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Guidelines

Perioperative Patient Blood Management (excluding obstetrics): Guidelines from the French National Authority for Health

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ABSTRACT

The French National Authority for Health (HAS) recently issued guidelines for patient blood management (PBM) in surgical procedures. These recommendations are based on three usual pillars of PBM: optimizing red cell mass, minimizing blood loss and optimizing anemia tolerance. In the preoperative period, these guidelines recommend detecting anemia and iron deficiency and taking corrective measures well in advance of surgery, when possible, in case of surgery with moderate to high bleeding risk or known preoperative anemia. In the intraoperative period, the use of tranexamic acid and some surgical techniques are recommended to limit bleeding in case of high bleeding risk or in case of hemorrhage, and the use of cell salvage is recommended in some surgeries with a major risk of transfusion. In the postoperative period, the limitation of blood samples is recommended but the

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monitoring of postoperative anemia must be carried out and may lead to corrective measures (intravenous iron in particular) or more precise diagnostic assessment of this anemia. A "restrictive" transfusion threshold considering comorbidities and, most importantly, the tolerance of the patient is recommended postoperatively. The implementation of a strategy and a program for patient blood management is recommended throughout the perioperative period in healthcare establishments in order to reduce blood transfusion and length of stay. This article presents an English translation of the HAS recommendations and a summary of the rationale underlying these recommendations.

1. Introduction

Patient blood management (PBM) refers to strategies implemented pre-, intra- and postoperatively to prevent, detect and manage anemia (and/or iron deficiency) and bleeding, while limiting the need for transfusion [1,2]. Perioperative bleeding may aggravate or be responsible for anemia, which is an independent risk factor for morbidity and mortality [3–5]. Frequently performed in the most anemic patients in surgical settings, transfusion may itself be an independent factor of mortality and morbidity, regardless of the patient's hemoglobin (Hb) levels and comorbidities [5,6]. There is therefore a double need to correct or limit perioperative anemia when surgeries are at risk of bleeding, and to avoid or limit the use of transfusion during this period. PBM is now recommended by a large number of medical authorities in various countries and specialties, including the World Health Organization [2].

Three pillars are classically presented, which are the three main objectives of perioperative PBM programs:

- Optimization of red cell mass
- Minimization of blood loss
- Optimization of anemia tolerance.

Perioperative PBM programs are recommended for all surgeries at risk of bleeding, with measures adapted to the procedure and to the patient. In September 2022, the French National Authority for Health (HAS) published recommendations covering all aspects of perioperative PBM [7]. This article presents an English translation of the HAS recommendations (with the exception of those concerning PBM in obstetrics and how to implement a PBM program) (Table 1) and a summary of the rationale underlying these recommendations. The full text of the rationale is available in French on the HAS website (www.has-sante.fr).

2. Methods

Several international recommendations on PBM have been published in recent years. In view of the absence of French recommendations on this topic, and given the major public health (decrease in morbidity and mortality) and economic (lower consumption of blood products) potential implications, the French Society of Anesthesia and Intensive Care Medicine (SFAR) and the National Collective of Obese Associations (CNAO) initiated the referral of this issue to the French National Authority for Health (HAS) in June 2019. This topic has therefore been included in the HAS 2020 work program. A working group of 19 experts (physicians, pharmacists, paramedics, and administrative staff) has been set up between March 2021 and July 2022, in response to requests from the relevant National Professional Councils (CNP) – which bring together healthcare professionals from the same specialty – and academic societies.

After a critical analysis of the literature, recommendations were formulated with supporting arguments, each graded according to the level of evidence: A, B, C, or expert agreement (EA) (Table 2). These Good Practice Recommendations have been established according to the method described in the HAS methodological guide available on its website: "Developing of Good Practice Recommendations" [8].

An external revision phase was carried out by a review group (44 people proposed by the CNPs or academic societies or members concerned with the theme). The group was consulted online (using the GRaAL tool available on the HAS website) and gave an opinion with ratings and comments on the content and form of the initial version of the guidelines.

The final version of the guidelines was reviewed and validated by the HAS board in July 2022 and subsequently posted on its website (www.has-sante.fr).

3. Management of preoperative anemia and iron deficiency

The algorithm summarizing the recommendations of this part is presented in Fig. 1.

3.1. Preoperative screening for anemia and iron deficiency

Rationale. Before these new guidelines, French and international guidelines already recommended the prescription of a blood count before surgery with intermediate or high cardiac risk [9,10], or if the probability of perioperative transfusion was >10% or perioperative blood loss >500 mL [11]. Prior to surgery at risk of bleeding or transfusion, the optimal Hb level seems to be at least 13 g/dL, regardless of gender [11]. This risk must be adapted according to the center and the patien's comorbidities.

In the event of a preoperative Hb level <13 g/dL, an etiological diagnosis must be made in order to optimize the treatment of the anemia [11]. Iron deficiency is the leading cause of anemia in the general population [12] and the prevalence of iron deficiency is high in patients, especially in cases of cancer (40–60%) [13], chronic renal failure (around 50%) [14] or heart failure (40–50% and up to 75% depending on the study) [15,16]. Besides these conditions, its prevalence is also often high before scheduled orthopedic surgery (from 20% to 57%) [17,18] or before cardiac surgery (around 40%) [19].

In clinical practice, the diagnosis of iron deficiency is based on measurements of serum ferritin and transferrin saturation (TSAT), possibly associated with C-reactive protein measurement to identify inflammation [11,12]. The serum ferritin thresholds for the diagnosis of iron deficiency in the preoperative context remain poorly defined and are probably between 30 and 100 μg/mL, *i.e.*, higher than outside the perioperative situation. Indeed, these patients will have increased iron requirements due to perioperative blood loss, which is a direct loss of iron. A value of TSAT < 20% helps for the diagnosis of iron deficiency in the case of serum ferritin between 30 and 100 μg/mL [11] or between 100 and

Table 1
French translation of the guidelines from the French National Authority for Health (HAS) on perioperative blood management (excluding obstetrics).

1. Preoperative management	
1.1. Screening for preoperative anemia and iron deficiency	
1.1.1. Screening for preoperative anemia	
In case of surgery at risk of bleeding, preoperative anemia and iron deficiency must be detected systematically and sufficiently in advance of surgery.	Grade A
In case of major surgery and in the presence of frailty, the presence of anemia should be investigated, even in the absence of associated bleeding risk.	Grade A
A preoperative hemoglobin level below 13 g/dL (in men or women) requires corrective measures in the context of patient blood management.	EA
1.1.2. Screening for preoperative iron deficiency	
In case of preoperative anemia, an iron workup including serum ferritin and transferrin saturation must be systematically performed.	Grade A
In the preoperative setting, iron deficiency is defined as serum ferritin <100 μg/L and/or transferrin saturation $<20\%$.	Grade C
1.2. Treatment of preoperative anemia	
1.2.1. Iron supplementation	
In case of iron deficiency anemia, iron supplementation is recommended to optimize red cell mass.	Grade A
For iron supplementation, the intravenous route should be preferred, and the dose must be sufficient and adapted to the patient's weight, in compliance with the instructions of the product's Marketing Authorization.	Grade B
Taking into account current safety data on available products, ferric carboxymaltose can be administered in the context of home hospitalization.	EA
The dose of 1 g of ferric carboxymaltose should be preferred (if weight >35 kg), as it can be carried out with a single 15-minute injection.	EA
If used, intravenous iron supplementation should be administered as early as possible before surgery (usually within a month prior to surgery).	EA
1.2.2. Erythropoiesis-stimulating agents (ESA)	
In major orthopedic surgery and cardiac surgery, the use of ESAs is recommended for patients with preoperative anemia to reduce the risk of transfusion.	Grade A
In presence of anemia of inflammation, ESAs can be used for all types of surgery with a risk of bleeding (outside the marketing authorization), in the same way as for preoperative orthopedic surgery.	EA
In such case, the use of ESAs should be discussed in relation with the benefit-risk balance, particularly in the case of cancer, in order not to exceed a hemoglobin level of 12 g/dL to limit the risk of thrombosis.	EA
Systematic iron supplementation, intravenous at best, is recommended at the start of ESA therapy to optimize erythropoiesis.	Grade B
It is recommended to adjust the number of erythropoietin injections according to the preoperative hemoglobin level, and to monitor its effectiveness by monitoring the blood count.	Grade C
It is recommended to start ESA treatment early enough, with a first injection about 3 weeks before surgery ideally.	EA
1.2.3. Vitamins	
Vitamin treatments (vitamin B9, vitamin B12) may be considered if plasma folic acid is <3 ng/mL and/or plasma cobalamin is <200 pg/mL.	Grade C
1.2.4. Referral to a specialist	
In case of preoperative hemoglobin level below 10–11 g/dL, a specialized etiological workup is recommended preoperatively, or, failing that, postoperatively, if the cause is unknown.	EA
2. Intraoperative management	
2.1 Pharmacological treatments	
2.1.1. Tranexamic acid	
Prophylactic use of tranexamic acid is recommended to reduce bleeding and transfusion in cardiac and major orthopedic surgeries.	Grade A
For other types of surgery, tranexamic acid can be used in case of bleeding risk for prophylactic or curative purposes.	Grade B
For prophylactic use, it is recommended to use tranexamic acid preferably by slow intravenous route at the start of the procedure at a dose of 1 g (or 10–20 mg/kg).	Grade B
The injection of tranexamic acid may be supplemented by reinjections or continuous infusion, particularly in cases of hemorrhage.	Grade B
Tranexamic acid can be applied locally in addition to the intravenous route, particularly in orthopedic surgery.	Grade B
In cases of severe hemorrhage or hemorrhagic shock, tranexamic acid use is recommended as soon as possible;	Grade A
in these cases, the 1 g intravenous dose, possibly followed by a second 1 g dose, is recommended (in the absence of a previous dose).	Grade B
2.1.2. Other hemostatic treatments	
Prophylactic fibrinogen administration is not recommended.	Grade A
2.2. Surgical methods	
It is suggested to carry out the application of surgical dressings (tamponade dressing) at the end of the procedure to detect a hemostasis disorder and reduce bleeding.	Grade C
In prosthetic knee surgery, the systematic use of a tourniquet to reduce cumulated perioperative blood loss is not recommended.	Grade A
Cell salvage devices are recommended for cardiac surgery, aortic surgery, spinal deformity surgery, complex prosthetic revision surgery of the lower limb, and any surgery where the risk of transfusion is deemed to be very high, particularly for certain patient populations (*e.g.*, rare blood groups).	Grade B
The use of these devices is possible in cases of infection or cancer, provided that the benefit-risk balance is assessed.	EA
Except for cardiac and thoracic surgery, it is recommended to limit the use of drains, if permitted by the surgery performed, in order to reduce postoperative blood loss and facilitate rehabilitation.	Grade A
2.3. General measures	
It is recommended that normothermia ($\geq$36.5 °C ideally) be maintained throughout the whole perioperative period to reduce bleeding complications.	Grade B
In case of major surgery or surgery at risk of bleeding, continuous intraoperative temperature monitoring should be used, by esophageal, bladder, rectal or blood route.	EA
In case of hemorrhagic surgery, blood loss must be estimated (direct measurement in suction bottles, estimated "visual" losses, weight of surgical dressings) and rapid intra- and postoperative hemoglobin level monitoring must be available.	EA
For surgeries at risk of bleeding, rapid assessment of hemoglobin levels and hemostasis must be available in the form of short circuits and/or delocalized biology, combined with decisional therapeutic algorithms.	Grade C
3. Postoperative management	
3.1. Monitoring and detection of postoperative bleeding and anemia	
It is recommended to limit systematic blood sampling and, if possible, the volume per sample, to reduce the incidence of anemia and transfusion.	EA
The use of rapid capillary hemoglobin tests at the patient's bedside can reduce the number of samples.	Grade B
Hemoglobin level monitoring is recommended in the early postoperative days in case(s) of preoperative anemia and/or intra- or postoperative blood loss and/or hemodynamic instability. These tests can be performed outside the hospital if the patient has been discharged.	EA
A repeat blood count and an iron workup are recommended around 4 weeks after a hemorrhagic surgery and/or in the event of postoperative anemia, with the involvement of the general practitioner.	EA
3.2. Iron supplementation	
In the event of postoperative anemia with a hemoglobin level below 12 g/dL due to significant blood loss and/or untreated preoperative iron deficiency, early administration of iron is recommended, preferably intravenously.	Grade B
The dose of one gram of ferric carboxymaltose should be preferred (for weights over 35 kg), as it can be carried out in a single 15-minute injection.	EA

3.3. Transfusion and transfusion thresholds

A "restrictive" transfusion threshold (target Hemoglobin level between 7 and 8 g/dL, or higher depending on comorbidities and patient tolerance) is recommended in the postoperative period of non-cardiac surgery for most clinically stable adult inpatients.	Grade A
A "restrictive" hemoglobin transfusion threshold of 7 g/dL is recommended for critical care patients in general, including septic patients, in order to reduce the need for packed red blood cell transfusion without increasing morbidity and mortality.	Grade A
A "restrictive" hemoglobin transfusion threshold between 7.5 and 8.0 g/dL is recommended in the postoperative period of cardiac surgery, in order to reduce the need for packed red blood cell transfusion without increasing morbidity and mortality.	Grade A
The transfusion threshold must be adapted to the patient's comorbidities, clinical tolerance and hemodynamic status.	EA
Transfusion of a single unit of packed red blood cells at a time is recommended (except in the case of active hemorrhage deemed important, or in the case of a hemoglobin level expected <7 g/dL with a single unit of packed red blood cells) to reduce the number of units of packed red blood cells transfused.	Grade B

Grade A: established scientific evidence; Grade B: scientific presumption; Grade C: low level of evidence; EA: expert agreement. See Table 2 for more details on the definitions of grades used for these recommendations.

Table 2
Definitions of the grades used for these recommendations from the French National Authority for Health (HAS).

Grade A	**Established scientific evidence** Based on studies with a high level of evidence (evidence level 1): high-powered randomized controlled trials without major bias or meta-analysis of randomized controlled trials, decision analysis based on well-conducted studies.
Grade B	**Scientific presumption** Based on scientific presumption provided by studies of intermediate level of evidence (evidence level 2), such as low-power randomized controlled trials, well-conducted non-randomized controlled studies, cohort studies.
Grade C	**Low level of evidence** Based on studies with a lower level of evidence, such as case-control studies (level of evidence 3), retrospective studies, case series, comparative studies with significant bias (level of evidence 4).
Expert agreement (EA)	**Expert agreement** In the absence of studies, recommendations are based on agreement between experts of the working group, after consultation with the review group. The absence of a gradation does not mean that the recommendations are not relevant and useful. It should, however, encourage further studies.

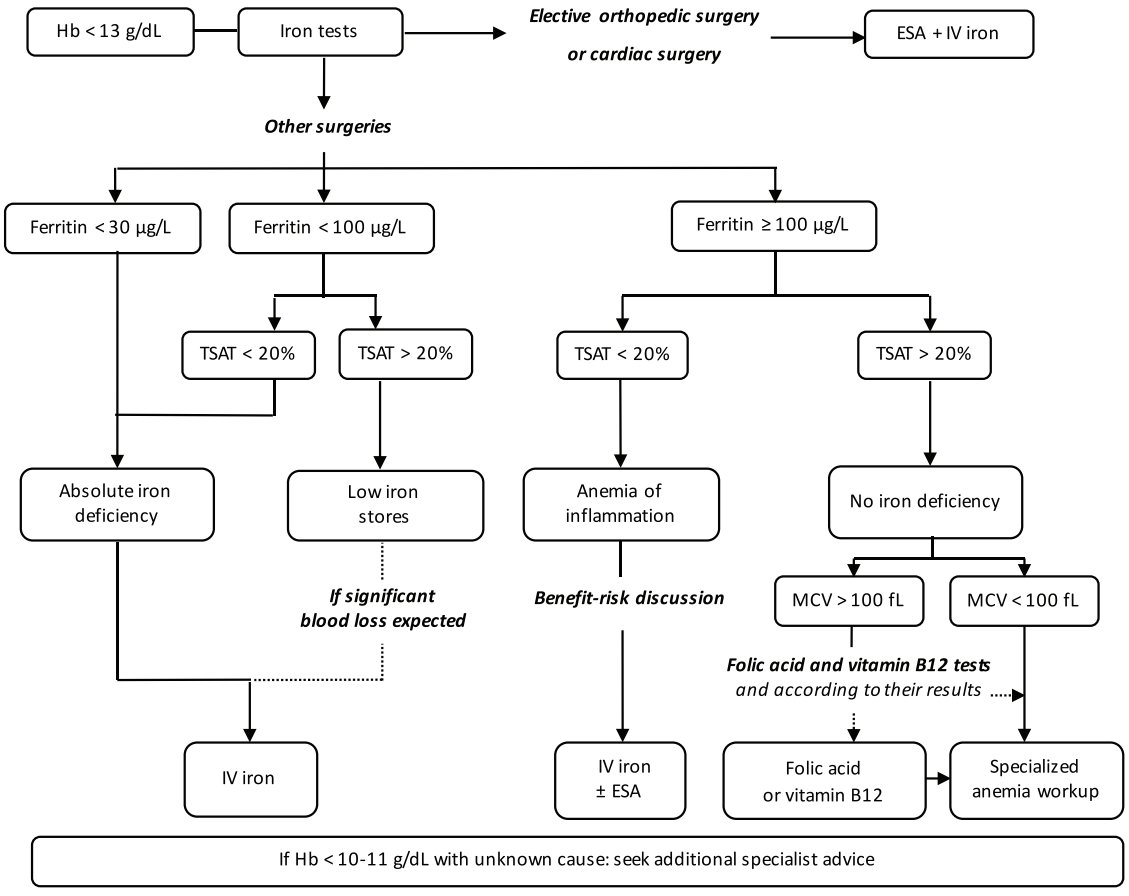

Fig. 1. Algorithm for the diagnosis, classification and management of anemia in the preoperative period.
ESA: erythropoiesis-stimulating agent; Hb: hemoglobin level; MCV: mean corpuscular volume; TSAT: transferrin saturation.

300 μg/L in patients with heart failure or inflammation [20]. Indeed, in the case of chronic inflammation, iron deficiency is said to be functional iron deficiency, as inflammation both increases ferritin synthesis and contributes to iron sequestration within stores (particularly in macrophages and liver cells). Inflammation therefore reduces iron bioavailability and transport to bone marrow (assessed by TSAT). There are of course intermediate situations where the diagnosis and/or the need for iron supplementation will be more difficult to determine. These situations (low ferritinemia with normal CST, very high ferritinemia with low CST, iron deficiency without anemia) may require personalized decisions and the absence of sufficient data did not allow experts to propose recommendations.

Otherwise, anemia without associated iron deficiency can be investigated using vitamin B12 and folate blood tests and may lead to the diagnosis of megaloblastic anemia (blood vitamin B12 < 270 pg/mL and/or blood folate <3 pg/mL) or another cause of anemia.

Recommendations.

- In case of surgery at risk of bleeding, preoperative anemia and iron deficiency must be detected systematically and sufficiently in advance of surgery (Grade A).
- In case of major surgery and in the presence of frailty, the presence of anemia should be investigated, even in the absence of associated bleeding risk (Grade A).
- A preoperative hemoglobin level below 13 g/dL (in men or women) requires corrective measures in the context of patient blood management (EA).
- In case of preoperative anemia, an iron workup including serum ferritin and transferrin saturation must be systematically performed (Grade A).
- In the preoperative setting, iron deficiency is defined as serum ferritin <100 μg/L and/or transferrin saturation <20% (Grade C).

3.2. Treatment of preoperative anemia and iron deficiency

3.2.1. Iron supplementation

Rationale. Many studies have shown the value of iron treatment for optimizing Hb levels in the preoperative period. A recent meta-analysis showed a significant reduction in the need for transfusion when intravenous iron was used preoperatively in orthopedic surgery, but this analysis also included studies with erythropoiesis-stimulating agents (ESAs) [21]. Another meta-analysis of patients undergoing surgery for a fracture of the upper extremity of the femur reached a similar conclusion [22]. However, in the context of major orthopedic surgery, it is the use of EPO, systematically associated with iron, which has shown greater efficacy in reducing perioperative transfusion (see Section 3.2.2).

In digestive surgery, several studies, including randomized controlled trials, have demonstrated the value of oral or intravenous iron therapy prior to major colorectal or abdominal surgery, in particular, to reduce the need for perioperative transfusion [23–26]. Although preoperative iron therapy did not always have an impact on perioperative transfusion in major digestive surgery, postoperative Hb levels were significantly increased several weeks after surgery in many studies [25]. In this context, intravenous iron appears to be more effective than oral iron in rapidly increasing Hb [27,28].

In cardiac surgery, the use of intravenous iron at a dose of 1000 mg in the preoperative period, even immediately before surgery, increases postoperative Hb levels, with fewer anemic patients in the weeks following surgery, but without reducing the need for transfusion [29]. Intravenous iron appears to be more effective than oral iron in increasing serum ferritin even when Hb levels have not risen significantly in the 3 weeks following injection [30]. Recent results indicate that serum ferritin <100 μg/L (with or without associated anemia) is associated with increased mortality, complications, transfusions, and length of hospital stay after cardiac surgery, thus encouraging the correction of iron deficiency in this context [31].

Recommendations

- In case of iron deficiency anemia, iron supplementation is recommended to optimize red cell mass (Grade A).
- For iron supplementation, the intravenous route should be preferred, and the dose must be sufficient and adapted to the patient's weight, in compliance with the instructions of the product's Marketing Authorization (Grade B).
- Taking into account current safety data on available products, ferric carboxymaltose can be administered in the context of home hospitalization (EA).
- The dose of 1 g of ferric carboxymaltose should be preferred (if weight >35 kg), as it can be carried out with a single 15-minute injection (EA).
- If used, intravenous iron supplementation should be administered as early as possible before surgery (usually within a month prior to surgery) (EA).

3.2.2. Erythropoiesis-stimulating agents

Rationale. The efficacy of ESAs prior to surgery (particularly orthopedic or cardiac surgeries) has been evaluated in many studies and meta-analyses [32–35]. In these studies, ESAs were shown to increase perioperative Hb levels and reduce perioperative transfusion and postoperative complications. In hemorrhagic orthopedic surgery, the use of ESAs in the preoperative period is currently recommended only in cases of anemia, whatever the cause of anemia, due to the potential risk of venous or arterial thrombosis [36]. When ESAs are used in this context, the benefit appears to be greater, with no apparent increased risk of thrombosis [33,35,37]. In cardiac surgery, the benefit of ESAs mainly concerns the reduction in perioperative transfusions in randomized controlled trials using single injections [38,39] and the reduction of postoperative renal failure [40]. Erythropoietins alpha (in biosimilar or non-biosimilar form) and zeta have now marketing authorization for their use to correct anemia prior to major orthopedic surgery. Various doses have been evaluated in the literature, with 600 IU/kg by subcutaneous injection (often rounded up to 40,000 IU) appearing to be the most widely used and more effective than 300 IU/kg [32–35,41].

ESAs administered preoperatively should always be combined with iron therapy, even in the absence of iron deficiency associated with anemia, due to the increased iron requirement resulting from the stimulation of erythropoiesis. Intravenous iron is preferable, as several studies have shown its superiority (with a single injection of ferric carboxymaltose) over oral iron in increasing Hb levels more rapidly and limiting preoperative iron deficiency when ESA therapy is administered prior to major orthopedic surgery [42,43] or before cardiac surgery [38,44]. The use of intravenous iron also allows a reduction in the number of injections of ESA to achieve a preoperative Hb level >13 g/dL, while maintaining a benefit in terms of reduced perioperative transfusions [45]. An example of preoperative EPO and IV iron administration is shown in Fig. 2.

In cancer patients, the efficacy of ESAs in increasing Hb levels and reducing transfusion has been demonstrated [46–48]. There are two concerns with ESA treatment in cancer patients: an increased risk of thrombosis and a potential increase in tumor progression. In recent studies and meta-analyses, mortality is not increased in cancer patients despite an almost systematic increase

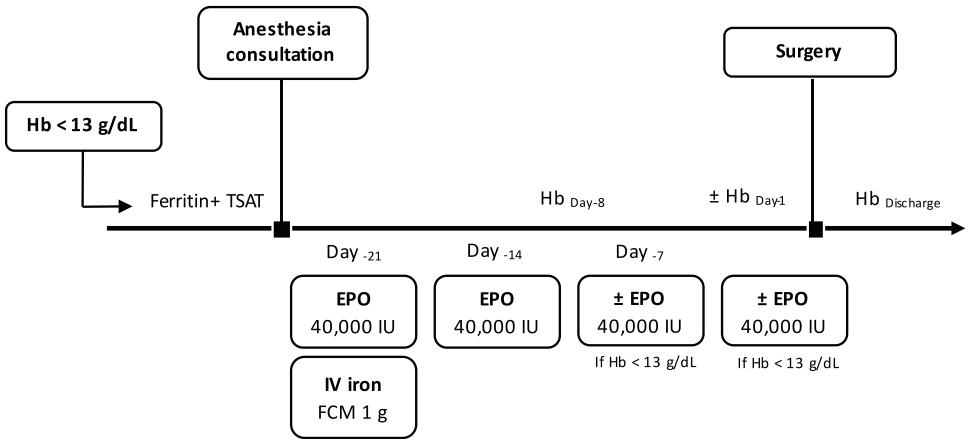

Fig. 2. Example of possible schedule for the use of erythropoietin in the preoperative period.
This protocol is proposed for the preoperative management of patients with a Hb <13 g/dL in case of: major orthopedic surgery (particularly total hip and knee arthroplasty), spinal surgery at risk of bleeding, and cardiac surgery. This protocol can be used for other types of surgery in case of inflammatory anemia. In the case of cancer, a benefit/risk discussion should be held with the surgeon and/or oncologist in charge of the patient. Any contraindications to EPO (particularly recent ischemic disease or uncontrolled hypertension) or iron must be respected. The EPO dose suggested on the diagram is 40,000 IU SC. However, it can be adapted to the patient's weight (600 IU/kg). Iron administration (IV or oral) should be systematic when EPO is used in this context (except in special cases of major hyperferritinemia). The intravenous route is preferred, and the injection should be made as close as possible to the first EPO injection. Ferric carboxymaltose at a dose of 1 g over 15 min can be used (500 mg if weight <35 kg). Days are given as a guide and can be adapted according to the possibilities (patient or carers).
EPO: erythropoietin; FCM: ferric carboxymaltose; Hb: hemoglobin level; TSAT: transferrin saturation.

in the risk of thrombosis [46,48,49]. This is why the prescription of ESAs must be the subject of a benefit/risk discussion with the surgeon in this context. Preoperative use of ESAs in cancer patients at risk of bleeding should probably be the same as for major orthopedic surgery, but probably with the objective of lower Hb levels (<12 g/dL) to limit the risk of thrombosis.

Recommendations

- In major orthopedic surgery and cardiac surgery, the use of ESAs is recommended for patients with preoperative anemia to reduce the risk of transfusion (Grade A).
- In the presence of anemia or inflammation, ESAs can be used for all types of surgery with a risk of bleeding (outside the marketing authorization), in the same way as for preoperative orthopedic surgery. In such cases, the use of ESAs should be discussed in relation to the benefit-risk balance, particularly in the case of cancer, in order not to exceed a hemoglobin level of 12 g/dL to limit the risk of thrombosis (EA).
- Systematic iron supplementation, intravenous at best, is recommended at the start of ESA therapy to optimize erythropoiesis (Grade B).
- It is recommended to adjust the number of erythropoietin injections according to the preoperative hemoglobin level and to monitor its effectiveness by monitoring the blood count (Grade C).
- It is recommended to start ESA treatment early enough, with a first injection about 3 weeks before surgery ideally (EA).

3.2.3. Vitamin treatments

Rationale. There is no or few enough data to justify the systematic prescription of vitamins B9 and B12 in case of preoperative anemia, in addition or not with iron or EPO [11,50,51]. These recommendations therefore propose their use in the event of observation of low plasma concentrations only.

Recommendations

- Vitamin treatments (vitamin B9, vitamin B12) may be considered if plasma folic acid is <3 ng/mL and/or plasma cobalamin is <200 pg/mL (Grade C).

3.2.4. Referral to a specialist

Rationale. If the etiology of the anemia is not known and not related to the surgery, experts recommend obtaining it, especially in case of Hb <10–11 g/dL, either directly or using a referral to another specialist (*e.g.*, hepato-gastroenterologist, gynecologist, internist, hematologist). Indeed, even if iron deficiency is diagnosed and treated, the knowledge of the etiology of this iron deficiency (in particular blood loss linked to gastrointestinal or gynecological bleeding) can facilitate the correction of this anemia after surgery. However, this diagnosis is sometimes difficult to make in clinical practice before surgery, due to the sometimes short times before surgery (especially in the case of semi-urgent surgery or cancer surgery). This etiological assessment can then be carried out postoperatively. This recommendation is an expert agreement because there is little or no data evaluating the value of the referral to an anemia specialist (other than an anesthetist or the surgeon). However, some international guidelines have already recommended the use of a specialist for certain types of anemia [52].

Recommendations

- In case of preoperative hemoglobin level below 10–11 g/dL, a specialized etiological workup is recommended preoperatively, or, failing that, postoperatively, if the cause is unknown (EA).

4. Intraoperative patient management in the context of patient blood management

4.1. Pharmacological treatments

Rationale. Tranexamic acid binds to plasminogen and prevents fibrin degradation. Many studies and meta-analyses have demonstrated its efficacy in reducing blood loss and intra- and postoperative transfusion in almost all potentially hemorrhagic surgeries, the majority of studies having been performed in major hip and knee surgery and in cardiac surgery [53–55]. Tranexamic acid has also demonstrated its potential interest in other surgical specialties. In liver surgery, for example, it reduces the need for transfusion without increasing the incidence of thrombotic events

[56] and reduces blood loss without increasing complications (including thrombosis) in abdominal, pelvic, gynecological, and urological surgery [57], with limited data however for colorectal surgery. Thus, the prophylactic use of tranexamic acid is recommended with a Grade A for orthopedic and cardiac surgeries and with a Grade B for other surgeries with a hemorrhagic risk, for prophylactic or curative purposes.

Tranexamic acid is effective on these parameters when used intravenously, "topically" by the surgeon, or orally, and seems even more effective when a "topical" and intravenous combination is used, particularly in major orthopedic surgery [53]. However, in the absence of contraindications, the intravenous route is the most studied route in this context and should be preferred. This is the reason why the preferential use of the intravenous route is recommended with a Grade B in these guidelines. The "topical" route can be used in combination or in the presence of contraindications to oral or intravenous use.

The dose and frequency of injections are still debated in the literature. However, if used intravenously, a dose of at least 1 g (or around 15 mg/kg if weight less than 65 kg), if possible before or at the same time as the surgical incision, is probably to be preferred in scheduled surgery where there is a risk of bleeding, as in the hemorrhagic shock and in postpartum hemorrhage [58–60]. Excluding hemorrhagic shock, repeating doses, or continuing an infusion in the hours following surgery is possible but its benefit has not been proven. In cardiac surgery under cardiopulmonary bypass, larger doses of around 50–100 mg/kg are regularly used in cardiac surgery centers and in studies on the subject [61–64]. These higher doses are associated with a statistically significant, but sometimes clinically irrelevant, reduction in bleeding and transfusion [61,62]. In addition, higher doses are associated in several studies with an increased risk of seizures [64]. Thus, doses higher than 100 mg/kg should not be used and doses below 50 mg/kg and close to common doses used in non-cardiac surgery are probably sufficient.

Different administration schedules proposed in the scientific literature are presented in Fig. 3. This figure reminds readers that, even in cardiac surgery, the dose of 100 mg/kg should not be exceeded.

A history of convulsions contraindicates its intravenous or oral use. However, this contraindication is relative in cases of major hemorrhagic risk.

Unlike tranexamic acid, fibrinogen has shown no clinically significant benefit in reducing transfusions when used prophylactically in recent randomized controlled trials, including in surgical procedures with bleeding risk, such as cardiac surgery or liver transplant surgery [65].

Recommendations

- Prophylactic use of tranexamic acid is recommended to reduce bleeding and transfusion in cardiac and major orthopedic surgeries (Grade A).
- For other types of surgery, tranexamic acid can be used in case of bleeding risk for prophylactic or curative purposes (Grade B).
- For prophylactic use, it is recommended to use tranexamic acid preferably by slow intravenous route at the start of the procedure at a dose of 1 g (or 10–20 mg/kg) (Grade B).
- The injection of tranexamic acid may be supplemented by reinjections or continuous infusion, particularly in cases of hemorrhage (Grade B).
- Tranexamic acid can be applied locally in addition to the intravenous route, particularly in orthopedic surgery (Grade B).
- In cases of severe hemorrhage or hemorrhagic shock, tranexamic acid use is recommended as soon as possible (Grade A); in these cases, the 1 g intravenous dose, possibly followed by a second 1 g dose, is recommended (in the absence of a previous dose) (Grade B).
- Prophylactic fibrinogen administration is not recommended (Grade A).

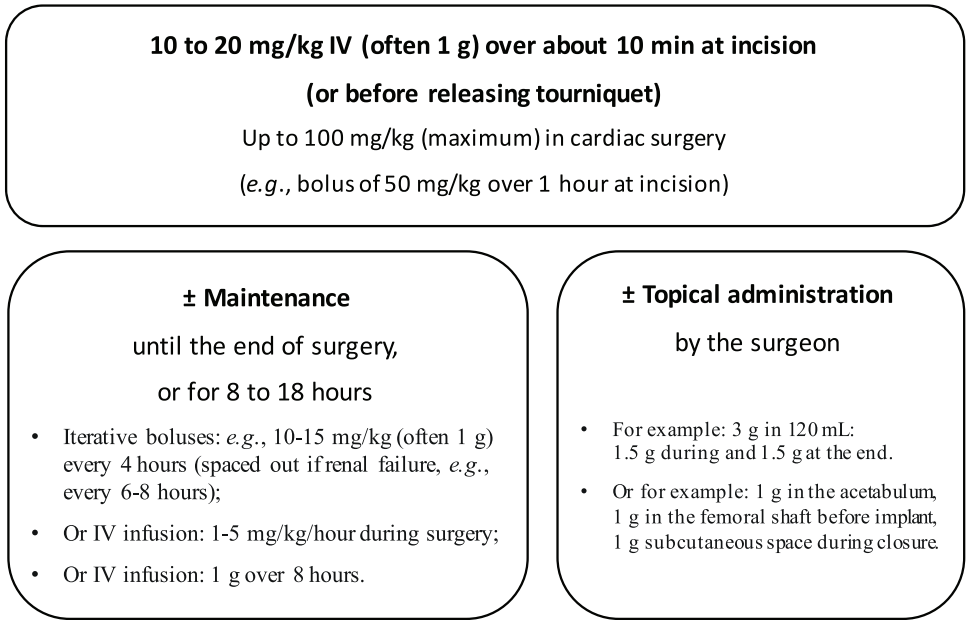

Fig. 3. Possible strategies for the perioperative use of tranexamic acid.
This regimen can be used preventively for all surgeries where a particular bleeding risk is identified and for major bone surgery. It is suggested to use it as soon as an unplanned hemorrhage is identified, whatever the surgery. Maintenance or one or more reinjections are preferable in cases of hemorrhagic surgery, or post-operative bleeding. Topical use alone is possible for certain surgeries with a lower bleeding risk, in special cases such as pediatric tooth extractions or certain diseases of hemostasis. Contraindications must be respected, in particular the presence of a recent thrombo-embolic event. However, experts agree that a benefit-risk discussion should be held systematically in cases of major hemorrhagic risk for use despite the presence of contraindications (notably a history of convulsion, renal insufficiency or a previous or recent thromboembolic event).

4.2. Surgical methods

Rationale. The use of a tourniquet in prosthetic knee surgery improves the visualization of structures and reduces intraoperative bleeding. However, a recent meta-analysis did not show a reduction in total blood loss or in the volume of blood transfused, and conversely showed a decrease in functional recovery and an increase in the incidence of postoperative venous thrombosis [66]. Other meta-analyses on this subject concluded to an increase in postoperative blood loss and postoperative pain [67,68].

The real benefit of cell salvage on postoperative complications and mortality remains debated. However, its use has allowed a decrease in homologous transfusion in potentially very hemorrhagic surgeries such as open aortic surgery, cardiac surgery, and scoliosis surgery [69–71]. However, the existing data seem reassuring on the risk of metastasis due to the use of cell salvage, with tumor cells reinjected potentially "ineffective" and at a concentration lower than that present in the circulating blood [72]. Similarly, the risk of infection associated with the use of cell salvage in a patient with an infection could not be demonstrated [73] and the use of a leukocyte filter remains to be assessed to reduce this risk.

Apart from cardiac and thoracic surgery, numerous studies have now shown that systematic and prophylactic postoperative drainage does not improve postoperative morbidity, including in orthopedic and digestive surgery [74–76]. Excluding complex situations or special patients, the use of systematic drains could even have a negative impact on blood loss since the introduction of PBM programs.

Recommendations

- It is suggested to carry out the application of surgical dressings (tamponade dressing) at the end of the procedure to detect a hemostasis disorder and reduce bleeding (Grade C).
- In prosthetic knee surgery, the systematic use of a tourniquet to reduce cumulated perioperative blood loss is not recommended (Grade A)
- Cell salvage devices are recommended for cardiac surgery, aortic surgery, spinal deformity surgery, complex prosthetic revision surgery of the lower limb, and any surgery where the risk of transfusion is deemed to be very high, particularly for certain patient populations (*e.g.*, rare blood groups) (Grade B). The use of these devices is possible in cases of infection or cancer, provided that the benefit-risk balance is assessed (EA).
- Except for cardiac and thoracic surgery, it is recommended to limit the use of drains, if permitted by the surgery performed, in order to reduce postoperative blood loss and facilitate rehabilitation (Grade A).

4.3. General measures

Rationale. Intraoperative hypothermia is associated with an increase in morbidity and mortality. The French guidelines have already recommended measures to avoid perioperative hypothermia, in order to reduce the occurrence of hemorrhagic complications in particular [77]. The link between hypothermia and blood loss has been observed in numerous studies and in meta-analyses [78,79]. Furthermore, a recent meta-analysis observed efficacy in reducing the use of transfusion [78], however not observed in other studies. Among the existing techniques for heating, forced-air warming systems seem effective in limiting blood loss [79].

Since anemia and hemorrhage are major risk factors for morbidity and mortality in the perioperative period, these two parameters must be closely monitored during surgery. The amount of blood loss can be estimated in containers or graduated collection bags, by the weight of the compresses, and visually in the operating field, the operator's gown, and the floor. This monitoring of blood loss can make it possible to anticipate symptomatic or corrective treatment before the appearance of clinical signs or to undertake surgical or medicinal therapeutic measures.

A rapid measurement of the hemoglobin level must be possible in the event of haemorrhage. The blood count in the laboratory is the reference technique but the delay between the sample and the result can be long. Some devices allow rapid measurement of capillary hemoglobin (Hemocue® for example) and are readily available. Their precision is generally satisfactory and they can therefore be an additional useful tool in this context [80,81]. More recent devices allow now the non-invasive measurement of hemoglobin (SpHb in particular). Their accuracy is relatively satisfactory too, but less than capillary hemoglobin and much less than hemoglobin measured in the laboratory, especially for low values of hemoglobin [80,81]. Some studies have shown an interest in guiding transfusion, but their real usefulness remains to be assessed.

Recommendations

- It is recommended that normothermia ($\geq$36.5 °C) be maintained throughout the whole perioperative period to reduce bleeding complications (Grade B).
- In case of major surgery or surgery at risk of bleeding, continuous intraoperative temperature monitoring should be used, by esophagus, bladder, rectal or blood route (EA).
- In case of hemorrhagic surgery, blood loss must be estimated (direct measurement in suction bottles, estimated "visual" losses, weight of surgical dressings) and rapid intra- and postoperative hemoglobin level monitoring must be available (EA).
- For surgeries at risk of bleeding, rapid assessment of hemoglobin levels and hemostasis must be available in the form of short circuits and/or delocalized biology, combined with decisional therapeutic algorithms (Grade C).

5. Postoperative management in the context of patient blood management

5.1. Monitoring and detection of postoperative bleeding and anemia

Rationale. The prevalence of postoperative anemia is around 80–90% after major orthopedic surgery [82] and 76% in cancer colorectal surgery [83]. Bleeding is a major complication of surgery, which can lead to an increase in morbidity and mortality, mean length of stay, and risk of admission to an intensive care unit [1].

In a study of patients undergoing lower-limb arthroplasty (hip or knee) or coronary artery bypass grafting, transfusion was predicted in 97% of patients by three independent variables: preoperative Hb level, degree of perioperative bleeding, and postoperative minimal Hb level [84].

Hb measurement is a routine postoperative test and, for most uncomplicated surgeries, Hb levels begin to rise after the 3rd or 4th postoperative day only. Non-invasive Hb monitoring devices may be of interest in the postoperative period too for monitoring occult bleeding, follow-up of hemorrhage, or response to treatment of anemia, but further studies are needed to assess their value.

Diagnosis of postoperative iron deficiency can be difficult, as the iron markers (serum ferritin and TSAT) are disturbed in the hours following surgery. Inflammation is almost always present, and is responsible for increased ferritin synthesis. Serum ferritin and TSAT are generally interpretable the first days after surgery [85].

In the postoperative period, the decrease of Hb levels is almost always related to blood loss (excluding hemodilution or hemoly-

sis). In most cases, this decrease of Hb levels results in direct iron loss, which can lead to iron deficiency if reserves were already low, and increasing Hb levels will therefore require iron supplementation. Consequently, if anemia appears or is more severe than preoperatively, oral or intravenous supplementation is necessary if the anemia is to be rapidly corrected. The indication for iron therapy is then based on the Hb level and not on serum ferritin. Furthermore, if iron supplementation (including intravenous iron) allows an increase in the hemoglobin level, this will be especially visible from the second to fourth weeks following the supplementation [86]. It is therefore after this time interval that it may be necessary to control the hemoglobin level.

Recommendations

- It is recommended to limit systematic blood sampling and, if possible, the volume per sample, to reduce the incidence of anemia and transfusion (EA).
- The use of rapid capillary hemoglobin tests at the patient's bedside can reduce the number of samples (Grade B).
- Hemoglobin level monitoring is recommended in the early postoperative days in case(s) of preoperative anemia and/or intra- or postoperative blood loss and/or hemodynamic instability. These tests can be performed outside the hospital if the patient has been discharged (EA).
- A repeat blood count and an iron workup are recommended around 4 weeks after a hemorrhagic surgery and/or in the event of postoperative anemia, with the involvement of the general practitioner (EA).

5.2. Iron supplementation

Rationale. Several randomized controlled trials have shown that intravenous iron supplementation reduces transfusion, length of stay, postoperative infection rates, and fatigue [17,29,87]. Some intravenous iron formulations, in particular the ferric carboxymaltose available in France, allow rapid infusion (15–60 min) of the necessary dose of iron (often around 1000 mg) and therefore allow, despite their higher cost, to be carried out at once during hospitalization and to avoid prolonged hospitalization or rehospitalization for infusion of a 2nd or 3rd dose to complete the estimated total dose.

The dose of iron to be injected must be adapted to the Hb level (*e.g.*, using the Ganzoni formula), the preoperative iron status, the extent of the decrease of Hb level, and any perioperative transfusion (one unit of packed red blood cells provides an average of 200 mg of iron). However, transfusion is not a contraindication to iron injections since, according to the rules of a "restrictive" transfusion strategy, the post-transfusion Hb level should in all cases be below 10 g/dL.

Major adverse effects such as anaphylaxis, infection or oxidative stress have been described with intravenous iron (mostly with dextran iron), but such side effects do not appear to be significant with newer preparations such as ferric carboxymaltose, iron isomaltoside and low-molecular-weight dextran iron.

A normal Hb level does not exclude the presence of iron deficiency. Iron deficiency anemia occurs at a relatively advanced stage of iron deficiency. Patients who are not anemic, but whose iron stores are depleted, may present symptoms associated with this deficiency, in particular asthenia and reduced exercise tolerance [88]. There are currently no data to suggest iron supplementation for pre- or postoperative iron deficiency in the absence of anemia (except in situations of pregnancy or heart failure).

Recommendations

- In the event of postoperative anemia with a hemoglobin level below 12 g/dL due to significant blood loss and/or untreated preoperative iron deficiency, early administration of iron is recommended, preferably intravenously (Grade B).
- The dose of one gram of ferric carboxymaltose should be preferred (for weights over 35 kg), as it can be carried out in a single 15-minute injection (EA).

5.3. Transfusion and transfusion thresholds

Rationale. Transfusion of packed red blood cells to correct perioperative anemia and blood loss is an independent risk factor for increased postoperative morbidity, mortality and length of stay [89]. Since the 2000s, many studies with a high level of evidence and several meta-analyses have shown that restrictive transfusion thresholds (Hb generally between 7 and 8 g/dL *versus* more than 10 g/dL) are well tolerated, do not increase morbidity and mortality at 30 or 90 days, and make it possible to avoid or reduce blood transfusion [90–92]. A recent meta-analysis that identified 19 systematic reviews pooling data from 68 randomized controlled trials reported no significant difference in mortality between restrictive and liberal transfusion strategies [93]. The restrictive strategy therefore appears safe as it reduces the number of patients transfused and the number of units of packed red blood cells received, without significantly modifying death rates and overall morbidity. French [36] or international guidelines [94–96] use Hb at 7 g/dL as the transfusion trigger threshold for patients with no particular history and who are hemodynamically stable. However, transfusion should not be guided by Hb alone, but by clinical tolerance. For elderly patients or those with a history of cardiovascular disease, many studies showed that transfusion thresholds should probably be less stringent than for the rest of the population, *i.e.* at least above 8 g/dL, and adapted to the patient's tolerance [97–99]. The values of these thresholds remain however theoretical, as most studies include methodological and statistical biases (definition of a restrictive or liberal threshold, timing of randomization sometimes done after transfusion, and definition of the Hb threshold to be reached). The fundamental criterion therefore remains the clinical tolerance of the anemia.

One single (*versus* multiple) unit of packed red blood cells per transfusion in patients without active hemorrhage and hemodynamically stable with clinical reassessment and/or with a different Hb level (post-transfusion) is a recommendation taken up by many international guidelines, based on medical common sense and on studies with currently a low level of evidence (retrospective or before-after studies).

Recommendations

- A "restrictive" transfusion threshold (target Hemoglobin level between 7 and 8 g/dL, or higher depending on comorbidities and patient tolerance) is recommended in the postoperative period of non-cardiac surgery for most clinically stable adult inpatients (Grade A).
- A "restrictive" hemoglobin transfusion threshold of 7 g/dL is recommended for critical care patients in general, including septic patients, in order to reduce the need for packed red blood cell transfusion without increasing morbidity and mortality (Grade A).
- A "restrictive" hemoglobin transfusion threshold between 7.5 and 8.0 g/dL is recommended in the postoperative period of cardiac surgery, in order to reduce the need for packed red blood cell transfusion without increasing morbidity and mortality (Grade A).
- The transfusion threshold must be adapted to the patient's comorbidities, clinical tolerance and hemodynamic status (EA).
- Transfusion of a single unit of packed red blood cells at a time is recommended (except in the case of active hemorrhage deemed important, or in the case of a hemoglobin level expected <7 g/dL

with a single unit of packed red blood cells) to reduce the number of units of packed red blood cells transfused (Grade B).

6. Conclusion

This article presents a summary of the argument and a translation of the recommendations of the French National Authority for Health (HAS) concerning blood management in the pre-, intra-, and postoperative periods (excluding obstetrics). The main interest of these recommendations is to group together all the measures to be taken over the entire perioperative period and according to the three main pillars of PBM, drawn up from the most recent data on the day of publication in September 2022. A certain number of these measures have high levels of evidence, in particular those concerning screening and treatment of anemia and preoperative iron deficiency and the use of tranexamic acid in the event of bleeding surgery. Other recommendations are based on lower levels of evidence and based on expert opinion. Additional studies will be necessary to clarify these points and may change these recommendations in the future.

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Declaration of interest statement

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The authors communicated their public declarations of interest to the HAS. They can be consulted on the website https://dpi.sante.gouv.fr. They were analyzed according to the analysis grid of the HAS guide to declarations of interest and management of conflicts of interest. The interests declared by the members of the working group were considered to be compatible with their participation in this work.

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