was to compare some local hemostatic modalities in anticoagulated patients without interruption of OAT, including a group of patients in whom local hemostatic agents were not used.

Methods

The study was initiated after it had been approved by local Ethics Committee and all study participants were provided with a written informed consent. The study lasted for ten months and included patients on OAT who were referred to the Department of Oral Surgery, Dental Clinic of Vojvodina by their general dental or medical practitioners in the need for tooth extractions.

The study included patients on long-term OAT whose INR was ≤ 3.0 on the day of the procedure and in whom extraction of one or two teeth could be done using local anesthesia without the need to raise a mucoperiosteal flap. The following patient categories were excluded from the study: patients with liver disease or bleeding disorders, patients taking medications that affect hemostasis, patients with severe bleeding after dental extractions even before starting OAT and patients who did not agree to participate in the investigation.

During a patient's first visit, retroalveolar or ortopanthomographic x-ray and fulfilling of the standard form on the basis of a patient's prior medical documentation were done. The underlying diagnosis which was the reason for starting OAT was noted, as well as the duration of OAT, type and dosage of oral anticoagulant used, recent INR values and every other medication a patient had been using.

The first 30 patients were randomized in the group A, next 30 patients into the group B and the remaining 30 patients comprised the group C. The INR value was determined for each patient on the day of the procedure. Antibiotic prophylaxis was given for patients at risk of endocarditis in accordance with the American Heart Association guidelines²⁴.

Group A patients underwent suturing of the extractional wound with "figure of eight" nonresorbable suture (black silk 3–0) without using of any local hemostatic agent. In group B absorbable gelatin sponge was used as local hemostatic agent without wound suturing. In the group C no additional local hemostatic measures were used, except local pressure with gauze.

All extractions were done by the same surgeon, on an outpatient basis. Lidocaine hydrochloride 2% with 1/80,000 adrenaline was used as local anesthetic. Local infiltration method and intraligamentary anesthesia were mostly used, although regional blocks of the inferior alveolar and lingual nerve were also used ²⁵. Extractions were as atraumatic as possible. Local pressure was applied in the patients of all the three groups afterwards, i.e. the patients were asked to hold sterile gauze in a firm bite for thirty minutes. The patients were observed for the next two hours. The first measure in case of post-extraction bleeding was a superficial gauze tamponade of the wound for ten minutes. This was repeated, if needed, twice at the most. It was planned, in cases of unsuccessful superficial gauze tamponade in the patients of the group A, to put a hemostatic agent, gelatin sponge, into the wound along with suturing, while in the same situation in the group B the wound would be sutured. In the group C the insertion of gelatine sponge was to be the first measure after which suturing of the wound would be done if necessary. Repeated hemorrhage in all the three groups of patients would be treated by insertion of a new hemostatic agent oxidized regenerated cellulose into the wound. Should there be hemorrhage that could not be controlled with repeated local measure, the attending physician would be consulted, and if needed vitamin K or fresh frozen plasma would be administered.

All the patients were advised to continue OAT after the procedure. Paracetamol was suggested for pain relief. Each patient was given a telephone number to contact the surgeon in case of hemorrhage.

All the subjects were examined thirty minutes, two hours, on the first, second and fifth day after the extraction, when sutures in the patients in the group A were removed. The hemorrhage was registered as an event if other than initial local hemostatic measure was needed or an additional oral surgeon intervention was required. Hemorrhages that occurred in the first two hours after the procedure, i.e. during the observational period until the dismissal of the patient were characterized as "immediate bleeding". Hemorrhages after this period were considered as "late bleeding".

Data were analyzed using χ^2 -test and analysis of variance (ANOVA) as appropriate, and the probabilities of less than 0.05 were accepted as significant.

Results

Initially, 98 patients fulfilled criteria to participate. Six patients who did not come to control examinations were ex-

Tabla 1

Table 2

cluded, but were contacted by telephone to exclude postextractional hemorrhage. Two patients who were on combined oral anticoagulant and aspirin therapy were also excluded. Finally, the study included 90 patients, 30 in each group. Indications for OAT are shown in the Table 1. local hemostatic measures and none of the patients had serious bleeding that would require systemic therapy. No statistically significant difference between these two groups of patients was found ($\chi^2 = .42$; p = 0.811).

Indications for anticoagulant treatment				
Indications	Group A	Group B	Group C	
	(n)	(n)	(n)	
Prosthetic valve replacement	11	4	7	
Cardiac arrhythmia (atrial fibrillation)	6	14	11	
Atrial fibrillation and valvular diseases	3	2	1	
Atrial fibrillation and cerebrovascular accident	1	5	3	
Deep vein thrombosis/pulmonary embolus	6	2	7	
Ischemic heart disease	1	none	1	
Cerebrovascular accident	1	2	none	
Dilated cardiomyopathy	none	1	none	
Thrombophilia	1	none	none	

n – number of patients; group A – patients underwent suturing of the extractinal wound; group B – patient with absorbable gelatin sponge used for local hemostasis; group C – patients with no local hemostatic measures except local pressure with gauze.

The mean INR values on the day of procedures were 2.35 ± 0.37 in the group A, 2.43 ± 0.4 in the group B and 2.36 ± 0.34 in the group C. The most common anticoagulant drug in all the three patient groups was acenocoumarol (28, 26 and 28 patients in the group A, B and C, respectively). All the other patients were taking warfarin. Basic characteristics of all the three groups of patients are shown in Table 2. The groups did not differ significantly in INR-values (p = 0.662), number of tooth extractions (p = 0.708), gender (p = 0.543) and age (p = 0.868).

Discussion

Most authors suggest that the vast majority of oral surgical procedures in anticoagulated patients can be safely done without alteration of their regular OAT, thus avoiding the risk of thromboembolic complications ^{1–20}. The need for efficient local hemostasis is emphasized. Local hemostatic measures usually mean the use of certain hemostatic agent such as oxidized regenerated cellulose, gelatine sponges, collagen sponges, fibrin glue and antifibrinolytic mouthwash.

Characteristics of patient	s under coumarin treatment	t undergoing tooth extraction
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Characteristics	Group A	Group B	Group C
Gender: (male/ female), n	19/11	16/14	20/10
Age (years), $\bar{x} \pm SD$ (range)	$65.5 \pm 11.1 \ (23-78)$	$66.9 \pm 9.8 (41 - 81)$	65.8±11.2 (36–85)
Mean INR on the day of procedure, $\bar{x} \pm SD$ (range)	$2.35 \pm 0.37 (1.74 - 3)$	$2.43 \pm 0.4 (1.76 - 2.95)$	$2.36 \pm 0.34(1.75 - 3)$
Single/double extractions, n	18/12	20/10	21/9
Causes for extraction, n			
periodontal disease	22	19	18
deep caries	20	21	21
Patients with postoperative bleeding, n (%)	1 (3.3)	2 (6.7)	2 (6.7)
Immediate / late bleeding, n	1/none	1/1	2/none
Procedure to control bleeding, n			
local pressure	1	none	none
sponge	none	none	1
suturing	none	2	1

INR – International normalized ratio; Immediate bleeding – hemorrhage that occurred in the first two hours; Late bleeding – hemorrhage that occurred after the first two hours; $\bar{x} \pm SD$ – mean \pm standard deviation; group A – patients underwent suturing of the extractinal wound; group B – patient with absorbable gelatin sponge used for local hemostasis; group C – patients with no local hemostatic measures except local pressure with gauze.

Postoperative bleeding was noted in 1 (3.3%) patient in the group A, and 2 (6.7%) patients in the groups B and C (Table 2). Except one patient in the group B with "late bleeding", which occurred several hours after the intervention and whose wound had to be sutured, all the other cases of postextractional bleeding were noted in the first two hours after the procedure and characterized as "immediate bleeding". All cases of hemorrhage were easily solved only with Studies that compare different local hemostatic measures do not confirm advantages of certain agents ^{21–23}. Nevertheless, having in mind limited possibilities in the use of some preparations (such as fibrin glue since it costs a lot and carries the risk of viral transmission; tranexamic acid in the form of mouthwash is not available commercially in many countries and may have an effect only on the superficial clot and not on bleeding from the depth of the socket), there is still a need

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to find the safest method for local hemostasis in these patients

In most studies that dwell on tooth extractions in anticoagulated patients, the suturing of the extractional wound had been done ^{2–8}. Ferrieri et al. ²⁶ point out that only suturing of the wound with local application of antifibrinolytics in cases of hemorrhage is sufficient for successful local hemostasis. Recent studies, however, suggest that suturing of the extractional wound is not always necessary ^{9, 19, 27}.

Up to now there is only one study by Campbell et al. ²⁸ in which tooth extractions in anticoagulated patients were performed without additional local hemostatic measures. The authors found no difference in blood loss among groups of patients who continued, stopped and have never been on OAT during oral surgery. However, the number of patients who continued OAT was small and only 12 patients with INR < 3 were included in the study.

The results of our study show that minor oral surgical procedures, such as extraction of one or two teeth, could be safely done without alteration of OAT and without the use of any topical hemostatic agent. Wound suturing is as efficient in local hemostasis as the use of topical hemostatic agent, but it is not necessary measure in each patient. However in patients on OAT in whom adequate primary local hemostasis

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cannot be achieved, suturing is a procedure of a great importance.

This study has some potential drawbacks and limitations: its relatively small sample size; only oral surgery procedures with low bleeding risk, simple extraction of one or two teeth, were performed; only patients with INR \leq 3.0 were included although the current recommendation is that oral surgery can be safely done if INR values are \leq 4.0. The reason for this is our intention to check safety of dental extractions without the use of any local hemostatic agents.

Conclusion

In therapeutically anticoagulated patients tooth extractions can be safely performed without altering the dose of anticoagulant medication, provided efficient local hemostasis. In most cases, in patients with INR \leq 3.0 after extraction of one or two teeth postoperative bleeding can be controlled with local pressure, without any additional local hemostatic measures.

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