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HAEMOSTASIS CONTROL IN DENTAL EXTRACTION WITH CALCIUM SULPHATE: A CASE SERIES

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Dental treatment performed in patients receiving continuous oral anticoagulant drug therapy is becoming increasingly common in dental offices. For these patients it is imperative to carry out careful anamnesis, as well as a multi professional clinical evaluation with regard to the risk and control of hemorrhagic or thromboembolic episodes. The aim of this study was to assess the haemostatic efficacy and safety of the topical use of Calcium sulfate (CaS) in the setting of dental surgery. Following the approval from of the Local Research Ethics Committee (CaS) as a haemostatic agent in Dentistry. No patient had wound infection and the healing process appeared to be normal. CaS is useful for the local hemostasis and wound healing in periodontal surgeries. In conclusion, the use of CaS controlled the bleeding from inside the extraction socket producing instantly a very good haemostasis.

The dentist today is seeing increased numbers of patients with chronic medical illnesses. Among these patients are those that are being treated with anticoagulant drugs or antiplatelet agents to prevent venous or arterial thrombosis. Therefore the likelihood of anticoagulant-treated patients requiring oral surgery is significant and increasing. The coumarin compounds are used world-wide to provide anticoagulation. In Europe, warfarin (warfarin sodium and panwarfarin) is the most commonly used oral anticoagulant. Anticoagulants present management problems in oral surgery mainly because of prolonged intra-operative and postoperative bleeding. However, about 90% of post-extraction hemorrhage is from other causes, including the following (1):

- Excessive operative trauma, particularly to oral soft tissues;
- Poor compliance with postoperative instructions;
- Interference with the extraction socket or operationsite (eg, by sucking and tongue pushing; plasminogen activators are present in saliva and oral mucosa and can thus cause fibrinolysis);
- Inflammation at the extraction or operation site, with resultant fibrinolysis;
- Inappropriate use of analgesia with aspirin or other nonsteroidal antiinflammatory drugs, which, by interfering with platelet function, induce a bleeding tendency;
- Uncontrolled hypertension;

Many clinicians have recommended interruption of continuous anticoagulant therapy for dental surgery to prevent hemorrhage. However, with review of the available literature, no well-documented cases of serious bleeding problems from dental surgery in patients receiving therapeutic levels of continuous warfarin sodium therapy were identified, but several documented cases were found of serious embolic complications in patients whose warfarin therapy was withdrawn for dental treatment (2). Fundamentally, the surgeon and treating clinicians must balance the need for reducing anticoagulant therapy and preventing undue hemorrhage against the associated increased risk from the diminution of the therapeutic benefit of anticoagulation therapy resulting in potentially

Key words: oral anticoagulant therapy, calcium sulphate hemi-hydrate, haemostasis, controlling bleeding

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life-threatening thromboembolism (3). A recent survey showed that of more than 950 patients receiving continuous anticoagulant therapy (including many whose anticoagulation levels were well above currently recommended therapeutic levels) who underwent more than 2400 surgical procedures, only 12 (1.3%) needed more than local measures to control hemorrhage (4). The recommendations concerning treatment emphasis, timing, and modifications of anticoagulant intake in relation to oral surgery have been controversial, and therefore it is important to have local validity hemostatic agents. One of the more common methods of intra-operative hemorrhage control involves the use of a topical hemostatic agent. A major concern in the management of dental patients taking antithrombotic agents is the potential for excessive bleeding after invasive dental procedures. It has been reported that some of these agents, such as bone wax and ferric sulphate, may produce an inflammatory response if left in situ (5, 6). It has also been reported that the use of hemostatic collagen, cellulose and vasoconstrictors for local haemorrhage control in endodontic surgery may produce a systemic-vascular response (7-9). Aim of the present paper was to describe a new approach for the control of hemostasis during dental extractions with the use of Calcium Sulphate (CaS).

MATERIALS AND METHODS

Ten teeth (8 mandibular teeth, 2 maxillary teeth) in 10 healthy patients (6 women and 4 men) with a mean age of 44.6 years (±13.2 years) were included in the study. The protocol of the study was approved by the Ethics Committee of the University of Chieti-Pescara. A total of 10 patients who were kept on warfarin as a maintenance dose for >1 year with INR >3.0 and required dental extractions were recruited for this study. Patients with history of chronic renal or liver disease or who were on drugs that could affect liver function or haemostasis, other than warfarin, were excluded. All patients were physically healthy, with underlying systemic disease as determined by medical history screening and with at least one tooth to be extracted. Before entering the study, patients were informed about the nature of the investigation, and signed an informed consent form. All patients received basic periodontal therapy and exhibited good oral hygiene. Informed consent was obtained from all participants who met the study criteria and they were randomized into two groups. Patients having one tooth scheduled for extraction were assigned to test and control groups at the time of their recruitment in the study. All patients continued warfarin therapy. The test extraction socket were filled with Calcium Sulphate in layers (P30, Ghimas, Casalecchio Di Reno, Bologna, Italy), a solution of Potassium Chloride (4%) was used to buffer the surface of the mould, to get a strengthening and hardening of the CaS itself, while was used for wound closure for patients in control group the gauze on the extraction site for at least 30 minutes and change the gauze with new at the end of their visit. Dental extraction was performed under local anesthesia with using articaine with adrenaline 1:100.000 infiltrated in the sub periosteum. Local hygiene treatment and antibiotics (amoxicillin + clavulanic acid, 1 gram twice per day; Neo-Duplamox, Procter & Gamble, Rome) were added for 5 days, starting from 12 hours prior to surgery (10). All patients were given detailed written postoperative instructions, the contents of which were verbally illustrated by the treating dentist. Patients were asked to wait for a minimum of one hour within the clinic area; they were closely monitored for bleeding status. All patients returned for postoperative follow-ups at days 1, 3, 5 and 7. The status of bleeding and healing were objectively monitored by an independent examiner blinded to the treatment protocol for the four treatment groups. Incomplete wound closure or the absence of scar tissue formation was considered poor healing (Fig. 1). The presence of a solid clot covering the extraction socket (Fig. 2) was considered as no bleeding, while the presence of a fresh clot that shed easily, or blood oozing was considered as positive bleeding. The statistical analysis has been carried out employing the Chi-square test according to the Statistical Package for Social Science (SPSS 8.0). The value of $p < 0.05$ was considered as significant (11).

RESULTS

Healing pattern was found to be approximately similar in all treatment groups, showing significant improvement at each consecutive visit. Bleeding at postoperative day 1 was significant, furthermore, the improvement continued and was approximate at day 5 and almost eliminated by the last visit (day 7). Bleeding at postoperative day 1 was not present, in the extraction site was present a calcium sulfate and a solid clot covering at 1 day. No a fresh clot that shed easily, or blood oozing was present at day 3. Cross-comparison among the two treatment groups did show significant difference in healing at the different postoperative visits.

Statistical analysis

A statistically significant difference in the adequate hemostasis was present between control group I vs test group II (calcium sulfate) (p-value = 0.0066).

DISCUSSION

A significant percentage of the population receives anticoagulation therapy in the prevention and treatment of thromboembolic disease states, such as deep vein thrombosis, pulmonary embolism, cerebrovascular disease, numerous cardiac disorders and the various prothrombotic states (Ce.: lupus, factor S and factor C deficiency) (12). Hemostatic failure is one of the most serious problems encountered by the dental professionals. It may cause excessive postoperative bleeding delay in wound healing and increase risk of infection (13). Local haemostatic methods non-resorbable sutures,

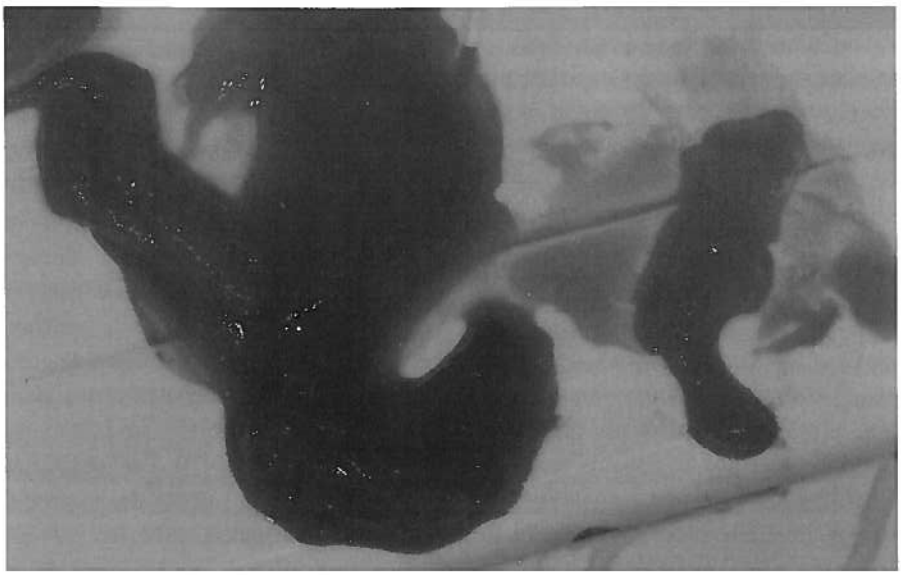

Fig. 1. *Presence of a fresh clot that shed easily in control group*

Fig. 2. *Extraction socket filled with Calcium Sulphate produce a very good haemostasis*

(fibrin glues), antifibrinolytic agents (tranexamic acid in mouthwash form), replacement therapy (recombinant or plasma derived clotting factors, platelet-rich plasma) and desmopressin are the usual management (14, 15). In our series hemostasis was achieved in all of the twenty two patients. No patient had wound infection and the healing process appeared to be normal. It is not necessary to reduce oral anticoagulant therapy in patients undergoing routine dental extractions with using local hemostasis (16). Reducing anticoagulant therapy to prevent hemorrhage against the associated increased risk from the diminution of the therapeutic benefit of anticoagulation therapy results in potentially life-threatening thromboembolism (3). For this reason it is important to have a valid local hemostatic agent. The CaS was highly absorbent and was used for wound protection and for control of oozing or bleeding in endodontic surgery procedure and surgical-orthodontic treatment of impacted teeth. As for application, this product should be held in place for approximately 1 to 3 minutes to achieve hemostasis and left in situ. The CaS material is completely resorbed within 1 to 4 mouths (17). In addition to serving as a mechanical obstruction to bleeding, these materials affect the coagulation process.

The residual presence of the CaS in the bony cavity is

not problem. It is reasonable to think that the CaS reabsorbs the blood proteins, therefore assuming a net negative charge. This resorption might start the intrinsic coagulation pathway (18). The resorption of Factor XII might in this case assume an important role in the biomaterial-induced clotting (19). As has been recently shown *in vitro*, contact between a biomaterial and blood determines the activation of Factor XII as well as precallicrein. Besides its influence on the clotting-mechanisms activation downfall, CaS used in the disinclusion of impacted teeth carries out a haemostatic effect through a compressive effect, insulating the tooth like a rubber dam. Moreover, the white color of CaS greatly facilitates visibility of the surgical area to the surgeon. In the present study, CaS has been used with the aim of controlling bleeding in patients receiving oral anticoagulant. It is important to keep in mind that the biomaterial is totally resorbable and biocompatible, and, no problems should arise if some CaS particles are left in the extraction socket (20-22). In conclusion, the use of CaS controlled the bleeding from inside the extraction socket producing instantly a very good haemostasis. Further studies are desirable, in order to confirm the simplicity, possibilities and limits of the proposed procedure.

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