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Article · February 2021

DOI: 10.31080/ASDS.2020.05.1046

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Acta Scientific Dental Sciences (ISSN: 2581-4893)

Volume 5 Issue 3 March 2021

Research Article

Efficacy of PARASORB Cone® for Prevention of Local Bleeding after Oral Surgery in Patients Treated Chronically with Anticoagulants (Dihydroxycoumarin Derivatives)

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Received: January 25, 2021

Published: February 19, 2021

Abstract

Background: Anticoagulant therapy with dihydroxycoumarin derivatives is often related to local bleeding in oral surgery. Accordingly, the purpose of this study was to determine whether PARASORB Cone® formulation enables oral surgery without discontinuation of anticoagulant therapy.

Materials and Methods: 35 patients with various cardiac disorders underwent 66 tooth and root extractions without discontinuation of anticoagulant treatment. The control group was composed of 30 patients with cardiac disorders in whom anticoagulant therapy was discontinued before tooth extractions. PARASORB® Cone Formulation was used topically with single sutures and compression. Sutures were removed after 7 days following tooth extraction. The visual assessment of bleeding and wound healing was performed on Days 2, 3 and 7 of follow-up.

Results: In the study group, clinical evaluation revealed no local bleeding in 32 patients (91.4%) during the follow-up. Local bleeding was observed in 3 patients (8.6%) on Day 3, however, it was residual. In the control group no local bleeding was observed in 27 patients (90%) during the follow-up. Local bleeding was also observed in 3 (10%) patients in the control group on Day 3. All wounds healed properly, except 5 (14.2%) patients in the study group and 5 (16.6%) in the control.

Conclusions: PARASORB Cone® formulation seems to be effective in stopping local bleeding after oral surgery without the need to discontinue treatment with dihydroxycoumarin derivatives. In addition, clinical effectiveness of PARASORB Cone® in the healing of post-extraction wounds was comparable in both groups.

Keywords: Anticoagulation; Oral Surgery; Local Bleeding: Dentistry

Introduction

It has been estimated that approximately 1% to 1.7% of the European population is currently treated with oral anticoagulation with vitamin K antagonists [1,2]. A large number of these patients are also treated with coronary artery bypass graft surgery and implantation of artificial valves [3]. Such a wide use of dihydroxy-

coumarin derivatives (DD) may result in increased bleeding in this cohort of patients. It is estimated that acute bleeding occurs in as many as 13% of patients treated with DD [4].

There are several urgent situations in which temporary discontinuation of oral anticoagulation therapy is required, including oral surgery. On the other hand, acute discontinuation of such therapy may lead to severe complications related to thrombosis [5].

Therefore, the purpose of this study was to determine whether PARASORB Cone® formulation enables oral surgery without discontinuation of anticoagulant therapy.

Materials and Methods

Thirty five consecutive patients referred to urgent oral surgery were enrolled in the study. All patients were on oral anticoagulation with vitamin K antagonists due to coronary artery bypass graft surgery or implantation of artificial valves. The exclusion criterion was lack of consent for the use of PARASORB Cone® preparation (RESORBA Medical GmbH, Germany). On admission blood tests were taken, including the international normalized ratio (INR).

The control group consisted of 30 patients in whom anticoagulation therapy was discontinued and a bridging therapy with subcutaneous administration of low molecular weight heparin (Enoxaparin) was used until INR level decreased below 1.5. In order to monitor the daily dose of heparin, Activated Partial Thromboplastin Time (APTT) was measured and was within the normal range.

All tooth extractions were performed under local anesthesia (Articaine 4%). Teeth and roots were extracted atraumatically. Based on the previous experience, one tooth or root was removed during one procedure. After the removal of the inflamed tissue from the wounds, PARASORB Cone® was formed into the shape of the alveolus and applied to the alveolus. Furthermore, pressure was applied with sterile gauze for 30 minutes and single stitches (of absorbable sterile monofilament strands in sizes 4-0) were used to stabilize the collagen cone. Polydioxanone sutures (round needle, ½ circle, 17 mm long) were used. Sixty six extractions were performed in total (56 roots and 10 teeth with gangrene of the pulp). Table 1 shows the characteristics of the study and the control groups. The same surgical procedure was performed in all study patients. However, a different type of standard collagen dressing was applied to the alveolus. Fifty extractions were performed (38 root extractions and 12 tooth extractions - gangrene of the pulp). Our patients received amoxicillin with clavulanic acid (initial oral dose of 2.0 g was administered 2 hours before surgery) for 7 days due to the underlying disease. Local bleeding from the sockets was evaluated using a three-point scale: (0) - no bleeding; Level 1- leakage or bleeding that required tranexamic acid mouthwash for 5-7 days; Level 2 - bleeding that required a broader approach, including oral or IM administration of 5-10 mg vitamin K. Local bleeding was assessed after 30 minutes and on postoperative Days 2, 3 and 7. Discomfort and postoperative pain were measured using the VAS scale (0-100 millimeters; 0 - no pain; 100 - the strongest possible pain). Postoperative wound healing was assessed visually using a two-point scale: 0- normal healing, 1- wound showing inflammatory features. Sutures were removed 7 days after the surgical procedure.

This study has been conducted in full accordance with the Word Medical Association Declaration of Helsinki. In addition, this study was approved by Ethic Committee of Medical University of Silesia, Katowice, Poland (KNW/0022/KB1/72a/I/11). We obtained verbal consent from all participants included in the study. This consent procedure was approved by the Ethic Committee.

Statistics

Statistical analysis was performed using StatSoft Statistica v.12, Inc. (2014). After determining distribution of the data in the study groups, the Student's t-test was used for normal distribution and the results were presented as mean and standard deviation. The U Mann-Whitney test was used for non-parametric distribution data and nonparametric variables and the results were presented as median, minimum and maximum values. The comparison of group sizes in the study groups was performed using the Pearson Chi2 test. The results were presented as absolute number and percentage. $P < 0.05$ was considered significant.

Results

The patient characteristics are presented in Table 1. No significant differences were observed between the study groups except for INR, which was significantly higher in the study group as compared with the control group [2.42 (1.71-3.69) vs. 1.14 (0.83-1.5), $P < 0.001$], respectively. In 32 (91.4%) patients (17 men and 15 women), no bleeding was reported despite abnormal hemostatic parameters confirmed by laboratory tests. In 3 (8.6%) cases postoperative bleeding (Level I) occurred on Day 3. Bleeding was controlled in an outpatient setting. In the control group, no bleeding was observed in 27 (90%) patients (12 women and 15 men). How-

	Study Group n = 35	Control Group n = 30	P
Age, years	56.6 ± 11.7	54.3 ± 7.4	NS
Sex, male/female	18/17	17/13	NS
Extraction of the teeth - gangrene of the pulp	10	12	NS
Root extractions	56	38	NS
Acenocoumarol (daily dose: 2-8 mg/ mean dose: 4 mg), n, (%)	21 (60)	18 (60)	NS
Warfarin (daily dose: 3-7.5 mg/mean dose 5mg)	14 (40)	12 (40)	NS
Enoxaparin (daily dose 40-80 mg/mean 59 mg)	-	30	-
INR, after discontinuation of the anticoagulant one day before extraction, median (IQR)	2.42 (1.71 - 3.69)	1.14 (0.83 - 1.51)	<0.001
Mechanical mitral and aortic valves	2	1	NS
Mechanical mitral valve	5	2	NS
Mechanical aortic valve	5	4	NS
Atrial fibrillation and pacemaker	3	4	NS
Atrial fibrillation and myocardial infarction	5	5	NS
Atrial fibrillation and insufficiency of the mitral valve	2	3	NS
Atrial fibrillation	13	11	NS

Table 1: Patient characteristics.
The values are expressed as mean with SD , and median with interquartile range (IQR).

ever, in 3 (10%) cases (2 men and 1 woman) postoperative bleeding (Level I) occurred on Days 2 and 3, although INR was within the normal range. Every bleeding was also controlled in an outpatient setting.

In the assessment of postoperative discomfort and pain, significant differences were observed between the study groups. Accordingly, Visual Analogue Scale (VAS) values presented as median and interquartile range were significantly lower in the study group compared to the control /35 (20-40) vs. 40 (30-60)/, respectively, P = 0.001 (Table 2).

VAS Scale 0-100 (mm)/ GROUP	Median	Minimum	Maximum	P
Study	35.0	20.0	40.0	0.001
Control	40.0	30.0	60.0	

Table 2: The level of pain (VAS) in the study groups.

Moreover, on Day 7, postoperative wound healing was more difficult to heal in 5 male patients (14.2%), including subjects with bleeding. Also, on the same day impaired wound healing was noted in 5 (16.6%) cases (3 men and 2 women) in the control group. Antiseptic Chlorhexidine and topical acetylsalicylic acid were used to improve wound healing,

Discussion

This study demonstrated that the use of PARASORB Cone® preparation without discontinuation of warfarin in patients treated with urgent oral surgery is safe and effective in this cohort of patients.

It is known that discontinuation of warfarin is associated with poor clinical outcomes in surgical patients treated chronically with DD [6,7]. In addition, maintaining anticoagulant therapy combined with topical application of the hemostatic substance may reduce both the duration and cost of oral surgery [8,9].

Bacci., *et al*. also reported no significant differences in the incidence of bleeding after extraction in 451 patients on warfarin (INR 1.8-4.0) compared to a group of 449 healthy subjects that underwent the same surgical procedure. These observations are consistent with our study results. In patients in whom anticoagulant therapy was discontinued, topical hemostatic silk sutures, sponges, fibrin and pressure sterile gauze soaked with tranexamic acid were used. Postoperative bleeding was noted in the study (n = 7) and the control (n = 4) groups. None of the complications required hospitalization or blood transfusion. Some researchers also considered it safe for patients to continue warfarin treatment if topi-

cal hemostatic measures were taken to reduce patient discomfort [10]. Motlagh., *et al*. [11] reported similar results in patients who had been recommended to rinse the mouth with tranexamic acid solution (5%) during and after dental surgery. No local bleeding was reported.

Conclusion

In conclusion, our data and previous reports support the continuation of anticoagulant treatment and the use of topical substances for local hemostasis following oral surgical procedures. Such procedures will reduce the duration and cost and also increase patient comfort. Moreover, continuation of anticoagulant therapy prevents the occurrence of embolism in these patients. Our study confirms that the use of the above procedure is the most effective in an outpatient setting. However, in the case of life-threatening complications, patients should be treated in hospital settings only. The use of PARASORB Cone® is simple, cheap and effective.

Acknowledgment

This study was supported by grant from Medical University of Silesia, Katowice, Poland (KNW-1-066/N/7/O).

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