How to prevent or manage Direct Oral Anticoagulant (DOAC)-induced bleeding complications? Guideline recommendations

Chair: Prof. Carolyn Weiniger

Monday 5th of June 2023

1. HOW TO MINIMISE BLEEDING COMPLICATIONS AFTER REGIONAL ANAESTHESIA

Sibylle Kietaibl, Austria

Why should we take into account if a patient receives anticoagulants before regional anesthesia?:

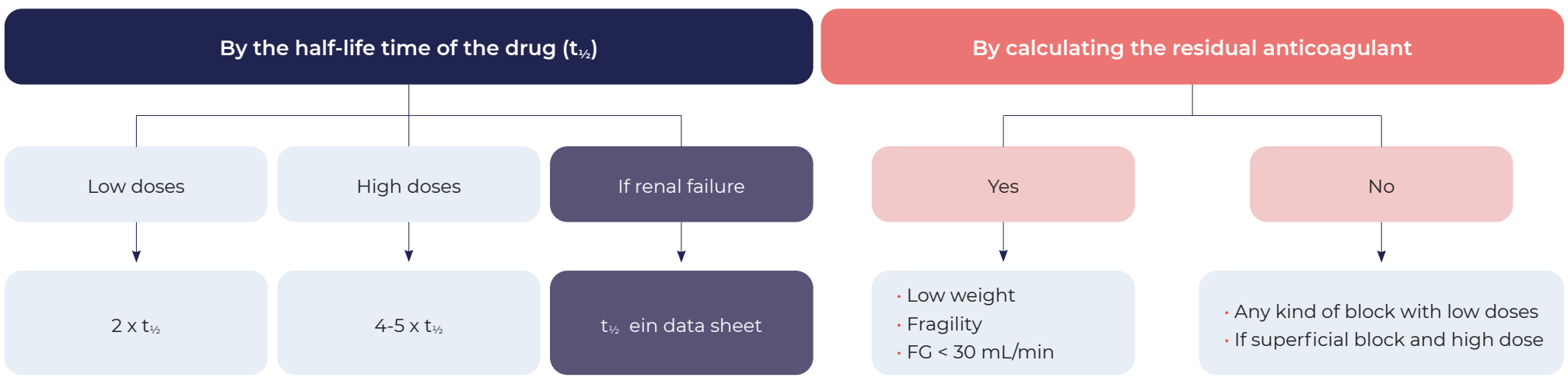
Because it increases the risk of hemorrhagic complications. Thus, in an epidural anesthesia, the risk for non-anticoagulated patients is 1:150,000; if they receive thromboprophylaxis, it is 1:18,000; if they receive aspirin and heparin, it is 1:8,500, and if they receive high doses of low-molecular weight heparin (LNWH), it goes up to 1:3,100.

In case of a regional anesthesia, what should we take into account in an anticoagulated patient[1]?

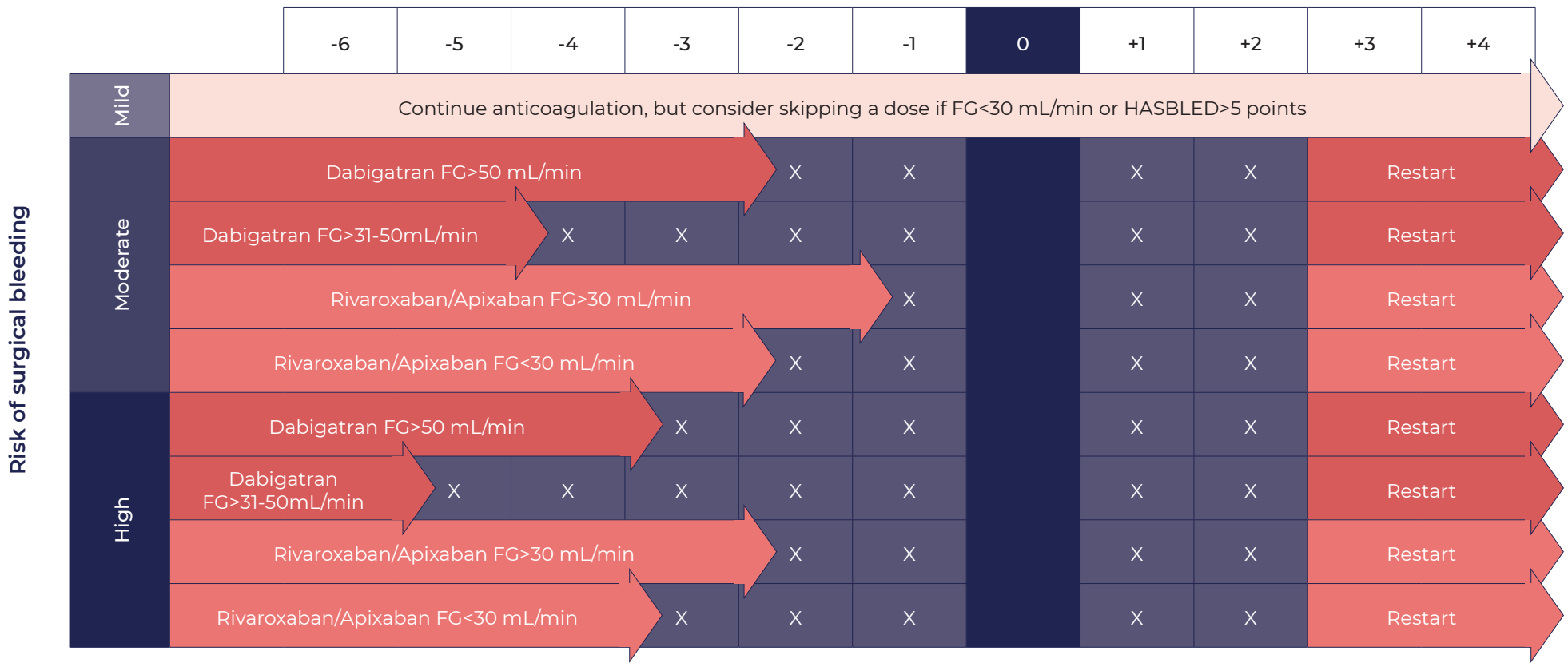
- The type of blockade: deep/neuraxial vs. superficial.
- The type of drug used.
- The **dose graded as high or low** (the exact dose in mg is not important).
- The characteristics of the patient (age, renal failure, liver failure...)

How can we prevent hemorrhagic complications in case of a regional anesthesia?

By adjusting periods without anticoagulation before and after the blockade or insertion and removal of the catheter and, if required, reversion of anticoagulation[1].



	Warfarin	Dabigatran	Apixaban	Rivaroxaban	Edoxaban
Peak action (hours)	<4	2	3-4	2-4	1-2
$t_{1/2}$	≈1 week	12-14 h	≈12	11-13	10-14
Renal excretion (%)	<1	85	27	≈33	50
Discontinue treatment in medium- and high-bleeding risk surgeries		3 days (FG>50 mL/min) 5 days (FG 30-50)	3 days (FG>30)	3 days (FG>30)	3 days (FG>30)



How should we proceed when reintroducing the drug after a regional anesthesia?

- Prophylaxis of deep venous thrombosis: Waiting for about 6 hours.
- Anti-thrombosis treatment: Waiting for about 24 hours.
- Reintroduction of DOACs only after having removed the neuraxial catheter.
- In combinations of drugs, the wider interval should be applied.
- Reversion of DOACs only in case of emergencies.

What if despite the precaution, a hemorrhagic complication appears in a regional anesthesia?

- Control on any neurological deficiency that may appear.
- If symptoms appear, perform clinical exam and NMR. If required, surgical decompression is recommended within 6 hours.

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2. HOW TO SUPPORT HAEMOSTASIS IN ACUTELY HAEMORRHAGING PATIENTS

Oliver Grottke, Germany

Should we **monitor DOAC levels** in patients requiring surgery?

- **Non-urgent surgery:** DOAC level monitoring would not be required in patients not suffering from renal and/or liver failure, and surgery can wait for 24 hours (in case of low risk of surgical bleeding) or 48-72 hours (in case of high risk of surgical bleeding).
- **Urgent surgery** (when a safe time cannot be observed) or patients with **renal or liver failure** (in risk of presenting high DOAC levels), DOAC level monitoring is suggested. The following table shows the usefulness of different coagulation tests based on the DOAC:

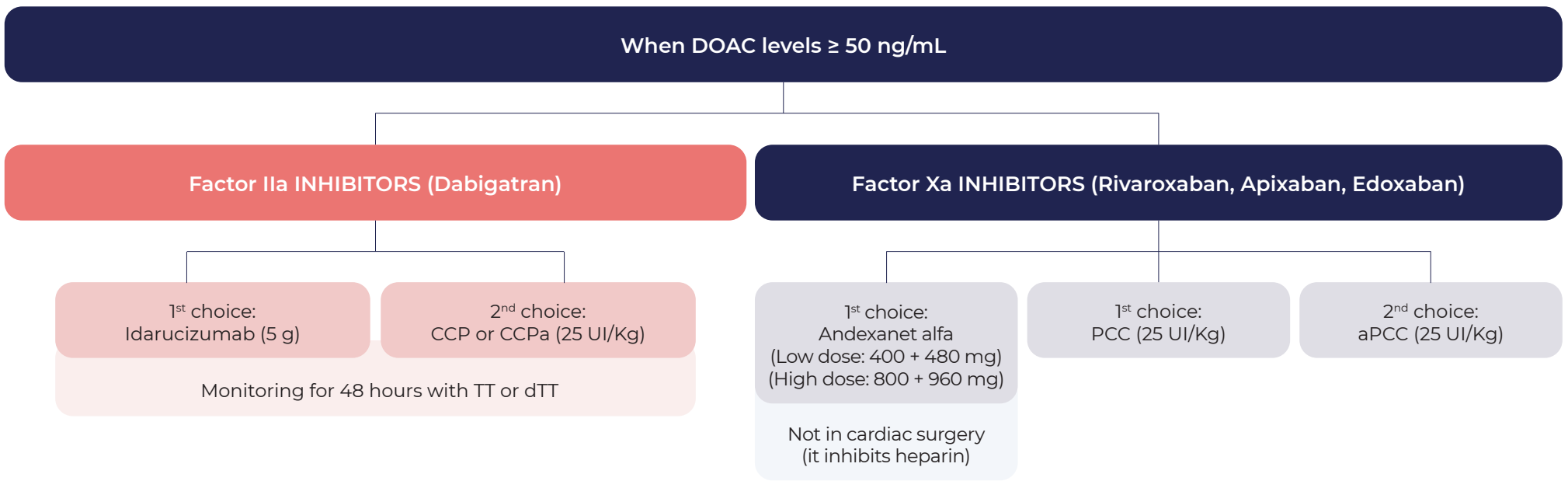
	Dabigatran	Rivaroxaban	Apixaban	Edoxaban
aPTT	✓	✗	✗	?
TT, dTT	✓	✗	✗	✗
ECT	✓	✗	✗	✗
Anti-Xa	✗	✓	✓	✓
PT	✗	✓	✗	✓
INR	✗	✗	✗	✗

aPTT: Activated partial thromboplastin time; TT: Thrombin time; dTT: Diluted thrombin time; ECT: Ecarin clotting time; PT: Prothrombin time; INR: International normalized ratio

Generally speaking, monitoring based on classic coagulation tests (PT and aPTT) are not recommended. Thus, in patients treated with anti-Xa DOACs (Rivaroxaban, apixaban, and edoxaban) monitoring by measuring anti-Xa measurement is suggested, and in patients treated with dabigatran (anti-IIa), dTT or TT are recommended.

Should we **revert coagulation** in patients treated with DOACs requiring **urgent surgery** with antidotes or non-specific hemostatic agents?

Whenever antidotes or hemostatic antidotes are required, **DOAC concentration-guided** management is recommended.



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CSL Behring

13S2 - Goal-Directed Therapy (GDT) in non-cardiac surgery

Chair: Dr. Alexandre Joosten

Sunday 4th of June 2023

1. WHAT ARE THE EVIDENCE IN 2023?

Rupert Pearse, United Kingdom

Ideally, we should be able to answer the questions: What fluid, when should it be introduced, and in what quantity? Focusing on the **quantity**:
It is very important to distinguish what is **replacement fluid** and what is a **maintenance fluid. Maintenance** fluids should be calculated based on the body mass index of the patient, whereas **replacement** fluids depend on the losses, which are often hard to estimate. That is why we can sometimes choose between a **more liberal replacement and a more restrictive one**. Thus, in abdominal surgery, the latest trial compares the liberal therapy (6.1 L in 24 hours on average) vs. the restrictive therapy (3.7 L in 24 hours on average), proves that:

Primary endpoint:
No differences in mortality or disability one year after surgery

Secondary endpoints:
Restrictive therapy was associated to a higher incidence of renal failure

The **effectiveness of the goal-directed therapy** in non-cardiac surgery has not yet been proven. This is probably due to the insufficient sample size in trials carried out so far. The latest most significant trials show:

Pearse RM, et al[2]
No differences in mortality or complications within 30 days after abdominal surgery

Gillies MA, et al[3]
No differences in the frequency of cardiac damage

Jessen MK et al[4]
Decrease in complications:
Pneumonia, ARDS, or local infections

However, what is our understanding of a "**goal-directed hemodynamic therapy**"? It involves the implementation of treatment algorithms based on different hemodynamic monitored variables (systolic volume, central venous pressure, pulse pressure variation...), also with different predefined hemodynamic goals (average blood pressure, lactacidemia, central venous saturation...) among the existing trials. This is a too simplifying approach to group together complex—and significantly different—hemodynamic treatment strategies. That is why some authors believe this term should no longer be used[5].

Conclusions:

Being generous in resuscitation

Being restrictive during maintenance

Optimizing selected patients, considering potential damage

The results of the **latest trials** on the issue will be made public within 24 months:

OPTOMISE II: International multi-center TRIAL to determine whether fluid therapy guided by cardiac output, with low doses of inotropes, is clinically effective when compared with the usual treatment in patients who have undergone elective major gastrointestinal surgery

FLO-ELA (Fluid Optimisation in Emergency Laparotomy): Same as Optomise II, but in emergency abdominal surgery

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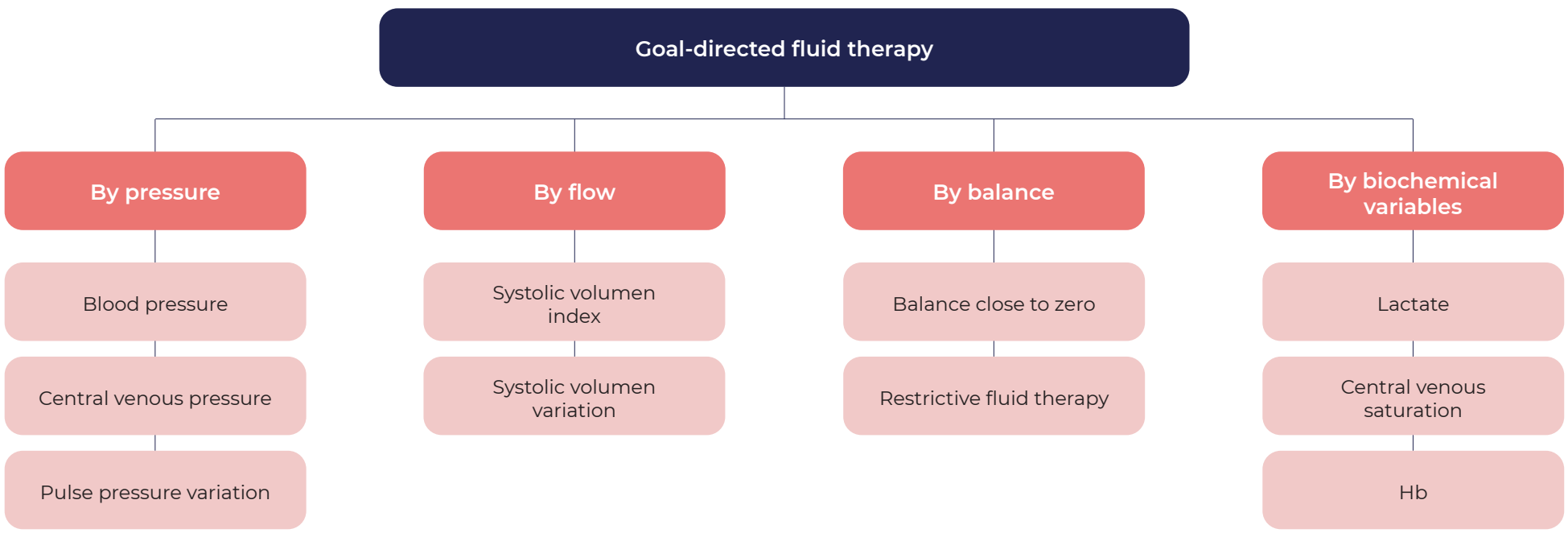
Sunday 4th of June 2023

2. GDT IN EMERGENCY ABDOMINAL SURGERY

Brigitte Brandstrup, Denmark

Goal-directed fluid therapy includes **many different treatment strategies:**



In patients who have undergone **elective abdominal surgery**, it has been proven that:

- A liberal fluid therapy, with a supply of up to 6 L within 24 hours, is associated to postoperative complications[6]:

Cardiopulmonary complications

Suture complications sutura

- An echo-guided fluid therapy supplying the maximum systolic volume adds no value to fluid therapy with a "near-zero" balance strategy[7]. Thus, a Cochrane systematic review did not find restrictive therapy to be restrictive vs. goal-directed therapy[8].
- Too restrictive regimes can cause renal damage.
- Oliguria should be treated with fluid therapy.

In patients who have undergone **emergency abdominal surgery**, it has been proven that:

- A liberal fluid therapy, with a supply of up to 6 L within 24 hours, is associated to postoperative complications[6]:

Balance > 2 L → Cardiopulmonary complications

Balance 1,5-3,5 L → Renal complications

- Flow-guided fluid therapy (maximum systolic volume) is not superior to pressure- and balance-guided fluid therapy (central venous pressure)[10].

No differences in survival or major complications

No differences in minor complications

One day less in hospital if pressure-directed

In general, a fluid therapy is recommended that is guided by a combination of pressure variables, balance, and biochemical parameters.

Next results: FLO-ELA trial (Fluid Optimisation in Emergency Laparatomy Trial).

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3. PROTOCOLIZED OR INDIVIDUALIZED HAEMODYNAMIC APPROACH?

Bernd Saugel, Germany

Historically, in 1975, Shoemaker approached for the first time hemodynamic monitoring through protocols to prevent undesired outcomes, and he included in his protocol some key concept in the maintenance of homeostasis, such as oliguria, hypotension, organic dysfunction, or central venous pressure, among others. However, in 2011, according to a publication, only 30% of European anesthesiologists declared having protocols for the hemodynamic management of surgical patients in your work centers[11]. In 2023 the situation is still similar, the percentage being 23%[12].

When implementing goal-directed therapy, one of the first questions that emerge is: **what goals have to be defined?**[5]

Pros and cons of protocolized individualized hemodynamic management:

Protocolized
Treatment standarization
Minimizing variability in care
Implementation in regular clinical practice

Personalized
Protocols do not reflect individual cardiovascular physiology
Interindividual variability
Need to cater for different hemodynamic profiles

Nevertheless, **protocols can be used and personalized** for each patient:

- The **individualization of systolic pressure** in high-risk major surgery patients decreases the incidence of systemic inflammatory response syndrome and the dysfunction of one or more organic systems, 7 days after surgery[13]. Currently, in this regard, the IMPROVE-multi trial is under way (Effect of personalized perioperative blood pressure management on postoperative complications and mortality in high-risk patients having major abdominal surgery)[14].
- The **individualization of systolic volume and cardiac output** is associated to fewer postoperative complications and less mortality within 30 days of surgery in patients undergoing major gastrointestinal surgery[2,15]. The PELICAN trial (Personalized Hemodynamic Management in High- risk Mayor Abdominal Surgery) will produce results on the maintenance of the cardiac index or, at least, on the baseline values for each patient before surgery.

Recommendations for the implementation of a goal-directed fluid therapy **(5-Ts)**[16]:

- **Target population:** Selecting the right patients (high risk).
- **Timing:** Early start of the intervention.
- **Type of intervention:** Combination of fluids, vasopressors, and inotropes based on the pathogenesis of the hemodynamic issue.
- **Target variable:** selecting the variable on which we want to intervene and monitoring it.
- **Target value:** setting and personalizing the values we want to approach.

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Lighting talks. Patient blood management in liver disease

Chair: Eleni Arnaoutoglou

Monday 5th of June 2023

1. PERIOPERATIVE PBM STRATEGIES IN PATIENTS WITH LIVER CIRRHOSIS

Mihai Popescu, Romania

Patients diagnosed with **liver cirrhosis (LC)** requiring abdominal surgery present a higher level of morbidity (coagulopathy, malnutrition, immune dysfunction, cardiomyopathy, and renal and pulmonary dysfunction) y mortality. Optimizing the patient before surgery and choosing the less invasive type of surgery (laparoscopy) has led to improved results[1].

Regarding the surgical approach:

It is well known that LC patients diagnosed with **acute cholecystitis** requiring laparoscopic cholecystectomy present a higher number of complications than the general population. A meta-analysis by Puggioni et al.[2] concluded that laparoscopic surgery to treat acute **cholecystitis** reduced the number of complications (blood losses, wound infection, time of surgery, hospital stay) and mortality versus a conventional approach with laparotomy. Likewise, the HiSCO[3] study also observed a decrease of postoperative complications in patients undergoing liver resection using laparoscopy rather than open surgery.

Regarding the optimization of the coagulopathy:

It is very common for LC patients to present severe thrombocytopenia (PLQ < 50x10^9/L), and when they require an invasive procedure, to receive **transfusions of platelets** or thrombopoietin-receptor agonists to reduce the risk of bleeding. Therefore, the main endpoint of the observational study by Ronca et al.[4] was to analyze the relationship between thrombocytopenia before the procedure and the perioperative bleeding in LC patients requiring surgery to treat hepatocellular carcinoma. Thus, they concluded that the risk of bleeding was not related to the platelet count, classified as low (PLQ ≤ 50x10^9/L), intermediate (PLQ = 50-10x10^9/L), or high (PLQ >100x10^9/L). In this study, the risk of bleeding was significantly and independently related to age, GOT level, anemia, and the liver resection, with respect to radiofrequency ablation.

Furthermore, given the coagulopathy (by conventional coagulation tests) presented by the LC patient, the **transfusion of frozen fresh plasma** (FFP) during surgeries and invasive procedures is frequent. LC patients present a balanced coagulation, so that an alteration in conventional coagulation tests do not always imply coagulopathy and bleeding risk, as proven by viscoelastic tests. Thus, in the observational study by Bednarsch et al.[5], they observed that LC patients requiring hepatectomy for hepatocellular carcinoma presented as the only independent predictive factor for postoperative mayor complications having received transfusions of FFP during the intervention. Bonnet et al.[6] proved that transfusion following thromboelastography-based algorithms to correct coagulopathy in severe hemorrhage of LC patients during liver transplant decreased the overall number of transfused blood products, particularly FFP. Likewise, Vuyyuru et al.[7] proved how TEG-guided transfusion reduced the transfusion of blood products without increasing the bleeding risk in LC patients requiring invasive procedures (liver biopsies).

Regarding the transfusion of packed red blood cells:

It is at **surgery** when we can better help to prevent transfusion of packed red blood cells. For that purpose, blood salvaging and autotransfusion are available, with no negative impact in the evolution of patients that have undergone cancer-related surgery[8].

The matter of how much anemia can be tolerated in case of an **upper digestive hemorrhage (UDH)** has always raised controversy, that is to say, what is the starting level of hemoglobin for transfusion. The clinical trial by Villanueva et al.[9] compared the efficacy and safety of a restrictive therapy (transfusion when Hb < 7 g/dL) versus a liberal therapy (transfusion when Hb < 9 g/dL). The results showed a higher overall survival after 6 weeks for patients randomized to the restrictive strategy. If the etiology of UDH was due to a peptic ulcer, the odds of death in the restrictive arm were similar to the liberal one. If the etiology was related to varicose veins in patients with Child-Pugh A or B, the odds of death were significantly reduced in the restrictive group [HR 0.3 (IC 95%: 0,11-0.85)]. If the etiology was due to varicose veins in patients with Child-Pugh C, there were no significant differences in terms of mortality between both arms.

Regarding the optimization of the anemia:

The incidence of postoperative **anemia** in cirrhosis patients requiring surgery is very high (80-90%). All patients requiring major surgery and suffering from anemia before surgery, or experiencing moderate to severe blood loss in the operation room, should be treated. The persistence of anemia is associated to a higher incidence of ischemic events and short- and long-term mortality.

These patients are often treated with **iron** supplements, which brings about an increase in hemoglobin, but besides that, not much is known on its benefits. In this regard, an observational study by Rashidi-Alavijeh et al.[10] concluded that this increase in hemoglobin was significantly associated to better survival after a liver transplant, and that administering iron together with rifaximin caused a more noticeable increase in hemoglobin. However, in clinical trial **HepciFer**[11], that randomized patients requiring liver surgery to receive 1 g of carboxymaltose 4 hours after surgery versus placebo, no significant increase in hemoglobin was observed with the administration of ferric carboxymaltose seven days after surgery. This is a relevant study, since it suggests that intravenous supplementation of iron right after surgery would be the appropriate administration method for iron, preventing blocking mediated by high hepcidin levels in the postoperative setting.

Conclusions. In liver cirrhosis patients:

- **They should preferably be operated on through laparoscopy**
- **Blood salvaging agents should be used in the operation room**
- **Transfusion of PLQ and FFP should be guided by transfusion algorithm based on viscoelastic tests**
- **Patients with UHD and Child Pugh A or B should be transfused with Hb < 7 g/dL**
- **The administration of iron to treat anemia should be intravenous**

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CSL Behring

Tranexamic acid (TXA) should be administered prophylactically for every caesarean delivery. Pro-con

Chair: Prof. Carolyn Weiniger

Monday 5th of June 2023

Postpartum bleeding is a major cause of maternal morbidity and mortality1. So far, uterotonic drugs are the only procedure that has proven to reduce postpartum bleeding after birth[2].

Tranexamic acid (TXA) is an inhibitor of plasminogen activation to plasmin, thus inhibiting fibrinolysis. TXA has proven effective in reducing bleeding in elective surgery and mortality in trauma patients with critical bleeding[3,4]. In obstetrics, the **WOMAN** clinical trial proved the reduction of mortality due to postpartum bleeding, particularly if administered right after birth[5]. **The World Health Organization recommends the administration of TXA in severe postpartum hemorrhage (preferably within three hours after birth), after either vaginal or C-section delivery**.

Several randomized clinical trials have been carried out to determine the role of TXA in postpartum bleeding prevention. Most of them were small trials with methodological issues. However, three of them were large and robust enough[6-8].

PRO: TXA SHOULD BE ADMINISTERED PROPHYLACTICALLY FOR EVERY CAESAREAN DELIVERY

Loic Sentihles, France

ARGUMENTS IN FAVOR OF USING TXA IN C-SECTION BLEEDING PREVENTION

- The safety profile of TXA in bleeding prevention has been proven after birth[6-8].
  - Some fatal cases have been published, but they were due to the mistaken intrathecal administration of TXA[9].
- An effect—mild yet significant—has been shown in bleeding prevention.
- Benefits of tranexamic acid **depending on the type of delivery**[6-8]:

C-section (TRAAP2[7])
- ↓Average blood loss (reduction in hematocrit variation).
- ↓Need for uterotonic drugs.
- Not a higher incidence of thrombotic events.

Vaginal (TRAAP1[6])
- No ↓ in risk of bleeding ≥ 500 mL.
- ↓ Need for uterotonic drugs.
- Not a higher incidence of thrombotic events.

- El TXA is cost-effective ([10], article under review).

The clinical trial by **Pacheco et al.**[8], recently published, did not observe a significantly lower risk in the primary endpoint (maternal mortality or blood transfusion) following the prophylactic use of TXA in C-section postpartum versus placebo.

The effect observed in terms of bleeding reduction, though mild, could end up having an impact on breastfeeding, the mental health of the mother, and the development and behavior of the children, among other outcomes that have not been sufficiently studied so far.

The benefit-risk ratio is favorable to the use of TXA in all C-section deliveries, particularly in low- to medium-income countries.

CON: TXA SHOULD NOT BE ADMINISTERED PROPHYLACTICALLY FOR EVERY CAESAREAN DELIVERY

Catherine Bagot, United Kingdom

ARGUMENTS AGAINST USING TXA IN C-SECTION BLEEDING PREVENTION

- Postpartum hemorrhage is due to the "4Ts" (uterine atony, trauma, retained tissues, and thrombin alteration). However, only 1% of hemorrhage cases are due to coagulopathy (thrombin alteration)[11].
- The coagulopathy can be a consequence of a higher fibrinolytic activity if the postpartum hemorrhage is poorly controlled, hence the benefit of TXA.
- According to the **WOMAN** study, TXA reduces bleeding and death due to bleeding in women suffering from postpartum hemorrhage, with no adverse effects if administered within 1 to 3 hours, probably at the onset of the coagulopathy[12]. Nevertheless, some data should be considered when interpreting the results of the WOMAN study[13]:

WOMAN[5]
- **No changes in all-cause mortality were observed (primary endpoint).**
- The absolute reduction of death due to bleeding was 0.4%.
- The absolute reduction of surgery to stop the bleeding was 0.4%.

- A systematic review by **Ferrari** et al. analyzed 22 publications on the role of TXA to prevent C-section-related bleeding[14]:

FERRARI et al.[5]
- **Out of 22 studies, only three approached bleeding from a subjective standpoint.**
- **All studies presented a high degree of heterogeneity.**

- In the **TRAAP2** study, TXA prophylaxis resulted in a reduction in the estimated blood loss volume > 1000 mL or red blood cell transfusion on day 2. Nevertheless, some data should be considered when interpreting the results of the WOMAN TRAAP2[7].

TRAAP2[7]
- **The benefits were only observed in C-sections performed before labor and in patients not at risk of postpartum hemorrhage.**
- **No significant improvements in hemorrhage-related secondary clinical results were observed.**

The recent Egyptian clinical trial **Shalaby** et al. shows a benefit in high bleeding risk patients requiring a C-section[15]. However, its robustness is low, and so further studies would be needed.

Other risks in prophylactic use of TXA
- **Decrease in the preeclampsia / eclampsia threshold.**
- **Risk of accumulation in renal failure.**
- **Not recommended in case of disseminated intravascular coagulation.**
- **Prothrombotic effect.**
- **Crosses the placental barrier.**

Therefore, in C-section deliveries, the benefits of TXA prophylaxis are minimal.

DISCUSSION-CONCLUSION

In favor of TXA administration in high bleeding risk C-sections.

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CSL Behring

Perioperative fluids and beyond

Chair: Dr. Manu Malbrain; Dr. Marlies Ostermann

Saturday 3rd of June 2023

1. HOW TO MONITOR VOLAEMIA STATUS?

Marlies Ostermann, United Kingdom

Up to when should we administer volume?:

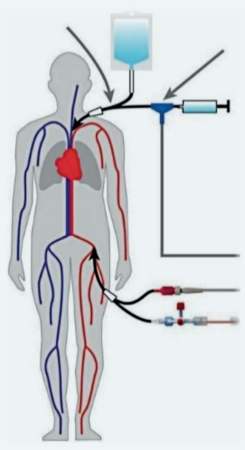
Fluid therapy should be administered during the Resuscitation and Optimization stages, following the ROSE model (Resuscitation, Optimization, Stabilization, and Evacuation), to prevent the harmful effects of using too much fluid[1].

How much volume should we administer?:

No current monitoring technique offers that information accurately. Current techniques can only estimate volumes and pressures, and they can be altered by cardiac function, capillary permeability, or intrathoracic pressures. This is why they should be interpreted within the clinical context of each patient. Therefore, there is a pressing need to include new techniques to assess the volemic status. What are currently the tools available?:

Symptoms and signs | Laboratory analysis | Fluid balance | Hemodynamic monitoring | Echocardiography | Ultrasound

When should we administer fluids?



Cardiac output too low

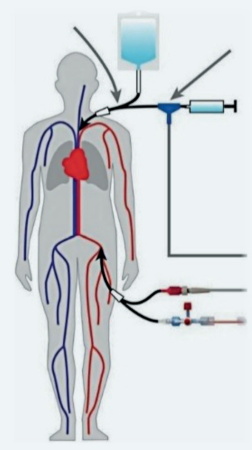
+

Signs of organic dysfunction

+

Signs of response to preload

When should we stop fluid



Acceptable cardiac output

+

No signs of organic dysfunction

+

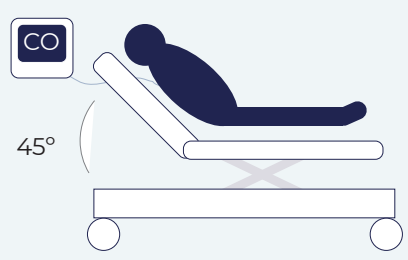
No signs of response to preload

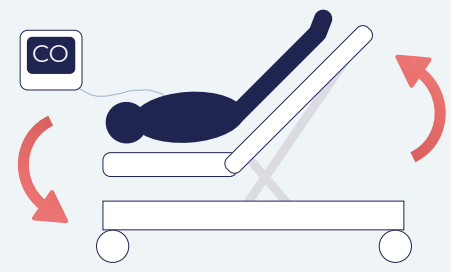
What are currently the tools available to know whether a patient will respond to fluid therapy?[4]

1. Patient in spontaneous ventilation: Respiratory variations >50% in the diameter of the inferior vena cava.

2. Intubated patient with mechanical ventilation: Respiratory variations >21% in the diameter of superior vena cava, presenting a triangular morphology, or respiratory variations >8% in the diameter of inferior vena cava inferior, or respiratory variations > 8% in the aortic flow.

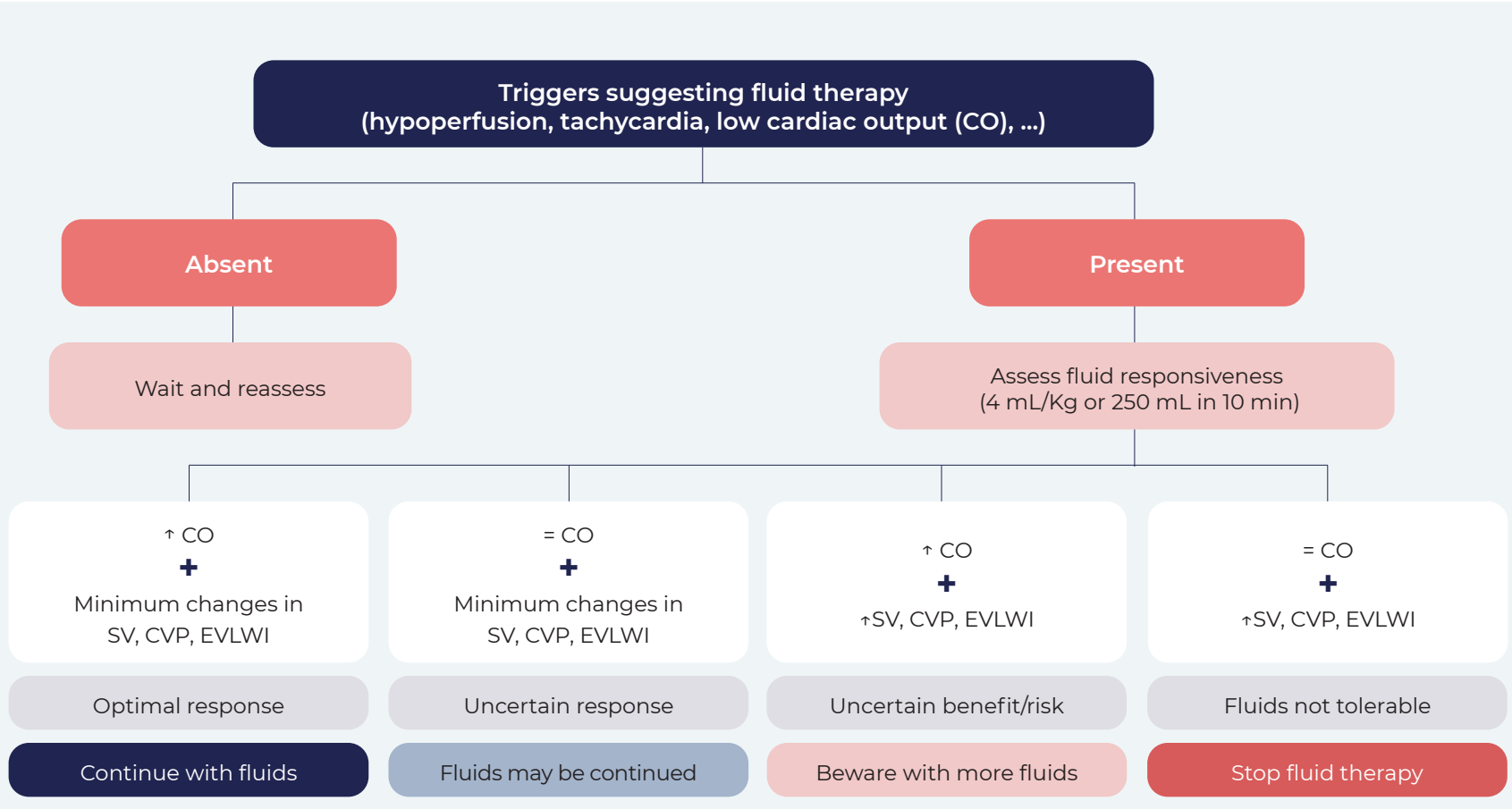
3. The test that has provided the most evidence so far in the assessment of the response to preload is the **lower extremity passive elevation test**, which would amount to an autotransfusion of about 300 mL of blood. It must be applied as follows2, and cardiac output should be monitored (CO), not blood pressure.





The dynamic evaluation of the response to fluids should be part of the routine clinical assessment, since it has been proven to decrease mortality, ICU stays, and the duration of mechanical ventilation[3,4].

Example of **fluid therapy management** according to Backer et al[4] adapted:



SV: Systolic Volume; CVP: Central Venous Pressure; EVLWI: Index extravascular lung water

Perioperative fluids and beyond

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2. IS LESS MORE? DISCUSSION OF THE RECENT EVIDENCE

Carmen Pfortmüller, Switzerland

The decision to administer fluids should be **personalized** for each patient.

If the decision is YES:

- **Restrictive** strategy in all groups of patients, equally[5-8]
  - Clinical benefit not proven versus a liberal strategy
  - but
  - No evidence of association to more damage
  - No impact on ventilation-free days, on circulatory support, or on renal results
- Resuscitation with **low volume**
  - Restriction in the supply of fluids (albumin)
    - No impact on mechanical ventilation time, hospital and ICU stays, or the need for renal replacement therapy[9, 10]
  - Increase in diuresis with hypertonic serum in patient that have undergone cardiac surgery[11]
- **Early** administration of **vasopressors**
  - Reduction in early mortality, net fluid balance, and risk of accumulation[12]

If the decision is NO[13,14]:

- **De-escalation:** reduce the dose or speed of administration of the fluid currently used
  - Stop resuscitation
  - Reduce or stop maintenance fluid
  - Minimize fluids administered with medication
- **Deresuscitation:** remove the excess of fluids using pharmacological/non-pharmacological strategies*
  - When patients show signs of fluid accumulation and organic failure
    - Diuretics
    - Ultrafiltration through renal replacement therapy

*Further randomized clinical trials are required because the evidence is low

CSL Behring

Perioperative fluids and beyond

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Saturday 3rd of June 2023

3. HOW BIG DATA CAN HELP GUIDING FLUID STEWARDSHIP

Manu Malbrain, Belgium

Fluid optimization can be defined as a series of coordinated interventions applied for the purpose of selecting the optimal fluid, dose, and duration to obtain the best clinical results, preventing adverse effects and cutting down costs.[16].

Fluid optimization programs result in[17, 18]:

- Reduction in the daily consumption of fluids
- Reduction in the use of saline solution 0.9%
- Increase in the use of balance crystalloids

EDHEN Consortium is a European initiative promoted by universities, organizations, private businesses, and other stakeholders with the following goal:

Obtaining a database with 100,000.000 records or European patients, aimed at extracting and publishing interesting observational data.

How?

By means of the Observational Medical Outcomes Partnership (OMOP).

Why?

- The average score obtained in an international survey about the knowledge on fluid therapy and anesthesiology, intensive medicine, and surgery, did not attain 50 %[15].
- It allows for a comparison between different centers to check whether national standards are met: **< 4 L/patient admitted and < 0.4 L/day in hospital**[17].
- It allows monitoring and comparing key indicators: resuscitation, maintenance, *fluid creep*, use of colloids.

The future lies in predictive models obtained from clinical practice real data (big data) treated by biomedicine and artificial intelligence

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