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Oral surgery in people with inherited bleeding disorder: A retrospective study

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Abstract

Introduction: The objectives were to describe the peri-operative management of people with inherited bleeding disorders in oral surgery and to investigate the association between type of surgery and risk of developing bleeding complications.

Materials and Methods: This retrospective observational study included patients with haemophilia A or B, von Willebrand disease, Glanzmann thrombasthenia or isolated coagulation factor deficiency such as afibrinogenemia who underwent osseous (third molar extraction, ortho-surgical traction, dental implant placement) or nonosseous oral surgery between 2014 and 2021 at Bordeaux University Hospital (France). Patients and oral surgery characteristics were retrieved from medical records. Odds ratio (OR) and 95% confidence interval (CI) were estimated using logistic regression.

Results: Of the 83 patients included, general anaesthesia was performed in 16%. Twelve had a bleeding complication (14.5%) including six after osseous surgery. The most serious complication was the appearance of anti-FVIII inhibitor in a patient with moderate haemophilia A. All bleeding complications were managed by a local treatment and factor injections where indicated. No association was observed between type of surgery (osseous vs. nonosseous) and risk of bleeding complications after controlling for sex, age, disease type and severity, multiple extractions, type of anaesthesia and use of fibrin glue (OR: 3.21, 95% CI: .69–14.88).

Conclusion: In this study, we have observed that bleeding complications after oral surgery in people with inherited bleeding disorders were moderately frequent and easily managed. However, in this study, we observed a serious complication highlighting the necessity of a thorough benefit-risk balance evaluation during the preoperative planning of the surgical and medical protocol.

KEYWORDS
dental extraction, dental implant, haemophilia, oral surgery, von Willebrand disease

1 | INTRODUCTION

Oral surgery procedures can lead to a moderate or high risk of postoperative bleeding, especially in patients treated with antithrombotic medications or those suffering from inherited bleeding disorders. 'Low-risk' procedures comprise scaling, simple dental extraction or single dental implant without bone grafting. Other procedures like multiple extractions, bone grafting, large cyst removal or gingival grafting could be defined as 'High-risk' for postoperative bleeding.[1,2]

Haemophilia A is an inherited deficiency of factor VIII (FVIII) and haemophilia B results from a deficiency in factor IX (FIX).[3] Its frequency ranges from 1/5000–1/30,000 (haemophilia B) new births in France. Factor VIII acts as a cofactor for factor IX to activate factor X. Once activated, factor X converts prothrombin to thrombin, which in turn converts fibrinogen to fibrin, resulting in blood clot formation. Haemophilia is classified as 'severe' if the total factor level is less than 1%, 'moderate' between 1%–5%, or 'mild' between 5%–30%.[4] Von Willebrand disease (VWD) is caused by deficiencies in Von Willebrand's factor, which plays a crucial role for platelets adhesion to subendothelium during vascular injury, and is essential for normal primary hemostasis.[5] Its prevalence in the general population is estimated .6%–1.3% but the symptomatic forms represent 1/10,000 patients in France.[6] Type 1 is a quantitative defect, type 2 is a qualitative defect and type 3 is characterised by undetectable von Willebrand factor. Von Willebrand disease, haemophilia A and haemophilia B account for 95%–97% of all coagulation deficiencies.[7] Glanzmann thrombasthenia (GT) is a rare platelet disorder, in which the platelets have qualitative or quantitative deficiencies of the fibrinogen receptor αIIbβ3. Most cases are hereditary, inherited in an autosomal recessive pattern, but acquired GT also occurs.[8] Finally, isolated factor deficiencies represent rare coagulation disorders, encountered in constitutional bleeding disorders, inherited abnormalities that occur when one or more clotting factors are absent or do not function properly, such as afibrinogenemia. Substitutive treatments (FVIII, FIX, VWF) and Desmopressin are used to prevent peri-operative bleeding, depending on disease severity, type of surgery and comorbidities of the patient.[5] The substitutive treatment is managed by the haematologist and requires a specific joined consultation to define the most appropriate surgical and medical protocol for each patient and each procedure.

Successful preventive treatment protocols for oral surgery procedures in these patients are described in the current literature using systemic treatment, antifibrinolytic agents and local haemostatic measures.[9] The most commonly accepted local haemostasis protocol includes the use of local anaesthesia with vasoconstrictor, haemostatic sponges, fibrin surgical glue and postoperative administration of antifibrinolytic agent (tranexamic acid).[2] This protocol is straightforward and applicable to any procedure with bleeding risk in oral surgery.

However, increased peri-operative bleeding remains the most frequent complication reported following oral surgery in this context. Previous studies have reported bleeding complications after oral surgery ranging from 2.9% to 35%, depending on the severity of the disease, the prophylactic and surgical protocol used.[3,10–17] The vast majority of these complications were minor and responded after local and/or systemic treatments. Finally, the most severe complication observed after dental extraction involved the development of inhibitors in patients with haemophilia.[3,15]

As the frequency of bleeding complications varies in the literature depending on the severity of the disease and the prophylactic and surgical protocol used, the main objective of this study was to describe the rate of complications observed in a group of people with inherited bleeding disorders who underwent various oral surgery procedures. The secondary objective was to investigate the association between type of surgery and risk of developing a bleeding complication.

2 | MATERIALS AND METHODS

2.1 | Study design and population

This study was a retrospective observational study conducted in the department of oral surgery at Bordeaux University Hospital (France). The patients included had haemophilia A, haemophilia B, von Willebrand disease (all subtypes), Glanzmann thrombasthenia or isolated coagulation factor deficiency; they had been treated with at least one invasive oral surgery procedure, between January 2014–March 2021. Invasive oral surgery was defined as extraction of temporary or permanent teeth (impacted or not), orthodontic surgery of impacted teeth or dental implant placement procedures. The interventions were performed under local or general anaesthesia.

Patients having other bleeding disorders or treated with antithrombotic drugs were excluded.

The medical files of the patients included in this retrospective study have been consulted after the agreement of the Research Ethics Committee of the University Hospital of Bordeaux, France (N°CER – BDX 2024 – 88). In accordance with French regulations, patients have given their consent for the use of their health data for research purpose.

2.2 | Surgical procedures and medical treatments

The surgical procedures were mostly performed at the beginning of the week to manage any bleeding complications in an outpatient modality. At the end of the surgical procedure, absorbable collagen sponges (Pangen®) and sutures were routinely placed in the surgical wound. Surgical fibrin glue (Tisseel® 2 mL) could also be used, but not routinely. This protocol, adopted in our unit, is not suitable for every practice setting, as the surgical fibrin glue is only available in hospitals in France. Patients were given standard postoperative advice (dental hygiene and food instructions), and tranexamic acid (Exacyl®1 g/10 mL solution) was prescribed, three times a day for 10 days. Paracetamol was mostly prescribed as analgesics (1 g, three times a day, for 2–5 days).

This local haemostasis protocol for pre and perioperative use was established in our oral surgery department. The medical substitute treatment was decided in collaboration with the department of haematology before surgery. Desmopressin (IV: Minirin® or nasal spray: Octim® was used for minor haemophilia A, nonsevere Type 1 VWD and some Type 2 VWD. In von Willebrand disease patients unresponsive to desmopressin or with contraindicated use, von Willebrand factor concentrate was used (Wilfactin®). The dosing regimen was a preoperative slow IV injection of 30–50 U/kg at H-1. Some patients received repeated injections every 12 h, from 1 to 4 times, at a dosage of 25–50 U/kg.

Patients with moderate or severe haemophilia A or nonresponders to desmopressin were treated with plasma-derived factor VIII concentrate (e.g., Factane®) or recombinant factor (e.g., Advate®). The dosage of the FVIII concentrate was a slow preoperative IV injection of 30–50 U/kg at H-1. The injections could be repeated postoperatively, every 12 h from 1 to 4 times, at a dosage of 30 U/kg. Patients with haemophilia B were treated with factor IX concentrate, either of plasmatic origin (e.g., Betafact®) or recombinant (e.g. Benefix®). The dosage of the FIX was a slow preoperative IV injection of 50–70 U/kg at H-1. The injections could be repeated postoperatively, every 12 h from 1 to 4 times, with a dosage of 30–50 U/kg.

2.3 | Data collection

The data collected in the medical records were: sex, age, disease type and severity, type of surgical intervention (osseous: third molar extraction, ortho-surgical traction and dental implant placement; vs. non osseous: simple/multiples dental extraction, periodontal procedure), number of extracted teeth, prophylactic treatment, type of anaesthesia (local/general), use of fibrin glue, the onset of a postoperative bleeding complication or other type of complications.

2.4 | Statistical analyses

Statistical analyses were performed with R software (version 4.1.2), and statistical significance was set at $p < .05$. For characterization of the sample, frequencies and percentages were reported for qualitative variables and medians, 1st and 3rd quartiles were reported for quantitative variables. Characteristics were compared according to the presence of a postoperative bleeding complication using chi-squared tests and Fisher's exact tests for qualitative variables and Wilcoxon rank sum tests for quantitative variables. Logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) for associations between patient or oral surgery characteristics and onset of a bleeding complication. Univariate analyses were performed for each characteristic potentially associated with postoperative bleeding complication. Then, a multivariate logistic regression model was applied to investigate association between type of surgery (osseous vs. nonosseous) and the risk of developing a bleeding complication while adjusting for sex, age, disease type, disease severity, multiple extractions (i.e., at least 2), type of anaesthesia and fibrin glue use. Missing data on disease severity (31%) were imputed using multiple imputation by chained equations (*mice* R package) as these data were missing completely at random (due to incomplete medical records).[18] The univariate and multivariate models that included disease severity as an explanatory variable were repeated using only complete cases for comparison with multiple imputation results.

3 | RESULTS

Eighty-three patients were included: 47 with haemophilia, 28 with von Willebrand disease and eight with another inherited bleeding disorder (isolated coagulation factor deficiency, afibrinogenemia, Glanzmann's thrombasthenia) (Table 1). Median age was 38 years (Q1: 22–Q3: 50.5) and 75% were men. Among these patients, 36% underwent an osseous surgery, 83% received fibrin glue and 16% had general anaesthesia. Osseous surgeries comprised wisdom teeth removal (24 patients), ortho-surgical traction (one patient) and dental implants (five patients, nine implants).

Twelve patients had a bleeding complication after surgery (14.5%), including four with haemophilia A, three with haemophilia B, three with VWD and two with GT. There were no statistically significant differences between patients' characteristics with and without postoperative bleeding complications (Table 1).

Of the 12 patients with postoperative bleeding complication, six undergone an osseous surgery. The surgical procedures followed by a bleeding complication ($N = 12$) were dental extraction ($N = 10$) including third molars extractions ($N = 3$); orthodontic surgical traction ($N = 1$); and implant placement ($N = 1$). A revision of the surgical site with curettage of the blood clot, placement of a haemostatic sponge (Pangen®), tight sutures and biological glue were performed. Exacyl® mouthwash was also prescribed. Depending on the patient, an additional injection of coagulation factor of desmopressin was administered. Postoperative monitoring 1 h after the procedure allowed to discharge the patient home, ensuring effective haemostasis. No relapse of local bleeding complication was observed in these patients.

The most serious complication was appearance of an anti-FVIII inhibitor in a patient with moderate haemophilia A, who underwent extraction of three third molars under general anaesthesia and received Factane® as a peri-operative treatment.

The univariate statistical analyses have not revealed any association between patient or oral surgery procedure characteristics and the onset of a bleeding complication.

The multivariate logistic regression model did not show any association between type of surgical procedure and risk of postoperative bleeding complications after controlling for sex, age, disease type, disease severity, multiple extractions, type of anaesthesia and use of fibrin glue (OR: 3.21, 95% CI: .69–14.88, $p < .134$) (Table 2). Similar results were found when analyses were performed on complete cases only.

TABLE 1 Characteristics of patients with inherited bleeding disorders who underwent oral surgery according to the presence of a postoperative bleeding complication. Department of Oral Surgery, Bordeaux University Hospital of (France), 2014–2021.

Characteristics	Overall (*N* = 83)	No bleeding complication (*N* = 71)	Bleeding complication (*N* = 12)	*p*[a]
Men	62 (75)	53 (75)	9 (75)	1.000
Age	38.0 [22.0–50.5]	39.0 [22.5–51.0]	37.5 [18.8–48.5]	.476
Disease type				.533
Haemophilia	47 (57)	40 (56)	7 (58)	
Willebrand	28 (34)	25 (35)	3 (25)	
Other	8 (10)	6 (8)	2 (17)	
Disease severity (26 m.d.)				.584
Severe	24 (29)	20 (28)	4 (33)	
Moderate	17 (20)	16 (23)	1 (8)	
Minor	16 (19)	13 (18)	3 (25)	
Type of surgery				.450
Non-osseous surgery	53 (64)	47 (66)	6 (50)	
Osseous surgery	30 (36)	24 (34)	6 (50)	
No. of extracted teeth	2.0 [1.0–3.0]	2.0 [1.0–3.5]	1.0 [1.0–2.2]	.266
Multiple extractions[b]	48 (58)	43 (61)	5 (42)	.220
Type of anaesthesia				.681
Local	70 (84)	59 (83)	11 (92)	
General	13 (16)	12 (17)	1 (8)	
Use of fibrin glue	69 (83)	60 (85)	9 (75)	.417
Infection following surgery	6 (7)	4 (6)	2 (17)	.207

Values in *N* (%) for qualitative variables; median [quartile 1–quartile 3] for quantitative variables.
Abbreviation: m.d., missing data.
[a]Chi-squared tests and Fisher's exact tests for qualitative variables; Wilcoxon rank sum tests for quantitative variables.
[b]At least two teeth extracted.

4 | DISCUSSION

This retrospective study focusing on the management of oral surgery in patients with inherited bleeding disorders has revealed a moderate number of bleeding complications (12/89; 14.5%), and all of them were managed in an outpatient protocol. Additionally, the type of surgery, whether osseus or not, was not associated with the risk of developing a bleeding complication.

Several retrospective studies have reported similar haemostatic protocols, including local anaesthesia with vasoconstrictor, haemostatic sponges, fibrin surgical glue and postoperative administration of antifibrinolytic agent (tranexamic acid), and they have found similar incidence of bleeding.[3,10–17] However, all these studies are difficult to compare as each of them had specificities: the distribution of patients and type of surgeries and the medical management of haemostasis varied from one study to another. However, our results are coherent with a recent literature review aiming to evaluate the effectiveness of factor replacement protocols in patients with haemophilia for dental extraction procedures: the authors reported that the overall postoperative bleeding rate was around 12% irrespective of the regimen of factor replacement therapy (both pre- and postoperative vs. single preoperative dose)[19]: they indicated that 'minimizing the use of clotting factor concentrate is possible if proper local haemostatic measures are provided'.

In our retrospective study, the complication rate was almost two times higher in 'osseous surgery' patients but it did not significantly differ depending on the type of oral surgery procedure, probably because of the limited sample size of the sample; however, this observation was in accordance with previous findings.[3] This result underlines the important role of factor substitution protocol and specific local surgical protocol, including thorough local haemostatic procedures. We have also confirmed that dental implant surgeries are possible in patients having inherited bleeding disorders with five successful cases. Previous case reports have illustrated such procedures in a patient with von Willebrand disease (immediate extraction-implantation) and in a patient with haemophilia A.[20,21] Another study documented a successful immediate extraction-implantation with bone grafting in a patient with severe haemophilia B.[22] Surprisingly, we have observed that none of the criteria that we previously selected to rank 'low-risk' or 'high-risk' procedures resulted in a statistical difference in the prevalence

TABLE 2 Association between patient or oral surgery characteristics and the onset of a bleeding complication in patients with inherited bleeding disorders ($N = 83$). Univariate logistic regression. Bordeaux Department of Oral Surgery, University Hospital of (France), 2014–2021.

Characteristics	OR	95% CI	*p*
Gender (men vs. women)	1.02	[.27–4.96]	.979
Age (for 10 years increase)	.86	[.59–1.21]	.387
Disease type			.618
Haemophilia vs. Willebrand	1.46	[.37–7.25]	
Haemophilia vs. other	.53	[.10–4.07]	
Willebrand vs. other	.36	[.05–3.19]	
Disease severity			.301
Moderate vs. minor	.17	[.02–1.64]	
Severe vs. minor	.74	[.18–2.96]	
Type of surgery (osseous surgery vs. non-osseous surgery)	1.96	[.56–6.90]	.286
No. of extracted teeth (for 1 unit increase)	.77	[.43–1.11]	.301
Multiple extractions[a] (yes vs. no)	.47	[.13–1.60]	.227
Type of anaesthesia (local vs. general)	2.24	[.38–42.82]	.461
Use of fibrin glue (no vs. yes)	1.82	[.36–7.29]	.421

Abbreviations: CI, confidence interval; OR, odds ratio.
[a]At least two teeth extracted.

of bleeding complications (osseous vs. non osseous surgery; number of teeth extracted; multiples extractions; postoperative infection): this suggests that the combination of the general treatment and local surgical procedures (haemostatic biomaterials, sutures…) is sufficient to prevent postoperative bleeding and that the procedure per se has a limited impact on the complication rate in this context. A systematic review of trials assessed the efficacy of anti-fibrinolytic agents to replace or reduce factor concentrate therapy but the authors could not reach a conclusion due to too many biases in the design of the studies included in the review.[23] Regarding fibrin glue, most of our patients were locally treated with this gel, so we could not evaluate its efficacy. It was shown before that fibrin glue could help to reduce the overall amount of coagulation factors used but this study was conducted in a limited number of patients.[24]

It is possible to obtain minimal rates of complications as shown by Goldman et al. in a case-control study: no difference was observed in this study regarding postoperative bleeding complications between a group of patients with haemophilia compared to a control group. The postoperative bleeding rate was 2.9% versus 1.4%, respectively, but all patients with haemophilia were treated in an inpatient modality with a level of factors > 50% during 3–4 days postoperatively.[17] The benefits of this procedure for patients should be weight against the high costs associated (hospitalization and factors) as most complications in oral surgery can be managed in an outpatient modality. Additionally, the development of immunoglobulins targeting factors VIII or IX following repeated administration of antihaemophiliac treatments must be considered. This complication occurs in 5%–10% of patients with minor haemophilia A, and can reach 35% in patients with severe haemophilia.[25] In our study, we have observed the development of inhibitors 3 months after removal of third molars in one patient. This complication has already been described in the literature in three patients.[15,3]

This study adds to the existing literature in favour of reducing the number of factor injections, as they represent an important cost, they increase the number and duration of hospitalization and the risk of severe complications. Most of our patients received a single preoperative injection of factor substitute or desmopressin, except patients with GT who systematically received several injections. The reasons for multiple injections were related to the duration and difficulty of the procedure, and also to the collaboration and the availability of the patient to return in the department of oral surgery in the case of complication. Previous reports have shown that it was possible to conduct oral surgery procedures with minimal or no coagulation factors administration. A systemic protocol in patients with haemophilia ($n = 77$) with a single preoperative injection associated with local haemostasis was proposed with no significant difference regarding bleeding complications compared with healthy patients ($n = 184$).[9] Moreover, in another study, out of 19 patients with haemophilia or von Willebrand disease who received local dressing (TachoComb®) with antifibrinolytic therapy alone for tooth extractions, two patients with haemophilia A and one patient with haemophilia B (15.7%) experienced a secondary bleeding.[26] In a case series, patients with haemophilia or von Willebrand disease received only local haemostasis measures and antifibrinolytics (tranexamic acid) and postoperative bleeding occurred in 20.5% of patients with severe haemophilia, 12.2% patients with moderate haemophilia and 6.1% patients with mild haemophilia.[16] All these complications were managed with factor administration and local haemostasis: this protocol allowed to reduce the overall use of coagulation factor therapy but it requires a specific follow-up of the patients.[16]

The main limitation of this study is the limited number of participants: this is due to the low prevalence of inherited bleeding disorders in the general population; this also explains the predominance of case reports in the literature.[12] The limited sample size may have induced lack of statistical power to detect the studied association. The retrospective design may also have induced a bias, as data were collected from medical records. Some data were missing but we were able to use multiple imputation to control for selection bias, and the complete cases analyses provided similar results. Finally, the multivariate analysis was adjusted for numerous confounding factors, although residual confounding may exist in this observational study.

In conclusion, we have observed a moderate rate of bleeding complications after oral surgery in patients with inherited bleeding disorder, including osseous surgeries such as dental implant placement. The bleeding complications were easily managed by a local treatment associated or not with factor injection. The serious complication caused by an anti-FVIII inhibitor in one patient is a reminder of the necessity to conduct a thorough benefit-risk balance evaluation during the planning of the surgical and medical protocol. The overall

prophylactic tendency is likely to decrease the amount and duration of coagulation factor substitution, and to focus on the local management of the surgical wounds using local haemostatic biomaterials and specific techniques of compression. Finally, even if the rate of complications can vary from one study to another, one important message to deliver to patients and their caregivers is that most oral surgery procedures are possible in these patients when an appropriate protocol is applied, and that the complications can be managed in an outpatient basis.

AUTHOR CONTRIBUTIONS

E. Fribourg: performed data collection and wrote the paper. **S. Castet**: provided and analysed data and revised manuscript. **M. Fénelon**: revised manuscript. **Y. Huguenin**: provided and analysed data and revised manuscript. **J.C. Fricain**: revised manuscript. **V. Chuy**: performed statistics and revised manuscript. **S. Catros**: performed data collection, wrote and revised manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors have no competing interests.

DATA AVAILABILITY STATEMENT

The data are available on request.

ETHICS STATEMENT

All patients included in this study have given their informed consent for the use of their medical data for this research.

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