Goal-Directed Fluid Therapy

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9.1 Introduction

Intra-operative fluid therapy is one of the most discussed and debated therapies in recent years as a result of a difficult assessment of the volume status and of the risks associated with a liberal attitude towards volume replacement.

In this regard, avoiding steering by sight, a careful haemodynamic monitoring in high-risk surgery is necessary to find parameters that can guide the therapy, optimizing the volume and reducing the risks associated with cardiovascular instability.

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During anaesthesia, cardiovascular instability is generally identified with intra-operative hypotension. This has a high incidence and is associated with the development of severe organ complications. In the current literature, several meta-analyses identify intra-operative hypotension as a predictive marker of kidney and myocardial injury. The critical value of hypotension cannot always be defined, depending on the patient's clinical condition and comorbidities, but a critical value of mean arterial pressure (MAP) lower than 65 mmHg, even if for a few minutes, seems the cut-off value to be avoided [1, 2].

In patients undergoing high-risk surgery, oxygen debt can have harmful consequences if not ensured early. In fact, an increase in the oxygen demand up to 40% is expected as a result of the development of intra- and peri-operative surgical stress [3]. Many randomized controlled trials have shown that the use of goal-directed therapy (GDT) protocols could improve the outcome, although their application is still controversial and limited [4, 5].

Moving away from Shoemaker's theories of the value of DO_2 above normal, a GDT, focused on preserving the balance between oxygen consumption and delivery, must provide fluid therapy optimization. The peri-operative fluid therapy is often too generous compared to the needs with medium-to-severe consequences in the post-operative period (canalization delay, surgical dehiscence, infections, etc.). It is necessary a Goal-Directed Fluid Therapy (GDFT) where the pre-load maintenance and optimization are critical for the outcome. At the same time, excessive restrictive fluid therapy is equally harmful to the opposite effects on kidney and circulation. Therefore, GDFT becomes essential for improving peri-operative outcomes. The theory is based on the management tailored to a single patient (Fig. 9.1).

After this theoretical introduction, very understandable but difficult to generalize, it is appropriate to develop strategies aimed at measuring fluid requirements in a patient with haemodynamic instability. Which criteria could be used? Normally, a fluid therapy reacting to low blood pressure does not determine optimal results in the medium term, because hypotension is not always and only caused by reduced pre-load. Static pressure parameters have shown not to be reliable in guiding intra-operative fluid management. The value of CVP, for example, far from being a trusted indicator of pre-load, is still too often used as a control measure for fluid load. Nonetheless, extremely low CVP values can lead to fluid therapy, while intermediate values do not reach this goal. However, it should be emphasized that high values of CVP (between 12 and 15 mmHg) can be prudently respected as limit values for

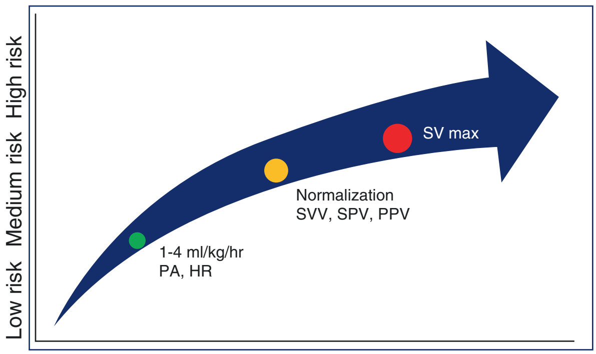

Fig. 9.1 Combination patient risk-duration intervention

volume replacement. Considering the changes in intra-thoracic pressure on cardiac function, we could use right and left ventricular pre- and post-load alterations to identify patients with a positive fluid response [6–8].

This dynamic and functional haemodynamic monitoring includes some essential requirements (controlled ventilation, tidal volume > 8 mL/kg, absence of arrhythmias, HR not less than 50 bpm, etc.) which make it very easily applicable in the operating room with the patient anaesthetized and curarized in mechanical ventilation. The cyclic changes in intra-thoracic pressure accurately establish the response to fluids in patients with haemodynamic instability. In fact, variations in pressure (Systolic pressure Variation, delta up/delta down, SPV), stroke volume (stroke volume variation SVV) and pulse pressure (pulse pressure variation PPV) are dependent on patient's pre-load, when they exceed well-established in the literature limit values. The greater the variation of these dynamic indices, the greater the probability that the stroke volume (SV)/cardiac output (CO) increases by 10% compared to its basal value in reaction to fluids (fluid responsiveness). All dynamic indices, including inferior vena cava collapsibility, correlate with a positive response to fluids with somewhat different sensitivity and specificity. PPV correlates better than SVV since PPV is directly measured and not calculated [9–11] (Fig. 9.2).

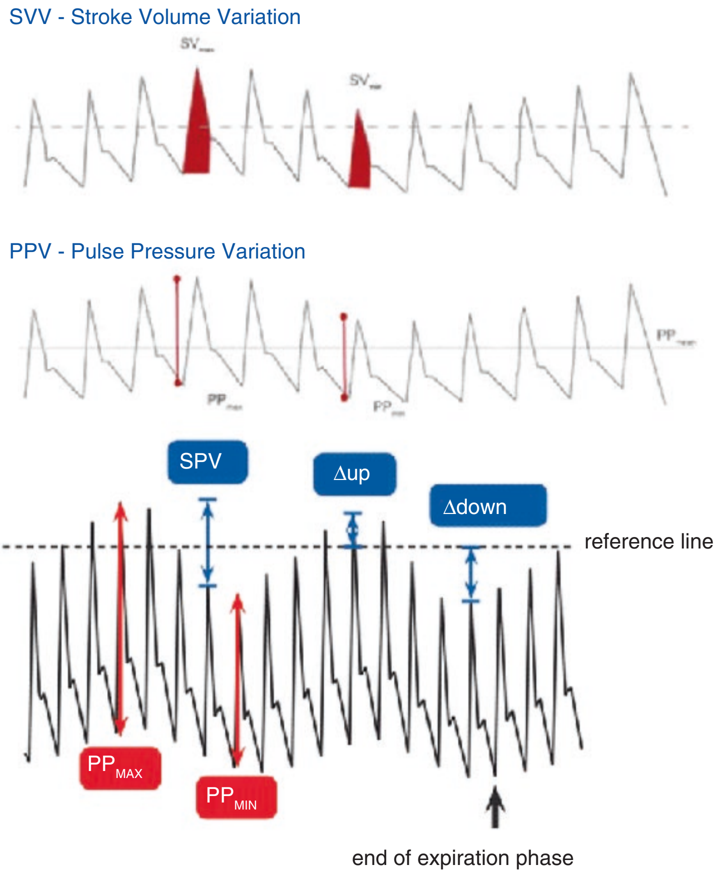

Fig. 9.2 Dynamic indices

Therefore, a targeted fluid therapy, guided by tailored GDFT protocols, should maintain stable the patient, ensuring adequate DO_2 in the critical patient. Studies on GDFT have used various protocols, based on different parameters, but with the same goal: reducing peri-operative complications. The increase in DO_2 and SV/CO and the normalization of dynamic indices (reduction of percentage changes) ensure appropriate tissue oxygenation with low lactate levels. In the post-operative period, these protocols can continue for a duration that depends on the specific clinical conditions of the patient who is monitored and receiving consensual therapy, but in general not less than 8 h.

9.2 Rationale

Despite the theoretical and practical effectiveness of the application of a GDFT protocol in the critical patient, in the literature of evidence-based medicine, there are no sufficient results suitable to recommend or not the adoption of a GDFT protocol. To reduce post-operative mortality in adult patients undergoing non-cardiac surgery, many papers suggest considering the use of a peri-operative GDFT protocol to tailor fluid therapy and reduce post-operative morbidity, just due to an excess/reduction of fluids.

Some meta-analyses [4, 5, 12] suggest that peri-operative GDFT reduces post-operative mortality, while other meta-analyses, which include patients undergoing abdominal surgery only [13, 14], make this evidence uncertain. Who is right? It is certainly necessary to consider the homogeneity of the patients, the different involved surgeries and the various basic comorbidities. Conclusions in agreement, on the other hand, are obtained by analysing the data relating to patients with high surgical risk, confirming that the application of GDFT can significantly reduce mortality in the peri-operative period. Thus, the first and essential step is to identify high-risk patients.

Many risk scores are considered: the LEE score in the cardiac patient, the Possum in the surgical patient and the Ariscat score to assess the risk of pulmonary complications. But recently the NSQIP (National Surgery Quality Improvement Program) seems to be the best one to define global complications, mortality and the risk of prolonged hospital length-of-stay.

There is no evidence in the literature on which is the best risk score for the identification of patients who require a haemodynamic optimization, given that there have been no studies that correlate the scores for risk assessment with the effectiveness of GDFT. Although there is currently no evidence on which risk score to use for identifying patients that could benefit from GDFT, the very recent ESA 2018 guidelines [15] confirm the usefulness of the ACSNSQIP score for the peri-operative risk assessment. This is a printable score that can be added to the informed consent for intervention to share with the operating team and the patient the possible complications and the risk of prolonged hospitalization, including re-hospitalization.

However, none of these scores can perfectly identify the risk of the patient that is added to the risk of surgery and to the availability of a PACU (Post Anaesthesia Care Unit) or Intensive Care Unit bed.

The analysis of recent systematic reviews has shown that literature agrees that a GDFT protocol can reduce post-operative morbidity, both in terms of global complications [4, 13] and in terms of organ complications [16–18]. The evidence is very strong as regards the incidence of renal, gastrointestinal and infection complications in the post-operative period.

9.3 Global Post-operative Complications

The systematic review and meta-analysis valued the incidence of post-operative complications, their type and frequency in relation to different fluid therapy therapeutic strategies.

In the literature, the application of GDFT protocols allows a clear reduction of complications in the treated group compared to the control [13].

Recently, a randomized controlled trial (RCT) [19] analysed the effects of peri-operative GDFT in patients with medium-low risk undergone to major surgery: in this class of patients too, the percentage who developed moderate or severe post-operative complications was significantly lower in the GDFT group than in the control.

9.4 Renal Complications

Some authors have shown that peri-operative GDFT is able to reduce the incidence of renal complications in surgical patients.

A recent meta-analysis [12] confirms that GDFT significantly reduces the incidence of post-operative AKI. This reduction is present both in patients at medium and at high risk and it is very evident if the haemodynamic optimization (GDFT) is prolonged to the immediate post-operative period.

9.5 Infectious Complications

A recent meta-analysis analysed infectious complications in patients treated with GDFT compared to control [18]. This showed that GDFT significantly reduces the number of infectious complications. The same study showed a significant reduction in the risk of post-operative pneumonia and urinary tract infections. A recent meta-analysis [20] that only includes patients undergoing abdominal surgery confirms that GDFT significantly reduces the incidence of surgical site-related infections. The incidence of sepsis was also significantly lower in the GDFT group than in the control.

9.6 Gastrointestinal Complication

The review of Brienza et al. shows that in non-cardiac patients treated with GDFT post-operative gastrointestinal complications were significantly reduced compared to the control group. And we talk about any complication, both minor (intestinal canalization) and major (dehiscence).

9.7 Cardiovascular Complication

GDFT is applied with difficulty by clinicians for fear of increasing the risk of cardiac complications, related to the use of fluid challenges and inotropes. A meta-analysis of 2014 [21] that analyses the incidence of cardiovascular complications in non-cardiac surgical patients shows that patients treated with the GDFT protocol have a lower incidence of global cardiovascular complications, but not of myocardial ischemia.

9.8 Application

Therefore, if we want to summarize the highlights of a peri-operative haemodynamic optimization process, we should:

(a) avoid periods of hypotension with mean arterial pressure below 65 mmHg. For this reason, the patient subjected to non-cardiac surgery should have continuous (invasive and non-invasive) monitoring of blood pressure.

Clearly, invasive blood pressure monitoring allows arterial samples to be added to the haemodynamic aspect, as well as providing information on the oxy-phoretic and metabolic profile. The use of parameters that allow the detection and monitoring of stroke volume/cardiac output is the right choice, together with dynamic parameters such as SVV and PPV, associated or not with the oxygen delivery (DO_2). In the high-risk patient, continuous monitoring of blood pressure allows in real time to identify even short periods of hypotension, which are considered as predictors of post-operative myocardial and renal injury.

(b) choose a GDFT protocol in the context of optimization protocols. In the literature, there are no comparative studies between different protocols and, consequently, it is not possible to suggest one, just as there are no studies comparing the methods of application of the protocols (reactive and proactive).

9.9 GDFT

The management of peri-operative fluid therapy can be guided by different parameters and protocols. These can be summarized in 4 categories:

(a) DO_2 optimization;
(b) optimization of stroke volume/cardiac output;
(c) evaluation and normalization of the so-called dynamic haemodynamic parameters, or fluid-responsiveness indexes, such as SVV and PPV;
(d) evaluation of not properly haemodynamic parameters, such as $ScVO_2$, O_2ER and lactate level.

The meta-analysis by Hamilton et al. includes 29 studies. They show that the administration of fluids guided by the Cardiac Index (CI) or DO_2 improves the patient's outcome in terms of mortality and post-operative complications in moderate and high-risk surgical patients. According to these results, the systematic review by Gurgel et al. [22] including 32 studies showed that in high-risk surgical patients the haemodynamic optimization guided by CO, DO_2 and Oxygen Consumption (VO_2) reduces post-operative mortality and organ dysfunction.

The meta-analysis by Pearse et al. [23] provided further supporting evidence. In particular, available data suggest that haemodynamic optimization based on CO/DO_2 measurements compared to classical fluid therapy shows a reduction in mortality up to 25%, a reduction in the risk of renal failure up to 33%, a reduced risk of ARDS up to 60% and a reduction in surgical site infections.

The recent meta-analysis by Michard et al. 2017 [24] included 19 randomized controlled trials in which peri-operative fluid therapy was managed using dynamic indexes based on pulse-contour analysis with uncalibrated method versus standard fluid therapy. Post-operative morbidity was reduced in the group treated with uncalibrated instruments. In favour of the use of uncalibrated instruments, there was a lower incidence of infectious, cardiac and abdominal complications as well as a reduced hospitalization.

In contrast, mortality, incidence of renal and respiratory complications were not found to be influenced by the use of this technology. In their extensive meta-analysis, Sun et al. [16] included 45 studies in which peri-operative fluid therapy was performed in 6344 patients with different haemodynamic parameters (CO, CI, DO_2, SV, SVV, PPV, PVI) versus a conventional approach (Fig. 9.3). The results showed that peri-operative fluid management guided by haemodynamic parameters/protocols is linked to a reduction in mortality both in the short and long term together with a lower total incidence of complications.

The protocol based on dynamic parameters of pre-load-dependence foresees the identification of fluid responders, based on the values of PPV, SVV, SPV, Plethysmographic variability index (PVI) and therefore a probable increase in cardiac output in response to a fluid load (3 mL/kg in 5–10 min) [25–27]. However, dynamic indices show less accuracy in some clinical contexts. First, to determine a heart–lung interaction such as to allow the use of these dynamic indices, it is necessary for the patient to be ventilated with positive pressure.

Therefore, the dynamic indices of fluid responsiveness do not find clinical application in spontaneously breathing patients. Furthermore, it is necessary that the thorax is closed: in the case of an open thorax, the positive intra-thoracic pressure is annulled leading to false negatives (low PPV and SVV). This precludes the use of SVV and PPV in cardiothoracic surgery until complete closure of the chest.

It is also essential that the cardiac rhythm is regular since cardiac arrhythmias determine SV variations independent of cardiorespiratory interaction, and in this case, the PPV or SVV variations would represent false positives (high PPV and SVV).

The ventilation with low tidal volume (<6 mL/kg) reduces cardiorespiratory interaction and, therefore, increases the possibility of false negatives. Similarly,

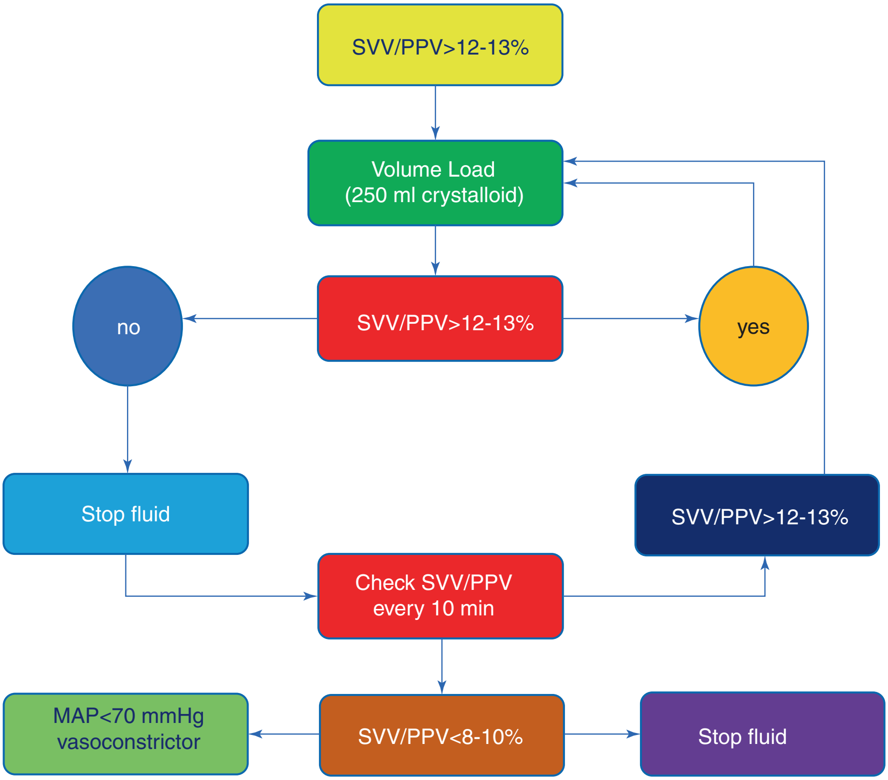

Fig. 9.3 GDFT Protocol based on dynamic indices

false negatives could be present in the case of low pulmonary compliance. A low heart rate/respiration rate ratio (<3.6) (respiratory rate set to 14 in the presence of bradycardia - 50 bpm) could be associated with false negatives [28]. Even increases in intra-abdominal pressure, modifying venous return, affect the validity of PPV and SVV (false positives) in indicating probable fluid responsiveness.

It should not be forgotten that in the case of changes in bi-ventricular compliance (e.g. right heart failure, cardiac tamponade) the changes in left ventricular pre-load will be more conditioned by the underlying pathology than by cardiorespiratory interaction, resulting in false positive PPV and SVV.

It is important to remember that the SVV derives from a calculation based on mathematical algorithms, while the PPV is a direct measure of the difference between systolic and diastolic pressure.

The SVV is calculated by the so-called pulse contour methods (PCM), continuous monitoring systems that analyse the pressure waveform and derive the SV and its variations, using dedicated algorithms. In all cases where a GDFT protocol based on dynamic indexes is not applicable, we can consider the SV measurement and use its 10% increase compared to a fluid challenge as a positive datum. This allows us to maximize the SV in successive steps up to the lack of further increase of it (Fig. 9.4).

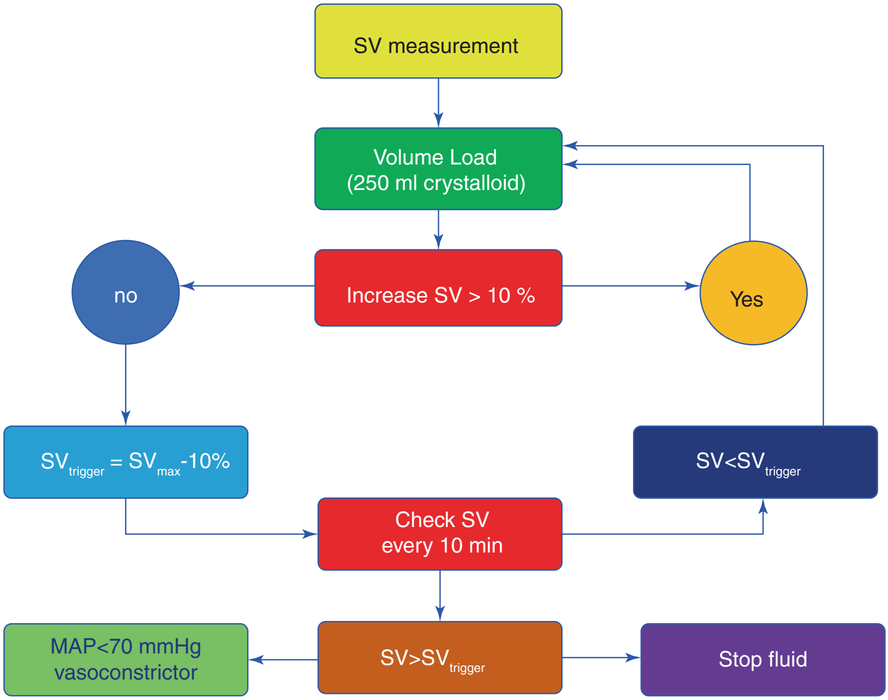

Fig. 9.4 GDFT Protocol based on SV max

The adoption of a GDFT fluid optimization protocol is strongly recommended in the literature in adult patients to be undergone to major abdominal surgery. Recent publications have shown that GDFT is able to reduce post-operative morbidity in patients undergoing abdominal surgery but not mortality or hospitalization.

A randomized pragmatic trial on "restrictive" versus "liberal" fluid therapy in the first 24 post-operative hours was published recently. It included about 3000 patients at an increased risk of post-operative complications [29]. Although there are no differences between the two groups, the "restrictive" group showed a higher incidence of surgical site infection, AKI and renal support therapy.

Differently, the Pang meta-analysis [30] showed that a restrictive peri-operative fluid regime reduces the risk of post-operative infectious complications, pulmonary complications and cardiac complications but not the risk of gastrointestinal and renal complications and has no effect on post-operative mortality.

The results of the same meta-analysis did not show a reduction in the total incidence of post-operative complications when using a restrictive strategy. Analysing the literature data on complications, it appears that the overall number of patients with post-operative problems was greater in the liberal fluid strategy.

A practical suggestion consists in the use of a fluid strategy, in high-risk adults undergone to major non-cardiac surgery, that aims as much as possible at a near-zero balance in the patient who starts the surgery under euvolemia conditions (as in the ERAS protocol), or weakly positive during the first 24 post-operative hours to reduce the risk of acute kidney injury.

It does not seem useful to implement a GDT through the only use of inotropic drugs, vasoconstrictors and vasodilators. However, vasoactive drugs may be useful for manipulation of the SV and the DO_2, where achieving the goal is impossible with only fluids.

The goal of GDFT, or haemodynamic optimization, should aim to prevent organ hypoperfusion, and therefore any type of complication up to the ambition to reduce mortality, through algorithms that tend to increase/normalize, in high-risk patients undergone to non-cardiac surgery, the SV and then the DO_2. The use of "dynamic" haemodynamic indices, linked to heart–lung interaction on venous return and cardiac output, has radically changed the idea of optimization. Monitoring has changed with less invasiveness and the fluid strategy has changed, tending to the "near zero" balance. In this perspective, inotropic drugs, as well as vasoconstrictors, have assumed a marginal and secondary role.

In some contexts, the use of a peri-operative GDFT protocol is associated with a reduction in the number of patients who develop post-operative complications, a reduction of the average hospitalization and consequently a lowering cost for the treatment of these patients.

The increase in post-surgical complications is recognized to be of great clinical and economic impact. After a major surgery, about 30% [3] of patients undergo at least one complication with unfavourable effects on survival and long-term quality of life. Complications are also responsible for a significant increase in hospitalization, the share of readmissions, missed scheduled hospitalizations, lengthening waiting lists and increasing costs. Numerous studies and recent meta-analyses have shown that the use of GDFT reduces the number of patients experiencing complications [23] with a cost reduction of between 600 and 1400 euros per patient.

9.10 Protocols

According to the patient's risk, surgery and the surgical technique used (laparoscopic vs. laparotomy, for example) a GDFT protocol can be chosen. In the low-risk patient (ASA 1 and 2) who undergoes surgery of medium duration, the fluid-therapeutic attitude is liberal, around 1–4 mL/kg/h. of crystalloids, trying to maintain a slightly positive or near zero balance.

The attitude in the medium-risk patient (ASA 2–3) subjected to medium/long-term surgery is different. In these cases, we recommend a GDFT based on the normalization of dynamic indexes that can regulate the use of fluids (crystalloids) on the basis of haemodynamic instability such as to generate, in the heart–lung interaction, a variation in flow/pressure indices (SVV, SPV, PPV). In patients at higher risk who undergo medium/long duration surgery, a fluid therapy approach of GDFT is advised, especially related to the optimization of SV with fluid increases, following haemodynamic instability, aimed at increasing the SV value by 10% upon reaching its maximum.

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