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# Haemostatic management for oral surgery in patients supported with left ventricular assist device– a preliminary retrospective study

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#### Abstract

We investigated haemostatic management, frequency of postoperative bleeding, and prognosis of patients who had left ventricular assist devices, and who were having oral surgical procedures between April 2002 and March 2014, to identify risk factors for bleeding and find out which were the best methods of haemostasis. Medical records were examined retrospectively and we recorded details of the patients, and frequency of bleeding together with factors associated with it. Twenty-nine patients had 39 oral operations, and there were 17 bleeds (44%). The first procedure for each patient was used for statistical calculations. Duration of bleeding tended to be longer for patients with implantable devices (median (interquartile range, IQR) 12.0 (3-18) days) than for those with extracorporeal devices (median (IQR) 3.0 (1-4) days; p = 0.079). There was a significantly greater difference in prothrombin time-international normalised ratio (PT-INR) before and after operation in patients who bled, whose median (range) was 0.85 (0.2-1.81), than in those who did not (median (IQR) 0.16 (-0.09-0.31) (p = 0.015). There were moderate correlations with postoperative bleeding were seen for the difference between preoperative and postoperative PT-INR (r = 0.479, p = 0.012) and PT-INR value when bleeding (r = 0.407, p = 0.035). In conclusion, postoperative bleeding occurred after oral operations in 17/29 patients with left ventricular assist devices by a median (IQR) of 0.85 (0.2-1.81) of the preoperative value. © 2015 The British Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.

*Keywords:* Heart transplantation; Left ventricular assist device (LVAD); Surgical dental treatment; Postoperative haemorrhage; Prothrombin time-international normalised ratio (PT-INR)

## Introduction

A left ventricular assist device, which is a form of mechanical circulatory support, is useful as a bridge to recovery or to heart transplantation for patients with unresponsive severe heart failure.<sup>1</sup> Patients using a pulsatile extracorporeal device are susceptible to thromboembolism and require large doses of antithrombotic drugs (prothrombin time-international normalised ratio (PT-INR) > 3.5), which result in a higher risk of bleeding in the form of cerebral haemorrhage or bleeding from surgical wounds.<sup>1</sup> Recently, compact, non-pulsatile, implantable devices have become increasingly popular and are managed within a PT-INR  $\leq$  3.0, so there is an increasing need for dental management aimed at removing lesions of odontogenic infection during the period of use.<sup>2</sup>

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The current consensus is that minor oral surgery for patients on antithrombotic treatment can be done without reducing the warfarin dose if the PT-INR is  $\leq 3.5$ .<sup>3–5</sup> However, in a report about oral operations done for patients with such devices in place, over half developed bleeding or thromboembolism.<sup>6</sup> Unfortunately there is a waiting period of at least 2 years for heart transplantation in Japan, and dental treatment can become necessary during that time.<sup>7</sup> For patients with extracorporeal devices who are taking high doses of anticoagulants, haemostatic management during oral surgery may be too difficult with the usual standard techniques, and alternative methods are required.<sup>8,9</sup> There is also a lack of evidence about appropriate methods for the management of haemostasis during oral operations in patients with left ventricular assist devices.

The purpose of this retrospective study was to investigate haemostatic management and prognosis in these patients, to identify risk factors for bleeding, and to find out which are the most effective methods of haemostasis.

#### **Patients and methods**

We studied the records of 29 patients who had 39 oral operations at the National Cerebral and Cardiovascular Centre and who were being given circulatory support with left ventricular assist devices between April 2002 and March 2014.

We recorded their age and sex, cardiac disease, dose of antithrombotic drugs, number of teeth extracted, number of teeth that required operative treatment (impacted tooth extraction, excision of a radicular cyst and apicectomy, sequestrectomy, or flap), frequency of postoperative bleeding, timing of the start and end of the bleed and its duration, preoperative PT-INR, PT-INR during treatment, PT-INR during the bleed, difference between PT-INR before and after operation, management of antithrombotic drugs (no intervention compared with intervention), and type of assist device(extracorporeal or implantable). The difference between PT-INR values before and after operation was calculated using the median of PT-INR values for 3 weeks before the procedure (usually measured every 2-3 days) as the preoperative value. PT-INR during the bleed was used as the postoperative value for patients with haemorrhage, and the maximum PT-INR during the 3 weeks after the procedure for patients who did not bleed. All patients who were taking aspirin continued to take it. For patients with preoperative PT-INR > 3.0, treatment was changed to low molecular weight heparin or prothrombin complex concentrate while the dose of warfarin was reduced (intervention group). Patients with preoperative PT-INR  $\leq$  3.0 continued to take their regular dose of warfarin (non-intervention group). The methods for giving heparin and prothrombin complex concentrate have been described in detail elsewhere.<sup>8,9</sup>

If a tooth was acutely inflamed antimicrobial drugs were given for about a week to prevent infective endocarditis according to the Japanese guidelines.<sup>10</sup> The procedure was then done after the acute symptoms had subsided.

The same oral surgeon did all the operations. The local anaesthesia used was 3% prilocaine (containing felypressin 0.054 IU, Dentsply-Sankin, Tokyo, Japan). Bleeding points in soft tissue were treated with electrocautery, the wounds were packed with oxidised cellulose (Surgicel<sup>TM</sup>; Ethicon; Somerville, NJ), and horizontal mattress sutures of 4/0 silk were then inserted. For a flap, the gingiva was incised and the periodontal flaps reflected before scaling, root planing, or curettage of inflammatory granulation tissue. For local haemostasis, we inserted Surgicel<sup>TM</sup>, and the flaps were sutured with 4/0 silk. The patient then bit down on gauze for 30 minutes for compression. Splints were used to protect open wounds after extraction of erupted teeth except when the wound was closed completely, as was the case for two patients taking aspirin alone. The sutures and splints were removed a week later. However, removal of sutures was postponed for up to 2 weeks if the patient had bled within the first postoperative week. If patients had several procedures, and had bled postoperatively on the first occasion, we used less invasive techniques, stricter haemostasis, and more stringent postoperative control of PT-INR for subsequent procedures.

Acetaminophen 200-400 mg, 1-3 times/day, or a tablet of combined acetaminophen 325 mg and tramadol hydrochloride 37.5 mg (1-2 tablets/day; Tramacet<sup>®</sup> Combination Tablets; Janssen Pharma, Tokyo, Japan) were given when necessary for analgesia.

The criteria for postoperative bleeding were either oozing that could be stopped by biting on gauze to apply pressure, or oozing or pronounced bleeding that could not be stopped with pressure and required intervention by the oral surgeon. Bleeding was assessed from 30 minutes after extraction of the tooth until 3 weeks later. All patients' platelet counts were kept at  $\geq 400 \times 10^{9/}$ L.

We used SPSS version 16.0 software (SPSS Japan, Tokyo, Japan) to assist with the statistical analysis, and data are expressed as median (interquartile range, IQR). We made statistical comparisons between the groups at the time of each patient's first procedure. The Mann-Whitney U test was used to assess the significance of differences between groups, and Spearman's rank correlation coefficient was used to assess correlations between variables and postoperative bleeding. Probabilities of less than 0.05 were accepted as significant.

The analyses in the present study included patients who had teeth extracted while taking low molecular weight heparin (dalteparin) and prothrombin complex concentrate as described previously.<sup>8,9</sup>

### Results

We did a total of 39 oral operations for 29 patients with a median age of 39 (range 16-59) years (Table 1). The procedures comprised 35 extractions (50 teeth), 1 excision of a radicular cyst and apicectomy (2 teeth), 2 flap operations (5

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