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Regular Article

Assessment of the risk of bleeding in patients undergoing surgery or invasive procedures: Guidelines of the Italian Society for Haemostasis and Thrombosis (SISET)

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ABSTRACT

Synopsis of recommendations: The Italian Society for Thrombosis and Haemostasis (SISET: Società Italiana per lo Studio dell' Emostasi e della Trombosi) promoted the development of a series of guidelines which would adopt evidence-based medicine methodology on clinically relevant problems in the field of haemostasis and thrombosis. The objective of the present guidelines is to provide recommendations for the pre-operative and pre-procedural assessment of the bleeding risk with the aim of reducing the incidence of preventable bleeding complications and limiting laboratory tests to the those necessary.

The predictive value of haemostatic tests for bleeding complications after surgery or invasive procedures has been evaluated in prospective or retrospective cohort studies only. All retrieved studies were of low methodological quality with a high potential for bias because none conducted a blinded outcome assessment. In addition, different criteria for the severity of bleeding events and different reference values of the laboratory tests were adopted. The low methodological quality limits the validity of the results of these studies. Some of the clinical queries proposed by the working group were not addressed by the studies available in the literature. The areas with evidence, although of low quality, are the following: general surgery in adults (for history, PT, APTT, platelet count and bleeding time), neurosurgery in adults (for history, PT, APTT, platelet count), adenotonsillectomy in children (for history, PT, APTT, platelet count and bleeding time), invasive procedures in adults (for PT, APTT, platelet count), dental extractions (for the bleeding time only), cataract extraction (for platelet count). No studies are available in children for major surgery other than adenotonsillectomy, neurosurgery and invasive procedures.

1-All recommendations by the multidisciplinary working group (MWG) are of grade D, as they are derived from expert consensus obtained with the RAND corporation method. The following criteria were considered for each consensus: prudential attitude for the necessity of a baseline value in case of subsequent unexpected abnormal bleeding, possibility to detect bleeding disorders especially in children.
2-The MWG recommended that a detailed personal and family history for bleeding, preferably with locally designed structured questionnaires, and physical examination should be considered good practice procedures before any surgical or invasive intervention.
3-The MWG consistently recommended that PT, APTT and platelet count should be performed routinely before surgery or invasive procedures (except for diagnostic endoscopies) both in adults and children even

Abbreviations: PT, prothrombin time; APTT, activated partial thromboplastin time; TEG, thromboelastography; PFA-100, Platelet Function Analyzer -100; NICE, National Institute of Clinical Excellence.

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in case of a negative history of bleeding. This recommendation differs from those of previously published guidelines which did not recommend pre-operative haemostatic tests in subjects with a negative history of bleeding, although with a grade C. The MWG of this guideline ascribed a relatively higher value to preventing bleeding events and a relatively limited value to cost.

4-The MWG consistently recommended that the bleeding time, plasma fibrinogen, PFA –100, thromboelastography and platelet aggregation tests should not be performed routinely before surgery or invasive procedures either in adults or children with a negative history of bleeding.

Introduction and objectives

Background

Surgery and invasive procedures can be associated with abnormal bleeding which is influenced by both patient related factors and type of intervention. The prevalence of acquired and congenital disorders predisposing to bleeding is uncertain, due to non-uniform diagnostic criteria, especially for mild, clinically silent forms, and the variability among different ethnic groups. Interventions can be associated with severe bleeding complications both in relation to their type (e.g., after adeno-tonsillectomy) and their clinical consequences (e.g., after endo-ocular surgery or neurosurgery or spinal or peridural anaesthesia).

The risk of bleeding is usually assessed by eliciting the personal and family history for abnormal bleedings, and performing laboratory tests that explore hemostatic functions. These laboratory tests generally include the prothrombin time (PT), the activated partial thromboplastin time (APTT), the platelet count, the bleeding time and, more rarely, PFA-100 closure time, thromboelastography and platelet aggregation tests. However, the choice and interpretation of these tests and the clinical management of patients with abnormal results is highly variable. The appropriate choice of laboratory tests requires an accurate assessment of the clinical situation, the evaluation of the prevalence of bleeding disorders, the test characteristics, the cost and the consequences of false-positive and false-negative results.

The accuracy of the aforementioned approach may be unsatisfactory, as the frequency of self-reported bleeding episodes may vary between 5% and 30% in the general population [1], and because the frequency of false-positive results of laboratory tests may be rather high. For instance, the finding of prolonged APTT is not uncommon due to the presence of anti-phospholipid antibodies or to FXII deficiency, which interfere with the in vitro test but are not associated with an increased risk of bleeding *in vivo*. An additional problem is the variability of the haemostatic tests, due to the lack of standardization for some of them (e.g APTT, bleeding time).

A systematic review of the literature evaluated the usefulness of pre-operative laboratory tests, including tests of haemostasis, before elective surgery in patients without a positive personal history for abnormal bleeding [2]. The reported frequency of altered haemostatic tests was variable and their clinical relevance appeared uncertain as the patient clinical management was changed in very few instances. The review concluded that the benefit of pre-operative tests in individuals without a positive history for abnormal bleeding is uncertain [2].

Evidence based guidelines on the use of pre-operative tests before elective surgery have been published by the National Institute for Clinical Excellence (NICE), a government organization in the United Kingdom, in 2003 [3]. The recommendations were based on expert consensus only, due to the scarcity of adequate evidence in the literature. Haemostatic tests, such as PT and APTT, were not recommended either in adults or children because of their low predictive value, except in the presence of personal or family history of abnormal bleeding. In adults, the use of haemostatic tests was suggested, but not recommended, only in patients with ASA (American Society of Anaesthesiology) grade 3 (i.e., with serious but not life-threatening systemic diseases) with kidney disease undergoing minor surgery, intermediate or major surgery and in ASA grade 3 patients with cardiovascular disease undergoing major surgery. In addition, the NICE suggested, but did not recommend, the use of haemostatic tests in case of cardiac surgery or neurosurgery both in children and adults. Platelet count was recommended in case of intermediate or major surgery in all subjects except than in subjects younger than 16 years of age undergoing intermediate or minor surgery and in subjects older than 60 years undergoing minor surgery. In the remaining cases, the platelet count was the only test suggested. The NICE guidelines concluded that the lack of evidence of the benefits of pre-operative tests limited the strength of recommendations, which were based on a consensus among the panel participants.

More recently, the British Committee for Standards in Haematology has published guidelines on the assessment of bleeding risk prior to surgery or invasive procedures [4]. On the basis of a literature review indicating a poor predictive value of pre-operative hemostatic tests, their recommendation is that patients with a negative bleeding history do not require routine coagulation screening prior to surgery. However, due to the lack of adequate studies, their recommendation is of grade C. Moreover, recommendations should take into account the cultural and social context in which they may be implemented. Accordingly, in the absence of any evidence against pre-operative hemostatic tests, any decision about their performance should take into account the necessity of baseline tests in case of unexpected peri- or post-operative bleeding complications, even in case of a negative personal and family history for bleeding.

The objective of the present guidelines is to provide recommendations to all those involved in the pre-operative or pre-procedural care (both hospital staff and general practitioners) with the aim of reducing the incidence of preventable bleeding complications and limiting laboratory tests to the bare necessary. The expected benefits of implementation of the guidelines is the reduction of complications, length of hospital stay, request of consultations or additional haemostatic tests, use of inappropriate testing, with the potential consequence of erroneously considering at risk of bleeding normal subjects, and postponing surgical or other invasive procedures.

Material and methods

The guidelines were issued following a predefined methodology defined by the SISET Guidelines program steering group and approved by the SISET Executive Committee. Details on the methodology are published elsewhere. A full description of the methods has been published [5].

Evidence and recommendations

Bleeding history and physical examination

Background

Patient history and physical examination are essential parts of the pre-operative or pre-procedural evaluation of the bleeding risk. Structured questionnaires have been recommended for eliciting the relevant elements of patient history with the aim of determining