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Minor Oral Surgery Procedures in Patients Taking Warfarin

A 5-year retrospective study at Sultan Qaboos University Hospital, Sultanate of Oman

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عمليات جراحة الفم الصغرى للمرضى المعالجين بعقار الورفرين

دراسة استعادية لمدة خمس سنوات بمستشفى جامعة السلطان قابوس، سلطنة عُمان

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الملخص: الهدف: عمليات جراحة الفم الصغرى للمرضى المعالجين بعقار الورفرين تحمل خطر النزيف بعد الجراحة. الغرض من هذه الدراسة هو تحليل ووصف الوضع الطبي والجراحي لمرضى عقار الورفرين الذين خضعوا لعمليات جراحة الفم الصغرى في مستشفى جامعة السلطان قابوس. **الطريقة:** ضمت هذه الدراسة الاستعادية 124 مريضا (41 ذكرا و 83 أنثى) ممن يستخدمون عقار الورفرين وكان معدل التقييس العالمي لهم ≤3.5 قبل خضوعهم لعمليات جراحة الفم بدون وقف العقار تحت التخدير الموضعي خلال فترة 5 سنوات من يناير 2004 إلى ديسمبر 2008. **النتائج:** خضع 90 مريضا (72.6%) لعمليات خلع أسنان بسيطة، و 26 (21%) لخلع جراحي للأسنان، و6 (4.8%) لعمليات خزعة لنسيج فمي لين وحالتين (1.6%) لاستئصال جذر السن مع إزالة التكيس. تم عمل الإجراءات الموضعية لوقف النزيف لجميع المرضى حيث شملت وضع قطن خاص لإيقاف النزيف وخياطة الجرح. تعرض 8 مرضى (6.5%) لنزيف بسيط بعد عمليات جراحة الفم، 5 منهم خضعوا لقلع أسنان جراحي و 3 لخلع أسنان بسيط، حيث تطلب عودتهم للمستشفى. تم معالجة جميع حالات النزيف بطريقة تحفظية عن طريق إعادة تلفيف و خياطة موقع النزيف بدون الحاجة لإدخال المريض للمستشفى. **الخلاصة:** يمكن إجراء عمليات جراحة الفم الصغرى للمرضى المعالجين بعقار الورفرين بأمان دون الحاجة لإيقاف العقار عندما يكون معدل التقييس العالمي 3.5≤ قبل العملية مع استخدام الطرق الموضعية المناسبة لوقف النزيف.

مفتاح الكلمات: عقار الورفرين، خلع الأسنان، جراحة الفم، نزيف ما بعد العملية، المضاعفات.

ABSTRACT: ***Objectives:*** Minor oral surgery (MOS) procedures in warfarinised patients carry the risk of post-operative bleeding. The aim of this study was to conduct a retrospective analysis and to describe the profile of warfarinised patients who underwent MOS procedures at Sultan Qaboos University Hospital. ***Methods:*** A retrospective study of 124 warfarinised patients (41 men and 83 women), who had a pre-operative international normalised ratio (INR) of ≤ 3.5 and underwent different MOS procedures under local anaesthesia, without discontinuation of their warfarin therapy, was carried out over a 5-year period from January 2004 to December 2008. ***Results:*** Ninety (72.6%) patients had simple dental extractions, 26 (21%) surgical extractions, 6 (4.8%) soft tissue biopsies and 2 (1.6%) had apicectomies with cyst enucleations. Local measures were applied in all patients, which included the use of oxidizing regenerated cellulose haemostatic agent (Surgicel) and suturing. A total of eight patients (6.5%), five who had surgical extractions and three who had simple extractions, bled enough post-operatively to require a return to hospital. All cases of post-operative bleeding were managed conservatively by repacking the bleeding site with haemostatic agent and re-suturing without the need for hospital admission. ***Conclusion:*** Minor oral surgery procedures can be safely conducted in warfarinised patients without interruption of warfarin regimen when the pre-operative INR is ≤ 3.5 and appropriate local haemostatic measures are used.

Keywords: Warfarin; Tooth extraction; Oral surgery; Postoperative haemorrhage; Complications.

Advances in Knowledge

1. *This study adds support to the available literature on the safety of conducting minor oral surgery procedures (MOS) in warfarinised patients without interruption of their warfarin therapy.*

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Application to Patient Care

1. *Medical and dental teams involved in the care of warfarinised patients should be aware of the latest evidence-based recommendations for management of warfarinised patients requiring dental surgery procedures.*
2. *Minor oral surgery (MOS) procedures can be safely conducted in warfarinised patients without alteration of warfarin therapy in outpatient settings when the pre-operative international normalised ratio (INR) is ≤ 3.5.*
3. *MOS procedures performed in warfarinised patients carry a low risk of minor post-operative bleeding.*
4. *Local haemostatic measures play an important role in the management of warfarinised patients undergoing MOS procedures.*

Warfarin, the most commonly prescribed oral anticoagulant, is a vitamin K competitive antagonist that impairs the synthesis of Vitamin K-dependent coagulation factors II, VII, IX, X and endogenous proteins C and S in the liver, resulting in impaired fibrin formation.[1,2] Warfarin is frequently used to prevent and treat thromboembolism in various recognised clinical conditions such as cardiac arrhythmias, valvular heart diseases and cerebrovascular accidents.[2-6]

The activity of warfarin is expressed as the international normalised ratio (INR), which is the standard introduced by the World Health Organization in 1983.[7] The INR specifically measures the responsiveness of thromboplastin to a specific warfarin induced defect, and it therefore measures the effect of warfarin and not liver function. It is expressed as a prothrombin ratio obtained by dividing the prothrombin time by the laboratory control prothrombin time.[1,2,7] The therapeutic range is the value of INR or degree of anticoagulation that is required to prevent the development of serious thromboembolism and is normally maintained between 2 and 4. The desirable range for the INR depends on the condition being treated, and the risk of bleeding increases as the INR rises.[8]

Published reports have shown an increase in the number of patients attending dental units worldwide who are on warfarin therapy.[1,2,5] For many years, controversy has surrounded the correct management of patients on warfarin therapy requiring minor oral surgery (MOS) procedures.[1,3,6] Over the last two decades, various clinical protocols were suggested for managing such patients, which included withdrawal of warfarin, reducing the dose, substitution of heparin for warfarin, and continuation of the normal dose of warfarin.[1-6] The risk of intra-operative or post-operative bleeding must be balanced against the risk of thromboembolism in patients whose warfarin is interrupted. Several published cases have highlighted the occurrence of serious thromboembolic complications, including death, in patients whose warfarin was withdrawn for dental treatment.[3,9-12] In addition, substituting heparin for warfarin often entails hospital admission, which results in an increase in the cost of health care services as well as an increase in patient discomfort.[1,2]

Recently, a considerable body of evidence from research studies has highlighted the relative safety of conducting MOS procedures in warfarinised patients at outpatient settings without ceasing or altering their warfarin therapy when the pre-operative INR is ≤ 4.[2,4-6,13-14]

There is no published work in Oman on the dental management of patients taking oral anticoagulants. The Oral Health Department of Sultan Qaboos University Hospital (SQUH) started managing warfarinised patients requiring MOS procedures under local anaesthesia without the interruption of warfarin in September 2003. Our protocol, as summarised in Table 1, states that the pre-operative INR must be ≤ 3.5 and local haemostatic measures are to be used in all patients which is in line with recommended evidence based guidelines.[2,4] This retrospective study was conducted with the aim of reporting and describing the profile of all warfarinised patients who underwent MOS procedures under local anaesthesia at our outpatient Unit over a 5-year period from January 2004 to December 2008.

Methods

All warfarinised patients requiring oral surgery procedures at the Oral & Maxillofacial Unit of the Oral Health Department, SQUH, are registered in the oral surgery procedures book. A search was conducted to identify all registered cases that underwent MOS procedures according to Unit protocol and under local anaesthesia without interruption of warfarin at our outpatient setting from January 2004 to December 2008. The patient's

Table 1: Protocol for minor oral surgery in warfarinised patients at the Oral Health Department, Sultan Qaboos University Hospital

Pre-operative assessment	- INR of ≤ 3.5 obtained on the day of surgery - No other coagulopathy - No liver disease - Absence of infection at surgical site - Patient should not be on aspirin or non-steroidal anti-inflammatory drugs
Intra-operative management	**MOS procedures:** - Simple dental extraction - limited to 1-3 in same quadrant - Surgical extraction - Soft tissue biopsy **During surgical procedure:** - Atraumatic surgical techniques - Respect soft tissue and avoid excessive manipulation **Local haemostatic measures:** - Packing extraction sites with Surgicel dressing - Suturing with resorbable sutures - 4.8% tranexamic acid can be given as 10ml mouthwash to be used four times daily for 3-5 days
Post-operative care	**Verbal and written post-operative instructions to patients:** - Dietary instructions (avoid hot drinks for 24 hrs; soft diet for a few days) - Limit usage of analgesics to 3 days if possible - Avoid taking any herbal remedies - Instructions on how to deal with bleeding at home and where to seek help if bleeding cannot be not stopped at home - Post-operative medications **Antibiotics:** - If required use oral amoxycillin for 3-5 days **Analgesics:** - Parecetamol - Compound paracetamol (co-codamol) - Codiene phosphate **Follow up appointment in 2 weeks**

Legend: *INR = international normalised ratio; MOS = minor oral surgery*

files were retrieved and data collected which included, age and gender, indication for warfarin therapy and the pre-operative INR. The nature of the MOS procedure was classified and recorded as either simple extraction; surgical extraction; biopsy or others. Surgical extraction was defined as raising a mucoperiosteal flap and removal of bone with a bur. Detailed information was also recorded on the operating surgeon; the local haemostatic methods used; pre- and post-operative antibiotic usage and other post-operative medications. In addition, data were also collected regarding any post-operative bleeding and its time of occurrence, the postoperative INR and the course of management of the post-operative bleeding. Prior to the start of the study, ethical approval was obtained from the local research committee.

RESULTS

At our Unit, total of 124 warfarinised patients underwent minor oral surgery procedures during the five-year study period without discontinuation of their warfarin therapy. There were 41 (33.1%) male and 83 (66.9%) female subjects with a mean age of 36 years (range 20-86 years).

The patients studied were on warfarin therapy for a number of medical conditions as summarised in Table 2. A prosthetic heart valve was the most common clinical indication for warfarin therapy, accounting for 62.1% of patients.

The oral surgery procedures performed in the study group were conducted by three senior surgeons under local anaesthesia and included simple dental extractions, surgical extractions, soft tissue biopsies and apicectomies with cyst enucleations [Table 3].

Table 2: Indications for warfarin treatment in the study group

Indication	No. of patients (%)
Cardiac arrhythmias	10 (8.1%)
Deep vein thrombosis	2 (1.6%)
Transient ischaemic attack and stroke	19 (15.3%)
Pulmonary embolism	5 (4%)
Prosthetic heart valve	77 (62.1%)
Myocardial infarction	4 (3.2%)
Others	7 (5.6%)

Table 3: Minor oral surgery procedures conducted in the study group

Procedure	No. of patients(%)
Simple dental extraction (1-3 teeth)	90 (72.6%)
Surgical extraction	26 (21%)
Soft tissue biopsy	6 (4.8%)
Apicectomy and cyst enucleation	2 (1.6%)

Simple dental extractions of 1-3 teeth accounted for 72.6% of the performed procedures with 149 teeth extracted. The mandibular first and second molars were the most commonly extracted teeth followed by the maxillary second molars. In patients who had surgical extractions, the mandibular third molars were the most commonly removed teeth followed by the upper first premolars. Soft tissue procedures were conducted as excisional biopsies of benign tumours and mucous extravasation cysts from the tongue, palate, labial and buccal mucosae. The two cases of apicectomies and cyst enucleations were performed on the upper central incisors.

All patients had local anaesthesia in the form of 2% xylocaine with adrenaline 1:80000. Infiltrations of local anaesthesia and nerve blocks were used to achieve the required anaesthesia for MOS. Blind infiltrations involving the floor of the mouth were avoided in all patients. All patients who underwent MOS procedures had a pre-operative INR taken on the same day of the procedure. The mean INR of the study group was 2.8 with a range of 2.1-3.5.

All patients who had simple and surgical extractions had local haemostatic measures which included the placement of oxidizing regenerated cellulose dressing (Surgicel, Johnson & Johnson) into the extraction sockets and closure with resorbable Vicryl sutures. Other patients (apicectomy and biopsy patients) had the surgical areas closed with resorbable sutures.

Seventy-seven patients who had a history of prosthetic heart valves had pre-operative antibiotic prophylaxis against infective endocarditis. All these patients had 3g amoxycillin orally one hour pre-operatively according to standardised international guidelines.[15-16] Twenty patients who had surgical extractions and apicectomies had a 3 day course of post-operative amoxycillin. Out of these 20 patients, only one patient also had a pre-operative antibiotic. All patients had a five day course of simple analgesics in the form of paracetamol (n = 60), co-codamol (n = 62) and codeine phosphate (n = 2). All patients were instructed to limit or consider lowering the usage of analgesics after the third day.

Following MOS procedures, all patients were instructed to bite on sterile gauze and were reassessed for immediate post-operative bleeding after 20 minutes before being allowed to leave. Both clear verbal and written instructions were given to patients, which included: post-operative instructions; dietary advice; home management of any bleeding and where to seek medical assistance for emergency bleeding. In addition, all patients were given a 2 weeks follow-up appointment.

None of the studied patients had any immediate post-operative bleeding. A total of eight patients (6.5%), five who had surgical extractions and 3 had simple extractions, bled post-operatively and had to return to hospital. The bleeding was reported in all these patients to be as continuous oozing from the surgical sites, which was not controlled by local measures at home. All these patients had their INR re-checked with most of them having a higher post-operative INR compared to the pre-operative INR. Table 4 shows a summary of patients who presented with post-operative bleeding. All these patients were managed in an outpatient setting and none required hospital admission, as they were all haemodynamically stable with normal vital signs. The management included repacking the bleeding site with Surgicel dressing and re-suturing.

All patients in the studied group attended the two week review visit. In the eight patients who had postoperative bleeding, the surgical sites had healed adequately and none of these patients reported any new episodes of bleeding from the

Table 2: Data of patients presenting with post-operative bleeding following oral surgery procedures

Patient	Age/Sex	Pre-operative INR	Procedure	Pre/post antibiotic use	Post-operative INR	Day of presentation
1	55/F	2.8	Surgical extraction	No	3.5	3
2	39/M	3.5	Simple extraction	Yes	3.8	2
3	48/F	2.4	Surgical extraction	No	2.3	5
4	40/F	3.2	Simple extraction	No	3.4	3
5	28/F	2.4	Surgical extraction	No	2.8	2
6	33/M	2.1	Simple extraction	No	2.8	4
7	49/M	2.8	Surgical extraction	Yes	3.4	3
8	52/F	3.1	Surgical extraction	Yes	3.7	3

Legend: *INR = international normalised ratio*

surgical sites. The remaining 116 patients also did not report any episode of bleeding that required any medical intervention and all had satisfactory post-surgical healing.

Discussion

Oral surgery is the main oral health care hazard in patients taking warfarin due to the potential risk of bleeding. For many years, controversy has surrounded the correct management of warfarinised patients requiring MOS procedures and various clinical protocols have been suggested for managing such patients.[1,3,5,6] The traditional management in most dental units, including our Unit, entails the discontinuation or reduction of warfarin therapy 2-3 days prior to dental surgery in order to prevent post-surgical haemorrhage.[3,12,14] However, this practice may increase the risk of potentially life-threatening thromboembolic events, especially in high-risk groups such as patients with prosthetic heart valves.[2,14] Furthermore, there is evidence that thrombosis may actually be more likely to occur due to rebound hypercoagulabilty that may ensue after cessation of warfarin.[9,11] To support this, the literature contains several documented cases of serious thromboembolic complications in patients whose warfarin was withdrawn for dental treatment.[2,17]

In recent years, continuation of warfarin therapy in patients undergoing oral surgery procedures has gained more attention in the scientific literature.[2,3,5,6,18] The 4th World Workshop in Oral Medicine recommended that warfarinised patients undergo MOS in an outpatients setting when the pre-operative INR is ≤ 3.5.[2] Published studies have shown the relative safety of conducting MOS in warfarinised patients without alteration of the warfarin regimen and recommended the use of local measures to stabilise the clot formation at surgical sites.[3-6] These local measures include the use of haemostatic agents such as oxidizing regenerated cellulose (Surgicel), fibrin glue and gelatin sponge.[6,19-22] Conducting the procedure atraumatically and careful closure of the surgical site with adequate resorbable sutures also helps to stabilise the wound and achieve haemostasis. In our Unit, Surgicel is routinely used as the local haemostatic dressing because it is widely available, easy to handle, inexpensive and does not interfere with healing or bone regeneration. Many published studies have demonstrated its use as an effective local agent with comparable efficacy to other agents.[3,20,22] Furthermore, other published reports also recommend the use of a tranexamic acid mouthwash in the post-operative period of warfarinised patients following MOS. Tranexamic acid mouthwashes tend to result in a good level of drug concentration in saliva, and thus help to prevent post-operative bleeding due to the continued local anti-fibrinolytic activity.[2,19,21] Despite the huge

body of evidence recommending the continuation of warfarin therapy in patients undergoing MOS, Linnebur *et al*.[23] identified inconsistencies between teaching practices in US dental schools and medical evidence available for the management of patients taking warfarin with most schools still teaching the practice of altering and/or interrupting warfarin prior to dental surgery.

In Oman, our Unit started treating warfarin patients requiring MOS in an outpatient setting in September 2003, according to the protocol summarised in Table 1. Before this date, there was no existing protocol and most patients were managed after consultation with their treating physician, almost all of whom tended to regard dental treatment, including simple extraction, as invasive and therefore aimed to reduce INR to <2.5, which is currently not in line with international clinical guidelines. As patients who are taking warfarin are increasing in Oman, dental and medical teams here need to be aware of the latest evidence-based guidelines, which are available for safe management of this group of patients.

With regard to the risk of post-operative bleeding following MOS, Wahl's review found little or no difference in terms of blood loss after dental surgery between patients who are anticoagulated and control patients.[17] Other studies conducted on patients taking warfarin, with INR in the therapeutic range (2-4) versus controls, found little or no difference in the incidence of clinically significant bleeding, even though some had warfarin levels above the present recommended therapeutic levels, and some underwent extensive oral surgery.[1] In a series of 2,400 documented dental operations, Wahl found only 12 patients experiencing post-operative bleeding that was not controlled by local measures.[24] The literature contains no report of patients experiencing serious harm from post-operative bleeding after dental extractions while continuing on warfarin. In our study, none of our patients had any immediate post-operative bleeding and 8 patients (6.8%) had minor post-operative bleeding that required a return to hospital for care. All these patients were managed conservatively by repacking the bleeding site and re-suturing. Our finding is in line with other published studies which highlighted that most post-operative bleeding in warfarinised patients tends to be minor in nature and can often be easily managed by simple local measures.[3,18,20,25-27]

Recently published work by Malden *et al*.,[28] showed an association between the degree of surgical intervention and the likelihood of anticoagulation being affected and they recommended that the post-operative INR in this group should be monitored carefully. Although the finding of our study is in agreement with the finding of Malden *et al*. as most of the patients who bled post-operatively had a much higher post-operative INR when compared with the pre-operative INR, our Unit does not recommend routine post-operative INR monitoring following MOS unless there is a clear indication.

Many reports highlighted the potential risk of post-operative bleeding which may result from drug interaction or the use of herbal remedies.[1,2,29] Many drugs, including non-steroidal analgesics and antibiotics, can interact with warfarin resulting in an alteration in anticoagulation activity and may contribute to an increase in post-operative bleeding.[1,29] According to our protocol, routine prescription of post-operative antibiotics is not practised unless there is a clear clinical indication. When a post-operative antibiotic is required, it is limited to oral amoxycillin for 3-5 days. Furthermore, our protocol for antibiotic prophylaxis has changed recently in accordance with the newly published clinical guidelines by the National Institute for Clinical Excellence, which ceased recommending routine antibiotic prophylaxis against infective endocarditis for dental procedures.[30] In addition, analgesics in form of paracetamol, compound paracetamol (co-codamol) or codeine phosphate are commonly prescribed and our patients are instructed to use them for up to 3 days and not to use other medications including non-steroidal analgaesics. All these measures are aimed to minimise possible interaction with warfarin. Furthermore, studies have shown that the use of herbal remedies, which are commonly used in our region, could be a common precipitating cause of post-operative bleeding in warfarinised patient.[1-2] To control this potential interaction, all our patients are screened and advised to avoid taking herbal remedies in the pre- and post-operative period.

Due to the limitation of the data available in this retrospective study, detailed analysis of the risk of post-operative bleeding was not possible and accordingly our Unit is now looking prospectively at risk factors of post-operative bleeding in warfarinised

patients undergoing MOS procedures.

Conclusion

Based on this retrospective study, our Unit protocol for the management of warfarinised patients undergoing MOS procedures in an outpatient setting is associated with a low risk of post-operative bleeding and our reported findings are in accordance with the available literature.[2,8,27,31-32] Furthermore, our study supports and recommends that warfarinised patients can safely undergo MOS procedures without alteration of their warfarin therapy when the pre-operative INR is ≤ 3.5. In addition, our study also stresses the importance of local haemostatic measures in preventing as well as managing post-operative bleeding following MOS procedures.

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CONFLICT OF INTEREST

The authors report no conflict of interest.

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