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Suggestions for individual risk assessment model and prevention

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Thrombosis prophylaxis for Oral and Maxillofacial surgery patients under general anaesthesia. Suggestions for individual risk assessment model and prevention

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ABSTRACT

Deep vein thrombosis (DVT) and pulmonary embolism (PE), known as venous thromboembolism (VTE), are the most preventable causes of death in surgical patients. About 10% of patients with symptomatic PE die within 60 min. Surgery, immobility, pregnancy and cancer are the most common causes, yet in 40% of cases VTE presents in previously healthy individuals with no medical history.

VTE is related to patient- and procedure-specific risk factors including postoperative ambulation and risk of bleeding. Screening for individual risk factors to tailor the use of anticoagulant prophylaxis is recognised, but the cut-off point for its usage varies between the surgical specialties depending on the bleeding risk.

At present, there are no national or international guidelines for VTE-prophylaxis in Oral and Maxillofacial surgery (OMS). The current guidelines for VTE are based on guidelines from the neighbouring specialties such as Ear, Nose and Throat Surgery and Plastic Surgery. This is flawed because the degree of patient- and procedure-specific risks for these patients is often higher than those encountered in OMS.

The article addresses this dilemma. A proposal of risk assessment and thrombosis prophylaxis in OMS surgery is presented. Mechanical thromboprophylaxis alone or in combination with low-molecular-weight heparin (e.g., Dalteparin (Fragmin®) is advocated.

Further studies within OMS are warranted.

1. Introduction

Venous thromboembolism (VTE) is the collective term for deep venous thrombosis (DVT) and pulmonary embolism (PE), and it is the most preventable cause of death amongst surgical patients [1,2]. Cancer, pregnancy, immobilisation, and recent surgery are the most common predisposing factors. In Denmark, the annual incidence of PE is approx. 3500 cases and approx. 80% are due to DVT in the pelvis/lower extremities but only 15% are symptomatic [1]. About 40% of VTE cases occur in previously healthy adults with no known risk factors. Untreated PE has a 30-day mortality rate of 30%, mainly within the first few days [1].

In Denmark OMS treatment under general anaesthesia (GA) is performed by general dental practitioners at clinics for Special Needs and in private and public hospitals. At present, there are no national nor international OMS guidelines for VTE prophylaxis. The VTE incidence in OMS is unknown, but is regarded as low (0.2-1.6%) compared with 30 – 90% amongst other specialties (urological, gynaecological, abdominal and orthopaedic surgery) [3,4]. A plausible explanation is that studies within OMS are difficult to compare. Some studies focus on specific procedures, e.g., orthognathic surgery, which predominantly has a target population of healthy young individuals, as opposed to head and neck cancer surgery, which is associated with an increased risk of VTE [5,6]. Other studies focus on various types of minor dentoalveolar surgical procedures with fewer patient specific risk factors (see later) (Fig. 1) [3,6]. Furthermore, the difference in the length of postoperative follow-up is of importance since the shorter the VTE follow-up the fewer reported cases.

Apart from the known surgical risks associated with a given OMS procedure under GA, the aim of this article is to demonstrate ways to reduce the incidence of VTE:

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1) Thorough medical history and individual VTE-risk assessment for all patients undergoing an OMS procedure under GA, with the patient's and the family's VTE history being the greatest predictive risk factor for VTE.
2) Mechanical thromboprophylaxis i.e., thrombo-embolus deterrent (TED) stockings alone or in combination with medical thromboprophylaxis in accordance with the patient's risk profile.
3) Change of dosage administration or postponement of the thromboprophylaxis to the postoperative phase in cases with greater risk of bleeding.
4) Adjust the length of thromboprophylaxis in accordance with any postoperative changes to the patient's risk profile (e.g., infection/immobilisation) during hospitalisation and on discharge.

Understanding the limitations that accompany lack of evidence, a proposal for risk assessment and thrombosis prophylaxis in OMS is presented (Fig. 1).

2. Risk factors for VTE

The Caprini Risk Assessment Model (CRAM) is the most recognised tool for identifying patients at high- or low-risk of VTE amongst medical and surgical patients irrespective of the type of surgery. Since 1991 the model has been updated in 2005, 2013 and 2019 [7]. The model consists of 39 questions, divided into four groups, of which each group represents a score (5 points = "*very high-risk*", 3 points = "*high-risk*", 2 points = "*moderate-risk*" and 1 point = "*low-risk*") corresponding to the individual group's predictive value for VTE (odds ratio). For women there is an additional obstetric group with a score of 1 point.

The accumulated point score defines the patient's risk of VTE as low, moderate, high or the highest risk. One low-risk factor cannot support the indication for thrombosis prophylaxis (low predictive value) but the accumulated effect of several low-risk factors can. The reliability of the evidence for the specific risk factors for VTE has been vigorously tested in conjunction with a 30 day incidence of VTE. An additional 6 risk factors for VTE exist (*Body Mass Index (BMI) >40, smoking, type 1-diabetes (IDDM), chemotherapy, blood transfusion, operating time >2 h*) but have not been tested in clinical studies [8,9].

A good correlation between the clinician's score and the patient's own score has been shown [7]. Critics of Caprini, however, stress the complexity of the protocol.

3. Risk of VTE in OMS: a review of the literature

At present, there are no national or international guidelines for risk stratification or VTE prophylaxis for OMS. Many previous studies are retrospective and focus on a range of surgical procedures using variable protocols assessing different risk factors; some include both mechanical and medical thrombosis prophylaxis, others do not. In addition, the patient population is heterogeneous with different risk profiles and VTE detection protocols which makes comparisons between these studies very complicated.

In a retrospective study, Forouzanfar et al. investigated the incidence and risk factors for VTE in 411 patients, who underwent various OMS procedures: dentoalveolar, reconstructive, orthognathic, gland and temporomandibular joint surgery. Thromboembolic prophylaxis was omitted [3]. VTE risk classification was according to Geerts et al. [9]. The VTE detection period was 53 days. The incidence of VTE was 0.5%. BMI and hospital stay were risk factors for VTE. Thromboembolism prophylaxis was concluded as justifiable if obvious risk factors were present.

Skorpil et al. retrospectively investigated 479 facial traumas all treated without mechanical or medical thromboprophylaxis [10]. All patients were classified according to Geerts et al. [9]. Follow-up took place at least once weekly for 6 weeks and after 3 and 6 months. VTE incidence was 2%. Correlation was shown between length of operation and VTE. It was concluded that high-risk patients only (elderly, previous VTE history, overweight, cancer) need antithrombotic prophylaxis.

In a retrospective systematic review of the incidence of VTE amongst orthognathic surgery patients, Kent et al. compared the prevalence of thrombosis and haemorrhage having divided the population into two groups, of which only one group was administered medical thromboprophylaxis [5]. The incidence of VTE was 0% for the thromboprophylaxis group versus 0.2% for the non-prophylaxis group. Reoperation following haemorrhage occurred in 2.7% in the thromboprophylaxis group versus 0.6% in the non-prophylaxis group. The authors emphasise the lack of comparable studies due to heterogeneity of the treatment

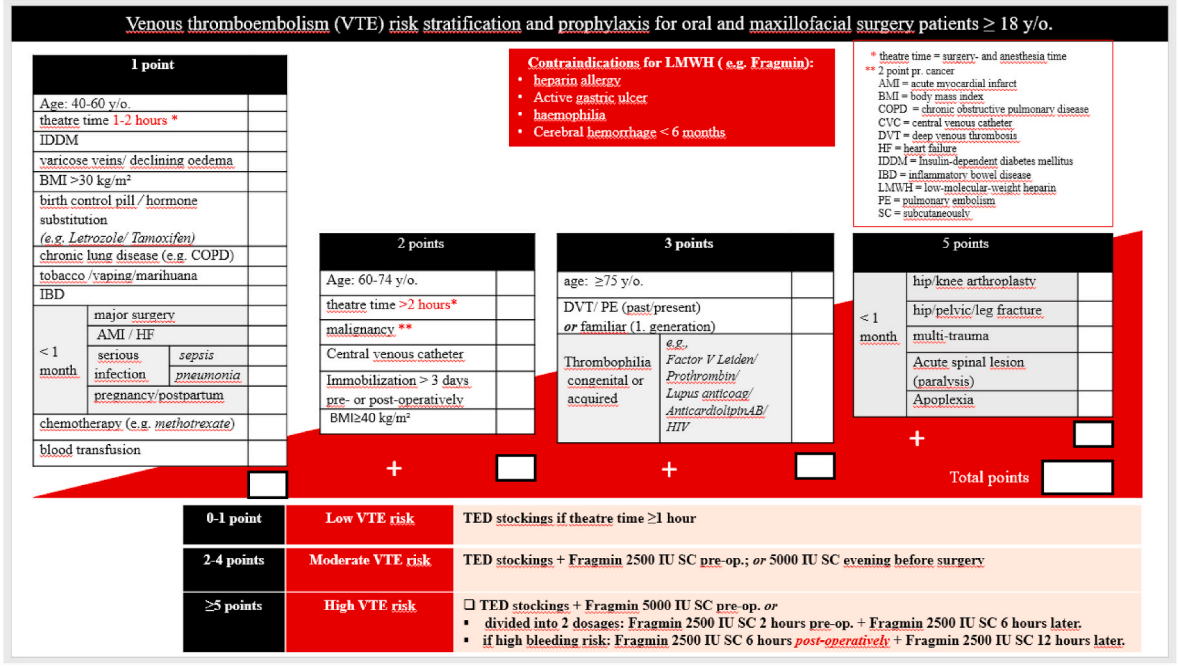

Fig. 1. Proposal for VTE Algorithm for Oral Surgery Patients ≥18 years old under General Anaesthesia.

protocols: incomplete documentation for the use of TED stockings/mechanical compression devises, incomplete mobilisation protocols and indications for reoperation. VTE detection was also very variable: low in studies with no routine follow-up and higher among routinely screened patients.

4. Risk factors for VTE in head-and-neck cancer surgery

Cancer patients have a two-fold risk of haemorrhage and a four-fold risk of DVT due to drug related interactions and varied drug absorption [1]. Regarding the type of cancer, Cramer noted an 11-fold increased risk of VTE in cancer of the airway and digestive system, compared to thyroid cancer [11]. As of yet, no risk stratification can distinguish between types of malignancies [12].

Despite a high incidence of VTE in cancer surgery and the general recommendations from the American Society of Clinical Oncology (ASCO), many authors apply a conservative approach to medical thromboprophylaxis in head and neck surgery in order to minimise the post-operative complications (haematoma) [6]. Some authors have noted that the VTE risk in head and neck cancer surgery is less than expected compared to other types of cancer surgery, possibly because the dissection is superficial and patients are quickly mobilised [6,12]. The use of TED-stockings and venous duplex ultrasonography (VDUS) for VTE detection has been advocated [6,13].

Kakei et al. examined the incidence of VTE and high-risk factors in a retrospective study of oral cancer resection with immediate reconstruction without thromboprophylaxis. TED-stockings were used perioperatively and until mobilisation. Routine VDUS was performed 2 days postoperatively and on follow-up 30 days after discharge. VTE was present in 26.3% (LE 2.3%, DVT 24%), but the high incidence was attributed to predominantly asymptomatic emboli. The only risk factor for VTE was a high Caprini score. Routine VDUS, especially of the high risk patients (risk score around 8), and swift mobilisation were recommended [6].

In a prospective single-centre study comprising 89 plastic surgery patients undergoing heterogeneous procedures, including cancer treatments and a zygoma fracture without VTE prophylaxis, Yago et al. advocate a pneumatic compression device and graduated thigh-high compression stockings during and after surgery, in addition to repeat duplex ultrasound scans on the second and seventh postoperative days [13]. Asymptomatic DVT was present in 8% (7 patients) including the zygoma fracture and amongst the skin transplant patients previously considered low-risk patients. A Caprini score $\geq$7 was independently associated with postoperative DVT and could predict postoperative VTE-complications. Intraoperative VDUS was recommended as a cheap and fast diagnostic tool.

In a review from 2018 Cramer et al. present an evidence based guideline to reduce VTE in Ear, Nose, and Throat (ENT) surgery due to lack of guidelines from the American College of Chest Physicians (ACCP) [12]. CRAM identified patients with high risk of VTE irrespective of the surgical procedure and the authors recommend double prophylaxis for all patients with a Caprini score $\geq$7. For a Caprini score of 5–6 the recommendation is either double prophylaxis or mechanical prophylaxis only, depending on the operation, the length of hospitalisation or immobilisation. For a Caprini score $\leq$4 only mechanical prophylaxis is recommended.

5. Discussion: OMS and VTE-risk factors

VTE is the most preventable cause of death in surgical patients [13]. A European study by Agnelli et al., in 2006 revealed that circa 75% of all VTE related deaths can be traced back to a previous hospital admission [2]. Should the patient survive, the complications and reduced quality of life for both patient and relatives are severe (e.g., chronic pulmonary hypertension, lymphedema, post thrombotic syndrome (incidence 20–50%)). Furthermore, a 25% risk of recurrence over 10 years [13].

The implementation of thromboprophylaxis (medical and mechanical) is reflected by the multitude of different surgical procedures and bleeding, complications which ultimately can lead to blood transfusion, reduced joint mobility, haematoma, dehiscence, infection, and delayed healing. The ACCP has published guidelines with recommendations for selected surgical specialties, none of which include OMS or ENT surgery [12].

The cut-off "score" for initiating medical antithrombotic prophylaxis is very variable depending on the surgical specialty in question. Since the risk of VTE is determined by patient specific risk factors, the surgical procedure and bleeding risk, the VTE recommendations should be defined by evidence-based clinical trials within the appropriate surgical specialty. According to Krauss et al. a risk score $\geq$10 defines the high risk group for VTE amongst hip replacement patients, whereas Gould defines the high risk group for VTE amongst general surgery patients as a score $\geq$5 [14,15]. Cramer argues a risk score $\geq$7 defines high risk amongst ENT patients advocating both medical and mechanical thromboprophylaxis, whereas a score of 5–6 is a "grey zone" meaning either mechanical or medical thromboprophylaxis, which depends on the bleeding risk of the surgical procedure [12].

6. Suggestions for thromboprophylaxis

Fig. 1 is an algorithm for risk stratification and thromboprophylaxis for OMS patients $\geq$18 years old, the purpose of which is to minimise the risk of VTE and easily apply in a clinical setting. The evidence, however, is inconclusive, based partly on OMS publications and those from the neighbouring specialties, i.e. ENT cancer surgery and plastic surgery combined with an adaptation of CRAM [3,5,7,12].

The details for each of the 39 risk factors are well described by Golemi [7]. Several of the risk factors are grouped under "headings" with "examples" in the algorithm to sharpen the attention of the reader. TED stockings only are recommended for procedures $\geq$1 h and are first discontinued upon mobilisation or discharge [16].

Guidelines regarding the *timing* of thromboprophylaxis is controversial. References are made to low molecular heparin (LMH), in particular Dalteparin (Fragmin®), because it is well documented/proven (other LMHs can be used, but due to differences in the molecular weight profile of these drugs, the dosages mentioned in the algorithm are only applicable to Fragmin®).

No studies within the field of OMS correlate the initiation of Fragmin® with its efficacy and safety (bleeding). It is not proven that preoperative or intraoperative initiation of Fragmin® is superior to postoperative prophylaxis [17]. Following major orthopaedic surgery, Raskob and Hirsh found no improved effect, but rather a greater risk of haemorrhage if LWH was initiated <2 h preoperatively. Postoperative initiation of antithrombotic prophylaxis had an improved effect, with no increased bleeding, if given 6 h postoperatively [17].

Exempt to the above is the group of "Day Cases" (see below), which at our hospital constitutes patients who are not admitted but attend the Day Case Unit 30 min before surgery. Following the procedure under general anaesthesia (1–2 h) and a few hours in recovery, the patients are discharged. VTE prophylaxis either 2 h before or 6 h after surgery is not logistically feasible. The patients are selected with reference to their medical history and the

low-risk surgical procedures. Any increased bleeding per- or postoperatively, which may follow the initiation of VTE prophylaxis given less than 30 min prior to surgery, is accepted and managed with standard procedures.

6.1. *Low-risk of VTE: 0–1 point*

According to Caprini the "anaesthesia time" is included in the "surgery time" since the risk of VTE commences on induction.

In the algorithm, surgery time for low risk VTE is <1 h without prophylaxis as opposed to Caprini's 45 min, since the OMS procedures

are regarded as less surgically traumatic compared to the procedures which inspired CRAM.

Mechanical thromboprophylaxis is recommended if surgery is ≥ 1 h.

6.2. *Medium-risk of VTE: 2–4 points*

Dual thromboprophylaxis is recommended.

Timing for Fragmin® (2500 IU) administration:

If day case: give 2500 IU SC preoperatively.

If admitted: give 2500 IU SC 2 h preoperatively; alternatively, give 5000 IU SC the evening prior to surgery.

6.3. *High-risk of VTE: ≥ 5 points*

Caprini's "high" and "highest" risk groups have been merged into one.

Dual thromboprophylaxis is recommended.

Several authors claim the greatest effect of dual thromboprophylaxis is for a risk score of 7–8 (i.e., balance between VTE and bleeding). However, as these procedures are regarded as more comprehensive with a higher bleeding risk than OMS procedures, the "cut-off score" for VTE prophylaxis has empirically been "reduced" to 5 [8,13].

Timing for Fragmin® (5000 IU) administration:

If day case: give 5000 IU SC preoperatively.

If admitted: divide dosage into 2 dosages of 2500 IU: dosage is given 2 h preoperatively and 6 h later.

If greater bleeding risk: give 2500 IU 6 h *postoperatively* and the remaining 2500 IU 12 h later (18 h postoperatively). Fragmin® is discontinued upon full mobilisation [17].

6.4. *Contraindications*

For LMH: Heparin allergy, peptic ulcer, cerebral apoplexy within the last 6 months, severe hypertension, and haemorrhagic diathesis.

For TED stockings: Severe arterial insufficiency, weak/absent foot pulses [16].

6.5. *Use of VDUS*

Only for selected cases, e.g., cancer patients. The incidence of VTE on autopsy of cancer patients is 50%, but only 4–20% are diagnosed or become symptomatic [4].

7. Conclusion

CRAM is a well-recognised tool to identify patients with an increased risk of VTE during surgery under GA. Furthermore, it identifies those patients with a minimal risk of VTE, provided the risk of VTE is less than the risk of bleeding during antithrombotic treatment.

There are, however, no national or international guidelines for VTE prophylaxis for OMS. Blindly applying VTE guidelines from neighbouring specialties to OMS incorporates a flaw because the congruence of patient-and procedure-specific risks are seemingly similar but not identical to those encountered in OMS. The cut-off score for advocating medical VTE prophylaxis in OMS is therefore uncertain and unproven.

We have presented an algorithm based on CRAM with recommendations for mechanical and medical VTE prophylaxis as a guideline for further studies within the OMS specialty.

Ethics statement/confirmation of patient permission

Not applicable.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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