

**Hemodynamic optimisation during major abdominal surgery**

**Doctoral (PhD) thesis**

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## **Introduction**

Major abdominal surgery is associated with significant risk of morbidity and mortality in the perioperative period, especially in the elderly or patients with significant co morbidities. Following the implementation of safety standards and due to better risk evaluation and management outcomes after anaesthesia have improved over the last decades. Although estimations of the perioperative complications and postoperative morbidity are difficult, it has been suggested that this may be between 3 and 17% of cases. It is well known, that using heart rate (HR), mean arterial pressure (MAP) and central venous pressure (CVP) to assess and guide hemodynamic support may be misleading and that they are inadequate in assessing perfusion or  $DO_2$ . There is mounting evidence that the role of CVP to evaluate preload and fluid load is limited. Several studies reveal the role of intraoperative hemodynamic monitoring and goal-directed management in the improving outcome following major surgery. In this case, cardiac output (CO), oxygen delivery ( $DO_2$ ) or the mixed/central venous oxygen saturation ( $SvO_2/ScvO_2$ ) are the end-point parameters of fluid resuscitation, vasoactive therapy and transfusion. Goal-directed intraoperative hemodynamic management results in reduced postoperative mortality and morbidity. Despite the increasing evidence, advanced hemodynamic monitoring has not become routine practice.

For a long time the pulmonary artery catheter was the gold standard for measuring CO. To measure CO the use of intermittent thermodilution by the pulmonary artery catheter (PAC) has been decreased in surgical patients over the past decades. Evaluation of CO was simplified by transpulmonary indicator dilution method. The two most widely used techniques are the lithium dilution and thermodilution. At the time we were conducting one of our studies making the ground of this thesis, the optimal assessment of the preload was debated, although intrathoracic blood volume index (ITBVI) measured by thermodilution was found to be probably the most accurate method for indicating preload status of the critical ill patient. ITBVI was found to be superior to pulmonary artery occlusion pressure for indicating preload status during liver and lung transplantation. No clinical trial had investigated the effects of single transpulmonary thermodilution measurement guided fluid therapy on the intra- and postoperative inflammatory response and organ dysfunction.

Using the methods mentioned above, knowing the oxygen content of arterial blood and measuring the cardiac output we can calculate the  $DO_2$  and have a sight on the imbalance between oxygen supply and demand. Another approach is measuring the oxygen content of

the returning venous blood. Assuming normal arterial oxygen content and demand we can estimate the  $DO_2$ . Although  $SvO_2$  measured by using pulmonary artery catheter is regarded as the most accurate indicator of the balance between global oxygen delivery and consumption, there is a good evidence that  $ScvO_2$  may serve as an easily obtainable and reliable alternative to manage therapy in critical ill patients.

In our clinical trials we compared the traditional, CVP guided intraoperative fluid management to ITBVI or  $ScvO_2$  guided hemodynamic management. In the first study our goal was to analyze the differences regarding the inflammatory response, in the second study postoperative complications were the end-point.

### **Volumetric and pressure guided intraoperative fluid management**

Patients underwent major abdominal surgery were included and randomized into CVP or ITBV group. Data of 20 patients were analyzed in each group. We did not find any significant differences regarding the demographics and clinical parameters of the patients or the surgical intervention as shown in this table:

	<b>CVP (n=20)</b>	<b>ITBV (n=20)</b>
<b>Age (year)</b>	59±9	61±11
<b>Sex (M/F)</b>	10/10	8/12
<b>Length of operation (minutes)</b>	220±89	230±94
<b>SAPS II score</b>	16±5	14±5
<b>Type of operation:</b>		
<b>Oesophagectomy</b>	10	9
<b>Total gastrectomy</b>	5	8
<b>Pancreas resection</b>	5	3

*Table 1.: Demographics; SAPS: simplified acute physiology score*

In the CVP group the target CVP pressure was 8–12 mmHg during surgery, as a widely used target. In the ITBV group the desired end-point was to keep the ITBVI between 850 and 950 ml/m<sup>2</sup> during the operation. The hemodynamic parameters were determined by single arterial thermodilution, using the PiCCO machine every 30 minutes during the surgery. Along with these measurements arterial blood gas analysis was performed as well. Blood samples were taken into serum separator tubes before anaesthesia was commenced

( $t_0$ ), hourly during surgery then on admission to ICU ( $t_{ICU}$ ), and subsequently 24, 48, and 72h after admission ( $t_{24}$ ,  $t_{48}$ ,  $t_{72}$ ). Serum C-reactive protein (CRP), procalcitonin (PCT) levels were measured, than the serum was stored at -70 C degree, and tumour necrosis factor- $\alpha$  (TNF- $\alpha$ ) levels were determined later.

## Results

The desired hemodynamic goals were reached in both groups. There was no significant difference between the CVP and ITBV groups regarding CVP, ITBVI, cardiac index, stroke volume index (SVI), contractility, heart rate, or mean arterial pressure at any measurement point. There was no clinical evidence of fluid overload. Extravascular lung water (EVLW) was normal, and urine output was similar during the study period in both groups as shown in the table below:

	CVP (n=20)	ITBV (n=20)
<b>CVP (mmHg)</b>		
$t_0$	10 $\pm$ 4	12 $\pm$ 4
$t_{30}$	13 $\pm$ 4	15 $\pm$ 4
$t_{60}$	12 $\pm$ 3	14 $\pm$ 4
$t_{120}$	11 $\pm$ 3	14 $\pm$ 5
$t_{240}$	12 $\pm$ 4	16 $\pm$ 6
<b>ITBVI (ml/m<sup>2</sup>)</b>		
$t_0$	875 $\pm$ 204	969 $\pm$ 308
$t_{30}$	942 $\pm$ 210	997 $\pm$ 210
$t_{60}$	912 $\pm$ 136	1009 $\pm$ 289
$t_{120}$	921 $\pm$ 136	1038 $\pm$ 346
$t_{240}$	997 $\pm$ 270	919 $\pm$ 193
<b>CI (l/m/m<sup>2</sup>)</b>		
$t_0$	2.57 $\pm$ 0.60	2.96 $\pm$ 0.64
$t_{30}$	3.64 $\pm$ 0.87	3.67 $\pm$ 0.93
$t_{60}$	3.39 $\pm$ 0.58	3.51 $\pm$ 0.91
$t_{120}$	3.50 $\pm$ 0.65	3.43 $\pm$ 0.84
$t_{240}$	3.78 $\pm$ 1.13	4.01 $\pm$ 0.99

<b>SVI (ml/m<sup>2</sup>)</b>		
<b>t<sub>0</sub></b>	36±11	44±12
<b>t<sub>30</sub></b>	45±10	49±12
<b>t<sub>60</sub></b>	42±9	49±12
<b>t<sub>120</sub></b>	47±14	50±13
<b>t<sub>240</sub></b>	49±9	42±8
<b>dP/dt<sub>max</sub> (mmHg/s)</b>		
<b>t<sub>0</sub></b>	688±227	769±261
<b>t<sub>30</sub></b>	788±294	793±362
<b>t<sub>60</sub></b>	739±176	852±413
<b>t<sub>120</sub></b>	775±223	887±258
<b>t<sub>240</sub></b>	772±336	747±243
<b>EWLVI (ml/kg)</b>		
<b>t<sub>0</sub></b>	8±3	9±4
<b>t<sub>30</sub></b>	8±3	9±3
<b>t<sub>60</sub></b>	8±3	9±4
<b>t<sub>120</sub></b>	8±3	9±4
<b>t<sub>240</sub></b>	10±4	9±4
<b>Heart rate (/min)</b>		
<b>t<sub>0</sub></b>	73±17	70±15
<b>t<sub>30</sub></b>	80±11	71±15
<b>t<sub>60</sub></b>	81±14	75±16
<b>t<sub>120</sub></b>	76±13	73±16
<b>t<sub>240</sub></b>	76±14	90±25
<b>MAP (mmHg)</b>		
<b>t<sub>0</sub></b>	87±26	87±21
<b>t<sub>30</sub></b>	86±16	83±20
<b>t<sub>60</sub></b>	87±12	83±15
<b>t<sub>120</sub></b>	78±13	76±13
<b>t<sub>240</sub></b>	71±8	74±12

*Table 2.: intraoperative hemodynamic parameters*

In the overall study population changes in the SVI showed a significant correlation with changes in CVP and ITBVI ( $r=0.288$   $p<0.001$  and  $r=0.508$   $p<0.001$ , respectively, although the correlation was weak, especially in the CVP group.

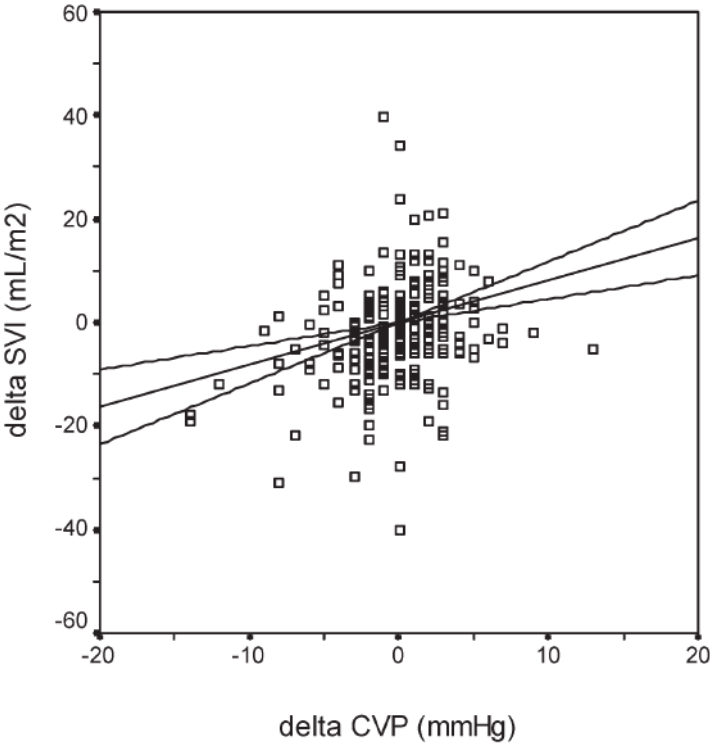


Figure 1.: correlation between the changes of SVI and CVP

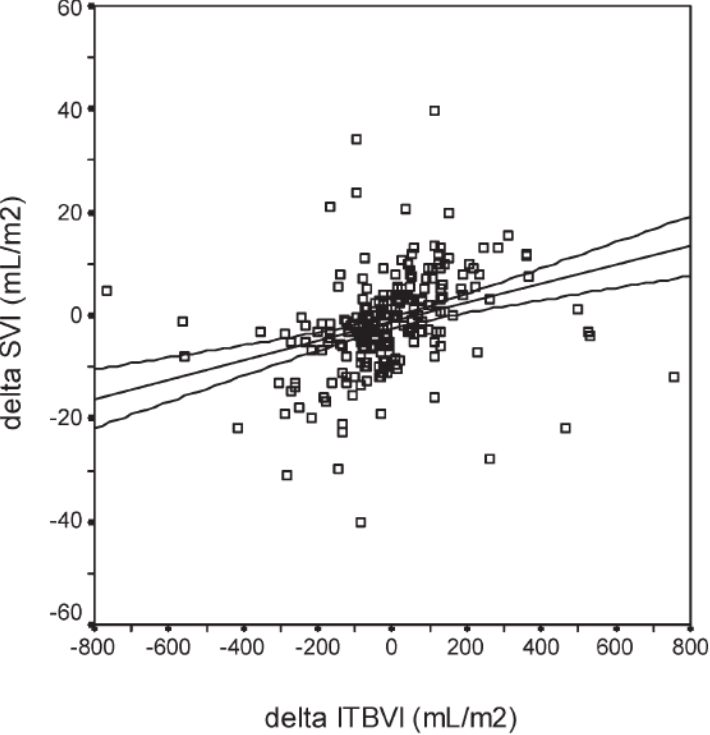


Figure 2.: correlation between the changes of SVI and ITBVI

Patients in the two groups received the same amount of crystalloid, colloid, and packed red blood. Hemoglobin levels in neither group changed significantly during the study.

	<b>CVP (n=20)</b>	<b>ITBV (n=20)</b>
<b>Fluid management</b>		
crystalloid (ml)	4043±1191	4047±1841
colloid (ml)	1255±971	1411±1040
Packed red blood cell (U)	2±1.5	2.5±1.0
Fresh frozen plasma (U)	2.5±1.0	2.8±1.5
<b>Intraoperative urine output (ml)</b>	755±528	757±533
<b>Hemoglobin (g/l)</b>		
t <sub>0</sub>	108±13	107±13
t <sub>30</sub>	102±11	106±15
t <sub>60</sub>	103±16	100±22
t <sub>120</sub>	99±17	93±14
t <sub>240</sub>	105±9	103±12
<b>MODS</b>		
t <sub>ICU</sub>	2±1	2±2
t <sub>24</sub>	2±2	2±1
t <sub>48</sub>	2±2	2±2
t <sub>72</sub>	2±1	2±2
<b>ICU days</b>	7±5	7±5
<b>Length of ventilation (days)</b>	3±1	3±1
<b>Survival/non survival</b>	19/1	18/2

*Table 3.: intraoperative fluid balance, postoperative outcome; MODS: multiple organ dysfunction score, ICU: intensive care unit*

TNF- $\alpha$  levels remained in the normal range intraoperatively and increased slightly but not significantly during the three postoperative days in both groups.

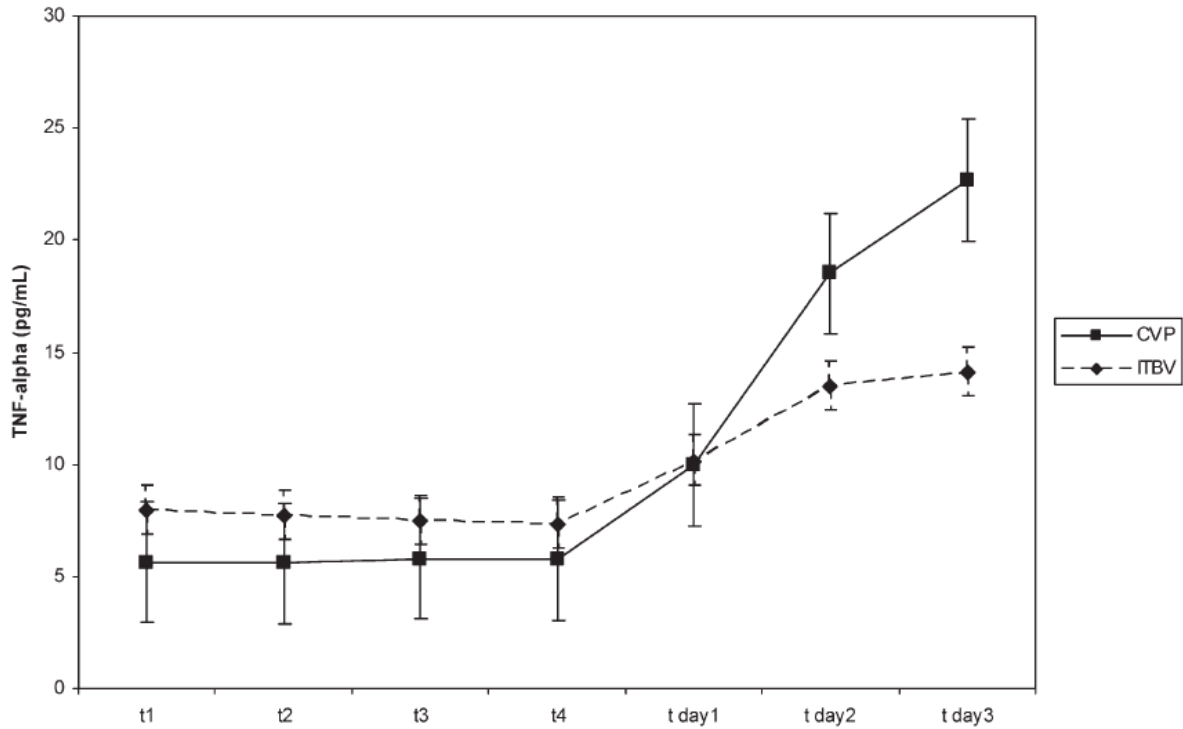


Figure 3.: changes of TNF- $\alpha$  during the operation and on the first three postoperative days

Serum PCT levels were normal in both groups preoperatively and on arrival in the ICU, but within 24 h levels increased significantly. Levels remained in the pathological range for the rest of the study with the maximum response observed 24 hours following the surgery. There was no significant difference between the two groups.

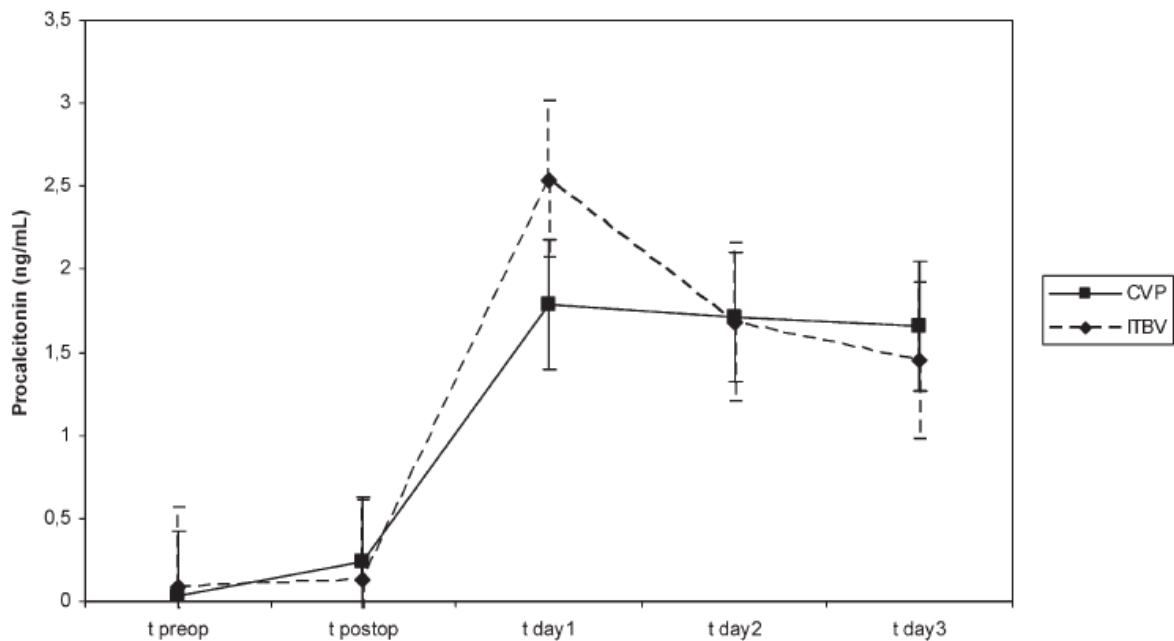


Figure 4.: changes of PCT during the operation and on the first three postoperative days



Serum CRP levels followed similar kinetics: they were within the normal range preoperatively and on arrival on ICU in both groups but increased significantly in 24 h and remained significantly elevated during the study period. In contrast with PCT the maximum response was observed 48 hours after the operation, without significant intergroup difference.

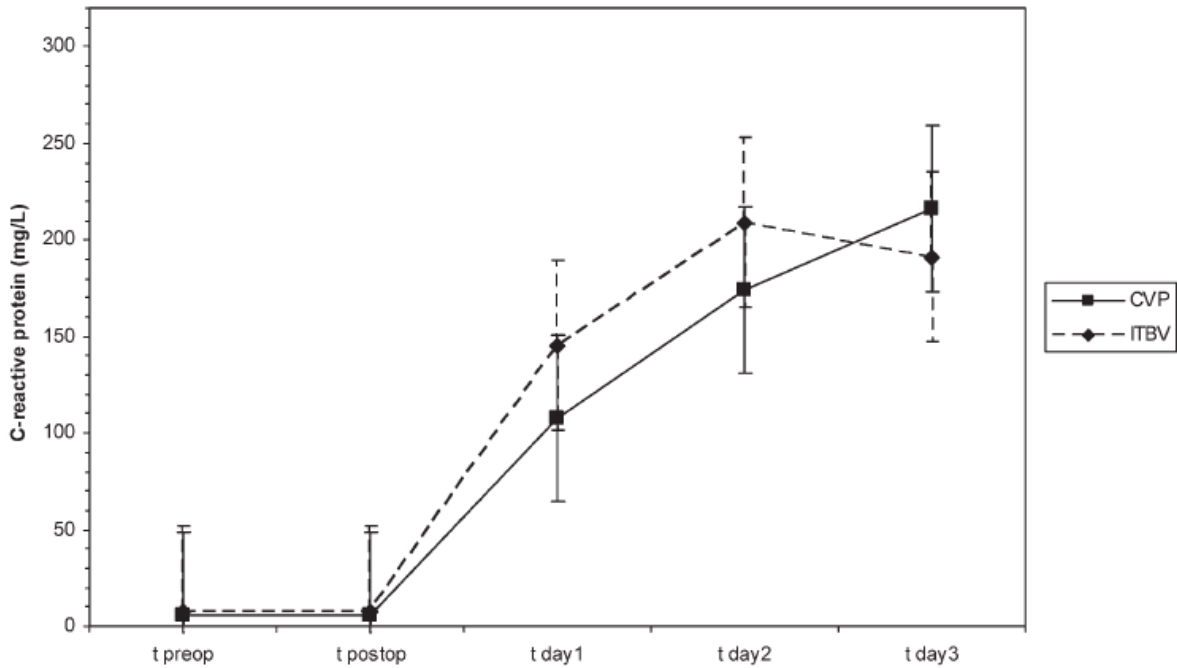


Figure 5.: changes of CRP during the operation and on the first three postoperative days

Regarding organ dysfunction the daily multiple organ dysfunction score (MODS) indicating any organ dysfunction did not differ significantly between the two groups throughout the study. Median length of ICU stay, length of mechanical ventilation during the overall ICU stay, and survival were nearly identical in the two groups (Table 3.).

## Discussion

In our prospective randomized clinical trial we found no significant difference between the two groups regarding intra- or early postoperative inflammatory response and organ dysfunction. Interestingly, in contrast to data finding volumetric parameters better indicator of preload as compared to filling pressures, we found weak, but significant correlation between the changes of SVI and the changes of both CVP and ITBVI. Despite these differences between the current and previous investigations no firm conclusion can be made as this study was neither aimed nor designed and powered to answer the question whether

ITBV or CVP is the better monitoring tool of cardiac filling during major abdominal surgery. Our results cannot be interpreted as CVP or ITBVI were equal regarding the assessment of preload during major abdominal surgery.

Previous investigations, including one conducted by our own workgroup, have shown that major abdominal surgery initiates an inflammatory response. In this study we examined three markers used for identification of inflammatory response. We could not find any significant differences in the postoperative kinetics of PCT, TNF- $\alpha$  or CRP, the levels were lower compared to our previous results or the pre-existing reference values. One of the possible explanations is that patients in the current study were successfully volume resuscitated by target values, reducing the risk of hypoxic tissue damage caused by hypovolemia, and this itself attenuated the inflammatory response. This is in accordance with previous findings that intraoperative hemodynamic monitoring and goal-directed management improves outcome following major surgery, as mentioned in the introduction.

### **Continuous central venous oxygen saturation assisted hemodynamic therapy during major abdominal surgery**

Patients undergoing elective major abdominal surgeries were enrolled into our prospective study. Patients were randomly allocated by envelope randomisation in a block-of-ten fashion into control, or ScvO<sub>2</sub> groups. Data of 41 patients in the control and 38 patients in the ScvO<sub>2</sub> group were analyzed. Distribution of the types of surgical interventions is shown in Table 4. Two patients of the control group died on the intensive care unit during the postoperative period, 28 days mortality was also significantly higher in this group (1 vs. 8, p=0.018).

	ScvO <sub>2</sub> (n=38)	control (n=41)	p
<b>Age (years)</b>	62 ± 8	62 ± 8	0.95
<b>Gender (M/F)</b>	28/10	29/12	0.77
<b>APACHE II score</b>	12 ± 4	11 ± 5	0.37
<b>ICU length of stay (days)</b>	3 (2)	3 (2)	0.663
<b>Length of surgery (minutes)</b>	247 ± 82	254 ± 45	0.76

<b>Type of surgery (number of patients)</b>			
<b>Oesophagectomy</b>	4	2	
<b>Total gastrectomy</b>	3	0	
<b>Radical cystectomy</b>	22	29	
<b>Aortobifemoral bypass</b>	5	7	
<b>Abdominal aortic aneurysm</b>	4	3	
<b>ICU survival (S/NS)</b>	38/0	39/2	0.17
<b>28 days survival (S/NS)</b>	37/1	33/8	0.018*

*Table 4.: demographics*

Central venous saturation was continuously monitored in the ScvO<sub>2</sub> group by using a fiberoptic catheter of the CeVOX monitor. In the control group cases of hypotension (as defined by MAP<60 mmHg) were treated with a fluid bolus if the CVP<8 mmHg, and norepinephrine if the CVP≥8 mmHg. In the ScvO<sub>2</sub> group, hypotension (MAP<60 mmHg) was considered primarily due to hypovolemia if the ScvO<sub>2</sub><75%, and patients received a fluid bolus. If the ScvO<sub>2</sub>≥75%, it was assumed that hypotension was primarily due to vasodilatation caused by general anaesthesia, and norepinephrine was administered. In addition to low MAP there was also another trigger for intervention in this group: if ScvO<sub>2</sub> dropped below 75% or there was a sudden decrease by more than >3%, patients received a fluid bolus regardless of the MAP. During the operation arterial and central venous blood gas analysis were done hourly. Blood samples for laboratory assessments such as kidney function, liver function, blood count and inflammatory parameters such as procalcitonin (PCT) and C-reactive protein (CRP) were taken before the operation, on arrival to the ICU and 24, 48 hours later. Arterial and central venous blood gas analyses were also performed at these time points.

## **Results**

There was no significant difference in ScvO<sub>2</sub> between the two groups at baseline. During the operation there was a decrease in ScvO<sub>2</sub> in the ScvO<sub>2</sub> group while it remained almost unchanged in the control group, reaching a significant difference between the two groups four hours after the start of the operation.

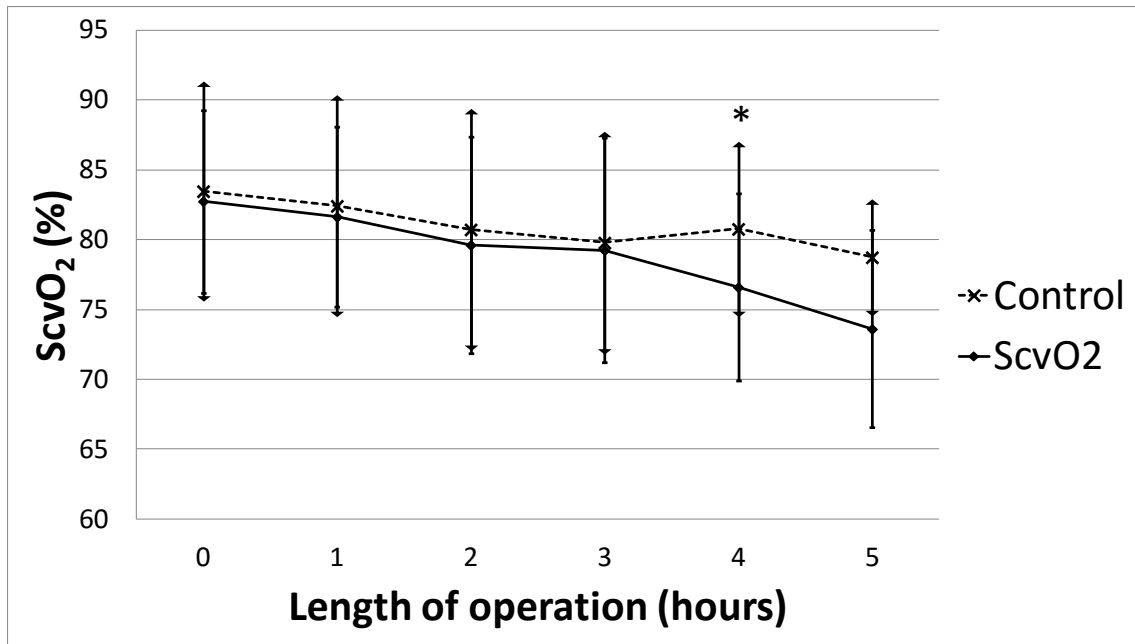


Figure 6.: changes of ScvO<sub>2</sub> during the operation

The target MAP was achieved in most cases with no difference between the groups. Regarding the CVP there was no significant difference between the two groups throughout the operation.

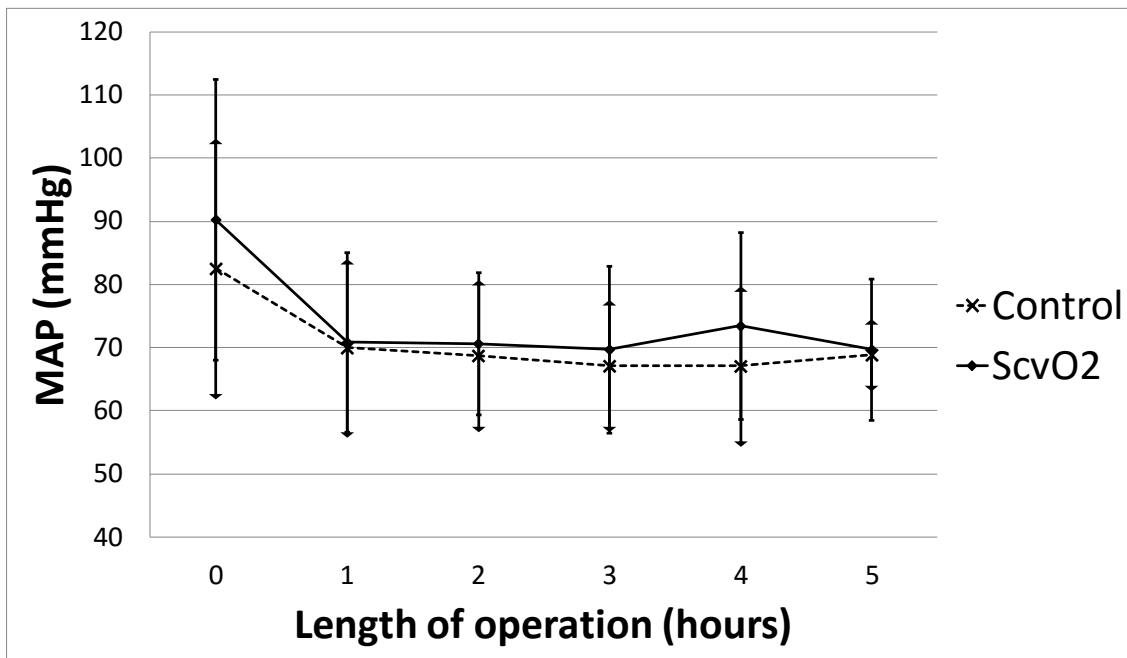


Figure 7.: changes of mean arterial pressure during the operation

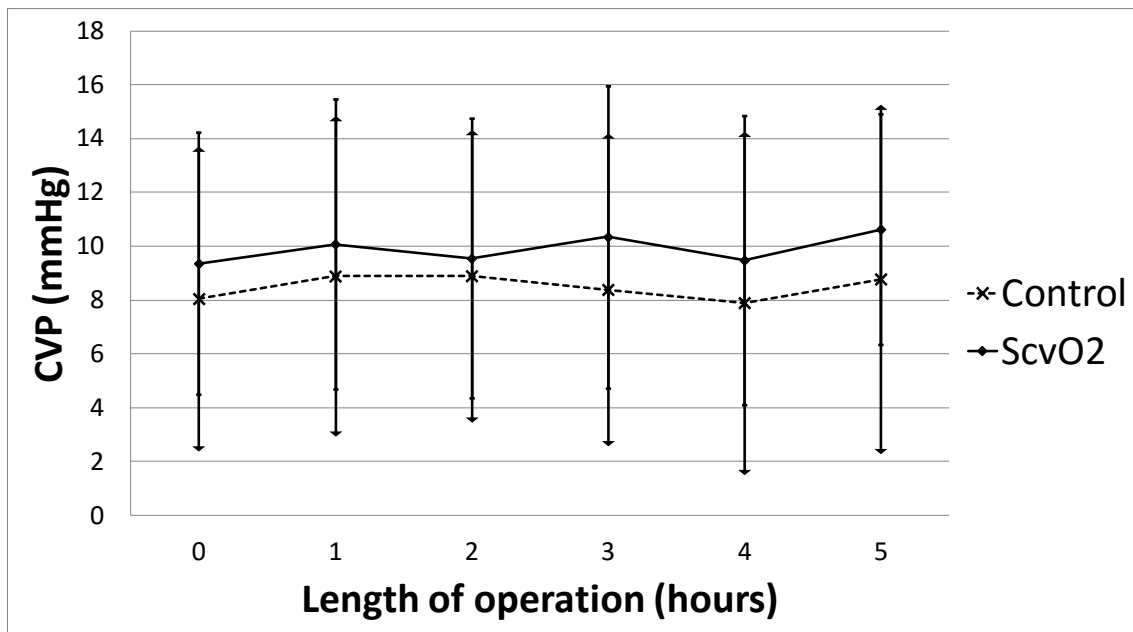


Figure 8.: changes of central venous pressure during the operation

Measurement of the urine output during the operation was complicated in 33 patients who underwent radical cystectomy. In their case we were unable to estimate the amount of urinary output. In cases where exact measurement was possible, hourly urine output showed a significant difference between the two groups: ScvO<sub>2</sub> group (n=23): 165 ± 98 ml/h vs. controls (n=23): 109 ± 92 ml/h, p=0.023. Intraoperative interventions are shown in Table 5.

	ScvO <sub>2</sub> (n=38)	control (n=41)	p
<b>Crystalloid infusion (ml/h)</b>	1126 ± 471	1049 ± 431	0.46
<b>Colloid infusion (ml/h)</b>	279 (161)	107 (250)	<0.001*
<b>Vasopressor need (nr of patients)</b>	11	15	0.47
<b>Dose of vasopressor (mcg/h)</b>	37 (107)	18 (73)	0.84
<b>RBC transfusion (nr of patients)</b>	24	15	0.02*
<b>Intraoperative blood loss (ml)</b>	973 ± 473	983 ± 574	0.99

Table 5.: intraoperative interventions

The lactate levels were normal in both groups during the whole operation without any significant difference or change:

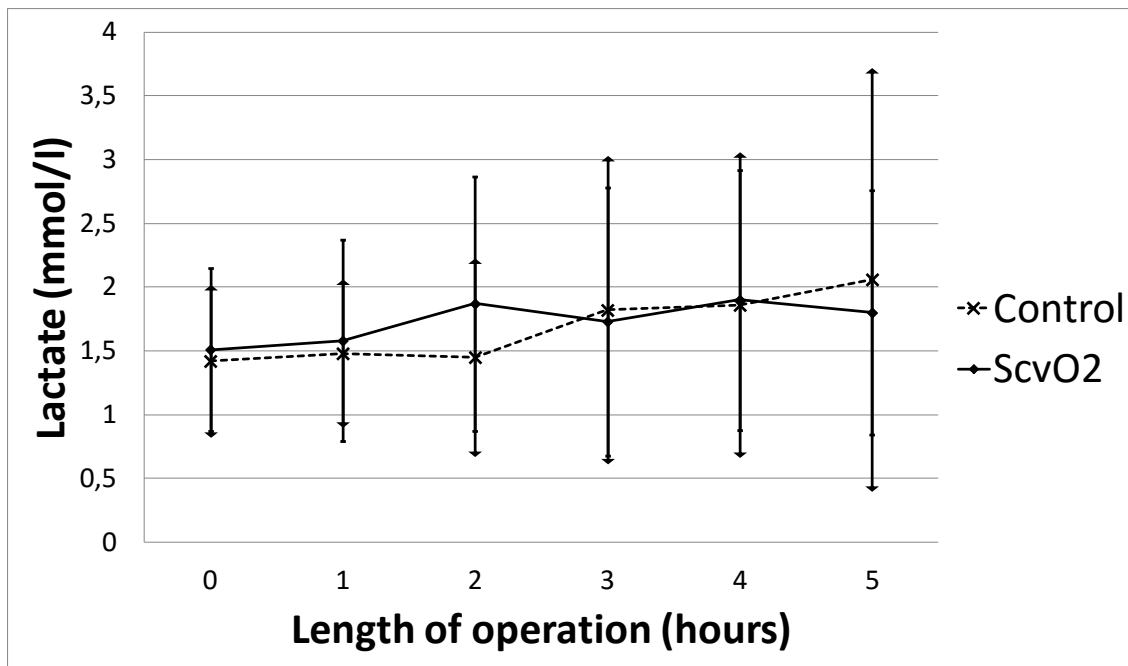


Figure 9.:changes of the level of lactate during the operation.

Regarding postoperative complications, there were more patients with complications in the control group but it did not reach statistical significance. However, pulmonary complications as determined by the  $PaO_2/FiO_2$  ratio were significantly higher on the first and second postoperative day in the control group. Distribution of postoperative complications is shown in Table 6.

	ScvO <sub>2</sub> (n=38)	Control (n=41)	p
<b>Infection</b>			
Respiratory tract	0	1	0.33
Abdominal	2	2	0.94
Urinary tract	0	1	0.33
Wound	0	0	-
>24 hours of postoperative ventilation	1	5	0.11
<b>Cardiovascular</b>			
Cardiac decompensation	0	0	-
Arrhythmia	1	4	0.19
Vasopressor need	9	14	0.31
Acute myocardial infarction	0	0	-
Stroke	0	0	-

	<b>Constipation</b>	2	3	0.71
<b>Abdominal</b>	<b>Upper GIT bleeding</b>	0	1	0.33
	<b>Reoperation</b>	1	2	0.60
<b>Urine &lt;500 ml/24 h or renal replacement</b>		1	3	0.34
<b>Postoperative surgical bleeding</b>		1	1	0.96
<b>Perioperative death</b>		0	1	0.33
<b>Number of patients with any complication</b>		10	19	0.07
	<b>&gt; 300 mmHg</b>	4	3	0.62
<b>PaO<sub>2</sub>/FiO<sub>2</sub></b>	<b>200-300 mmHg</b>	24	15	0.02*
	<b>100-200 mmHg</b>	10	22	0.01*
	<b>&lt; 100 mmHg</b>	0	1	0.52
	<b>no injury</b>	27	29	0.59
<b>Acute kidney injury</b>	<b>KDIGO 1</b>	7	10	0.36
	<b>KDIGO 2</b>	3	1	0.28
	<b>KDIGO 3</b>	1	1	0.73

Table 6.: postoperative complications

There were no significant differences in any of the investigated inflammatory markers (CRP, leukocyte count, fever, microalbuminuria – data not shown) throughout the perioperative period. PCT also showed almost identical kinetics and absolute values in the two groups at  $t_{0-24-48}$  (ScvO<sub>2</sub>: 0.06 [0.00] - 0.66 [1.21] - 0.45 [0.98]; controls: 0.06 [0.01] - 0.53 [1.4] - 0.42 [1.03] ng/ml, respectively).

## Discussion

In this prospective randomised study we found that ScvO<sub>2</sub> and MAP based intraoperative hemodynamic management resulted in more intraoperative interventions, better intraoperative diuresis and less pulmonary dysfunction in the postoperative period compared to a MAP and CVP guided therapy, however the overall complication rate was not reduced significantly. Although controversy still exists about the interpretation of ScvO<sub>2</sub>, it is universally accepted that “low” values suggest a global oxygen debt, imbalance between the oxygen supply and demand. The “target” or in other words “normal” intraoperative ScvO<sub>2</sub> value remains uncertain. Theoretically ScvO<sub>2</sub> should be “higher” than the physiological value determined in awoken subjects or found in patients in ICU, due to the reduced oxygen demand/consumption during general anaesthesia. Compared to the routinely used target level of ScvO<sub>2</sub> in critical care, which is 70%, a number of studies

found higher values in the intraoperative settings. Therefore, in the current study we decided to use an interventional threshold of  $ScvO_2 \leq 75\%$  or a decrease of  $>3\%$ , and observed more therapeutic interventions compared to the MAP and CVP guided control group: patients received more colloid fluid and blood transfusions. Any decrease in  $DO_2$  might have been recognised earlier by  $ScvO_2$  than CVP and resulted in more frequent interventions. These interventions possibly resulted in better tissue perfusion and oxygen delivery, also shown by the significantly better intraoperative diuresis which might have led to better outcomes. The aim of our study was to investigate the role of  $ScvO_2$  as an easily obtainable parameter in the hemodynamic therapy of high risk surgery. Continuous measurement of  $ScvO_2$  requires extra instrumentations, but we believe that similarly to the critical care repeated measurement of  $ScvO_2$  during the operation provides useful information regarding the hemodynamics of the patient and the necessity of any intervention (fluid bolus, vasoactive drug, transfusion).

## **Conclusions**

### **Volumetric and pressure guided intraoperative fluid management**

1. We were not able to identify any significant difference regarding the effects of ITBV or CVP guided intraoperative fluid management on the postoperative inflammatory response following major abdominal surgery.
2. The inflammatory response in the whole sample was attenuated compared to previous results and data. We think that this is due to the determined and fulfilled hemodynamic goals in both groups, which led to reduced intraoperative hypovolemia and hypoperfusion resulting in the attenuated inflammatory response.
3. Both the changes of CVP and ITBV showed correlation with the changes of SVI, although the relationship was weak. During the planning of our study the investigation of this relationship was not one of our aims. Therefore, we cannot conclude that these two parameters are equivalent regarding the estimation of the cardiac preload.



## **Continuous central venous oxygen saturation assisted hemodynamic therapy during major abdominal surgery**

1. In accordance with previous results we found higher values of ScvO<sub>2</sub> in the intraoperative setting compared to the levels used as target in critical care.
2. ScvO<sub>2</sub> guided intraoperative hemodynamic management resulted in more intraoperative fluid administration and transfusion and higher urinary output compared to CVP guided strategy.
3. In the ScvO<sub>2</sub> group the observed decrease of the central venous saturation from a supranormal value to the previously aimed target level could be explained with the improved microcirculation caused by higher fluid intake. This decrease was not detected in the CVP group.
4. The occurrences of postoperative complications were lower in the ScvO<sub>2</sub> group. The only significant difference was in the postoperative oxygenation, which was better in the group receiving more fluids. The explanation could be the improved hemodynamics and attenuated inflammatory response.
5. Based on these results ScvO<sub>2</sub> assisted intraoperative hemodynamic management may be a useful and at least equivalent alternative to CVP and may also lead to improved outcomes.

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Euroanaesthesia 2014. Stockholm

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