

Transcutaneous continuous carbon dioxide tension monitoring reduced incidence, degree and duration of hypercapnia during combined regional anaesthesia and monitored anaesthesia care in shoulder surgery patients

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Abstract We studied the impact of transcutaneous continuous carbon dioxide tension (PtcCO₂) monitoring on ventilation and oxygenation during monitored anaesthesia care (MAC) in patients scheduled for shoulder surgery with continuous interscalene block. 50 patients were randomised either to the intervention (I-group) or the control (C-group) group. In both groups MAC was performed using target controlled infusion of propofol and remifentanyl. MAC regimen was adapted to PtcCO₂ values in the I-group, whereas the C-group was blinded for these values. Primary outcome was the incidence, degree and duration of hypoventilation stages. In the I-group and the C-group the mean ± SD [range] of PtcCO₂ and PaCO₂ was 5.79 ± 0.84 [4.37] and 5.44 ± 0.59 [2.78] kPa, as well as 6.41 ± 1.17 [6.29] and 6.01 ± 0.96 [7.15] kPa. Periods of PtcCO₂/PaCO₂ > 6.5 kPa were 21.0 ± 35.7/1.2 ± 4.2 min in the I-group and 45.6 ± 40.0/18.6 ± 26.8 min in the C-group. Severe hypercapnia (PtcCO₂ and/or PaCO₂ > 7.5 kPa) was detected in 3/0 patients of the I-group and in 10/3 patients of

the C-group. PtcCO₂ and PaCO₂ showed a strong correlation ($r = 0.78$), but only moderate agreement with a mean bias (LOA) of -0.37 (-1.69 ; $+0.95$) kPa showing an overestimation of the PaCO₂. Sensitivity and specificity of PtcCO₂ to detect changes of PaCO₂ was 0.94 and 0.56, respectively. In no patient SpO₂ or SaO₂ values lower than 90 % were measured. Despite a moderate agreement between PaCO₂ and PtcCO₂ the PtcCO₂ monitoring significantly reduced incidence, degree and duration of hypercapnia in shoulder surgery patients with MAC.

Keywords PtcCO₂ and SpO₂ monitoring · MAC · Shoulder surgery · Ventilation

1 Introduction

Regional anaesthesia combined with mild to moderate sedation using monitored anaesthesia care (MAC) is commonly used in orthopaedic surgery [1]. MAC involves administration of drugs for anxiolytic, hypnotic, amnestic, and analgesic effect in order to achieve general anaesthesia, preserving the patients spontaneous breathing. Oxygenation of the spontaneous breathing patients is frequently supported by increasing the inspiratory oxygen supply and respiratory function is routinely monitored by pulse oximetry partial oxygen saturation (SpO₂). However, pulse oximetry is not sensitive for fast detection of ventilation disorders. Especially in shoulder surgery patients in beach chair position with a mild to moderate sedation, significant ventilatory impairment and subsequent decrease of oxygen saturation could occur. Adequate ventilation is best monitored by the arterial carbon dioxide tension (PaCO₂), which requires arterial cannulation for repeated blood gas analyses. This invasive, discontinuous and potentially complication-prone

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monitoring is used only if additional information like continuous blood pressure monitoring is needed. Next to the end-tidal carbon dioxide reading the transcutaneous continuous partial carbon dioxide (PtcCO₂) measurement represents a non-invasive alternative, which has been clinically used for more than 30 years [2]. In the last decade, combined assessment of PtcCO₂ and SpO₂ using a single ear-lobe clip sensor has been increasingly used in adult patients during non-invasive mechanical ventilation [3], transport of critically ill adults [4], bronchoscopy [5], sleep studies [6, 7] and pulmonary stress testing [8]. However, the findings of studies on neonates, infants and adults remain contradictory [4, 9–11]. Most recently, the revised V-Sign 2 sensor (V-SignTM 2 sensor, SenTec Digital Monitoring System; SenTec AG, Therwil, Switzerland) has become commercially available and its usefulness has been demonstrated during polysomnography-monitored sleep studies in 24 patients receiving non-invasive ventilation [12] and in patients after cardiac surgery [13]. The primary outcome of this study was to investigate the incidence and duration of significant states of hypoventilation and states of deoxygenation in patients scheduled for shoulder surgery in beach chair position with continuous interscalene block and MAC adapted or not to the PtcCO₂ values. The second outcome was to demonstrate that significant states of hypoventilation and desaturation can be reduced by modifying the compilation of the sedative and analgesic drug concentration during surgery maintaining a calm, pain-free and cooperative patient.

2 Methods

This prospective, assessor-blinded study was approved by the Cantonal Ethics Committee Zurich, Switzerland (Registration Number: 2010-0170/4). After obtaining written informed consent fifty patients scheduled for elective, unilateral shoulder surgery were included. In all patients regional anaesthesia was combined with MAC to achieve mild to moderate sedation. Randomisation was performed the evening prior to surgery according to a computerised randomisation list allocating 25 patients to the intervention (I-group) and 25 patients to the control (C-group) group. Exclusion criteria were age <18 years; known clinically relevant cardiac, pulmonary or vascular shunts; too small ear-lobe for appropriate transcutaneous measurement; contraindications for placement of an interscalene catheter or arterial line and not sufficient german language skills. Mild to moderate sedation was defined according to Standards, Guidelines and Statements of the American Society of Anesthesiologists [14] and was monitored using the modified Observer's Assessment of Alertness/Sedation scale (OAAS) [15, 16] and the Bispectral index EEG (BIS). The OAAS score 4 (lethargic responses to name in normal

tone) corresponded to mild and the OAAS score 3 (responds only after name is called loudly and/or repeatedly) to moderate sedation level. [1] According to the manufacturers depiction BIS values in the range of 89–80 and 79–70 were defined to correspond to mild and moderate sedation level, respectively.

Oral premedication of all patients consisted in midazolam 0.1 mg/kg body weight up to a maximum of 7.5 mg 30 min prior to MAC induction. All patients received a standard monitoring (ECG, non-invasive blood pressure and pulseoximetry) and placement of an intravenous access in the induction area. A self-adhesive BISTM 4 Electrode Sensor (BIS) was placed on the forehead according to the manufacturer's recommendations. The radial artery was cannulated on the non-operated arm. Additionally, a V-Sign 2 sensor of the sentec device (SenTec Digital Monitor; SenTec AG; Therwil, Switzerland) was placed on the earlobe opposite to the surgical field and connected to the SenTec device. PtcCO₂, V-Sign 2 sensor SpO₂ (VsignSpO₂) and V-Sign 2 sensor pulse rate (VsignPR) values displayed on the Sentec device were visible for the anaesthesiologist in the I-group, whereas in the C-group the anaesthesiologist was blinded. According to the institutional standards for shoulder surgery in beach chair position, an interscalene catheter with an initial bolus administration (30–40 ml ropivacaine 0.5 %) was placed. After block success was assessed, in all patients MAC was started to attain a mild or moderate sedation level of the spontaneous breathing patient. [17] The desired sedation level and analgesia for comfort during beach chair position was achieved using a combined target controlled infusion of propofol and remifentanyl. After proper patient positioning and with the beginning of the sterile surgical field preparation the sedation with propofol (0.5–0.8 µg/ml effect site concentration) and analgesia using remifentanyl (0.5–0.8 ng/ml effect site concentration, target-controlled infusion pump, Graseby; SIMS Graseby Limited Watford, Herts, UK) was started. In both groups the target sedation level during surgery was an OAAS score of 4–3 to ensure a mild to moderate sedated but cooperative patient. Additionally, the PtcCO₂ values in the I-group were kept in a range between 4.5 and 6.0 kPa. To maintain the PtcCO₂ values in the I-group between 4.5 and 6.0 kPa the anaesthesiologist varied the effect site concentrations of propofol and remifentanyl. According to our experience, hyperventilation derived from incommodiousness due to the sitting position. Additionally, the patients were contacted and interviewed for possible pain or discomfort. First line treatment was the intravenous application of the peripherally acting analgesic paracetamol in a dose of 10–15 mg/kg body weight. Additionally, the effect site concentration of remifentanyl was increased. Second line treatment included the intravenous application of the centrally acting α₂-

adrenergic agonist clonidine. Clonidine 0.075 mg was dissolved in 100 ml sodium chloride 0.9 % and infused over a period of 30 min to avoid cardiovascular complications. Increasing the propofol effect site concentration was the third line treatment. Hypoventilation states were treated by reducing the remifentanyl effect site concentration first, and secondly reducing the propofol effect site concentration. Body temperature was maintained at ≥ 36.0 °C using a forced-air warming system (3 MTM Bair HuggerTM Temperature Management Unit 775, 3MHealthCare, UK).

All data generated by the V-Sign 2 sensor (PtcCO₂, VsignSpO₂ and VsignPR) were recorded continuously by an online computing system. The time points of the arterial samples and the results of the respective corresponding blood gas and blood oxygenation values were also collected in the online computing system. Moreover, these data, excluding the data of the C-group, were recorded simultaneously in an offline protocol. The data of the C-group produced online at the respective time points were documented offline at the end of the study protocol. Additional offline recordings at the time points of arterial blood sampling included BIS, OAAS, pulse rate (PR), systolic, diastolic and mean arterial pressure (MAP), pulse oximetry saturation (SpO₂), inspired oxygen fraction (FiO₂) in L/min, arterial oxygen saturation (SaO₂), arterial partial oxygen pressure (PaO₂) and arterial partial carbon dioxide tension (PaCO₂). Blood samples were taken before placement of the interscalene catheter (1), after starting MAC (2), every 15 min during surgery until the end of surgery (3–14). Additionally, the cumulative doses of propofol (mg) and remifentanyl (µg), clonidine (µg), paracetamol (mg), epinephrine (mg) and the number of interventions for ventilation support were recorded.

PaCO₂ was measured at a standard temperature of 37 °C and SaO₂ was determined by multi-wavelength pulse oximetry (ABL 800, Radiometer Medical A/S Akandevej 21 DK-2700 Bronshøj, Denmark). Prior to the study start and 2, 4 and 12 h after removal of the V-Sign 2 sensor from the earlobe peripheral skin perfusion [I = warm and dry, II = cool, and III = cold] and skin status [0 = no reddening, 1 = slight reddening, 2 = reddening, 3 = intensive reddening, and 4 = blister] were assessed and documented.

After transfer to the post anaesthesia care unit (PACU) the following events were assessed: the incidence of respiratory depression, postoperative nausea and vomiting (PONV), the cumulative volume of crystalloid and colloid fluids, the cumulative doses of morphine, the time of discharge from the PACU to the ward, the pain level according to the Visual Analogue Scale (VAS/, for 0 = no pain; 100 = worst imaginable pain) and the Aldrete Score [18]. Discharge criteria were VAS ≤ 30 and Aldrete score ≥ 9 .

Hypercarbia as result of hypoventilation was defined as a value of PtcCO₂ ≥ 6.0 kPa (>2 min) and classified as mild (PtcCO₂ $\geq 6.0 < 6.5$), moderate (PtcCO₂ $\geq 6.5 < 7.5$) and severe (PtcCO₂ ≥ 7.5). Respiratory depression was defined as a persistent (>2 min) decrease in SpO₂ below 90 %, or a sustained (>2 min) increase in PtcCO₂ above 7.0 kPa, or the need for active ventilatory support.

2.1 Statistics

The use of a paired *t* test power calculation revealed a sample size of 42 patients (21 patients in each group) to achieve an 80 % power to detect a mean difference of 0.6 kPa (with $\alpha = 0.05$) between the two groups with an estimated standard deviation (SD) of 0.7 kPa. The mean difference was determined based on clinical experience and previous studies with the used device. [13] This estimation hypothesised an uniform distribution of the actual data. The sample size calculation was performed with the StatsDirect Statistical Software Version 2.8.0 2013 (StatsDirect Ltd, Altrincham, UK). Continuous variables are presented as mean \pm SD. Normality of distribution was assessed with the Shapiro-Wilk test. Paired *t*-test or as appropriate the Mann–Whitney U-test were used to test continuous variables on differences. Categorical variables were tested for differences with the Pearson's Chi-square-test or the Fisher's exact test as appropriate. Bland–Altman analysis was performed for determination the agreement of PaCO₂ and PtcCO₂; PR and Vsign-PR and SaO₂ and Vsign-SpO₂. [19] BIS, OAAS, PtcCO₂, PaCO₂, SaO₂, Vsign-SpO₂, Vsign-PR and MAP were compared across time intervals using repeated measures of variance (ANOVA) and paired *t*-test. A *p* value <0.05 was considered significant.

3 Results

Fifty patients were included in the study. No significant difference was found between groups regarding patient characteristics, surgical procedure, surgery and sedation time (Table 1). Propofol, remifentanyl and clonidine consumption were not significantly different between groups, although a trend towards increased remifentanyl and decreased propofol doses was shown in the I-group compared to the C-group (Table 2). Paracetamol doses were significantly higher ($p = 0.007$) in the I-group (Table 2). During the process the mean \pm SD of the BIS and of the OAAS scale were similar in both groups (Table 3; Fig. 1a, b). No colloid fluid, vasoactive drugs or morphine were applied in both groups. No patient suffered from PONV or needed breathing or ventilatory support during and after surgery. Time of discharge from the PACU and crystalloid fluid consumption were not significantly different between

Table 1 Patient and procedural characteristics; values are expressed as mean \pm SD or numbers

	Intervention group	Control group	<i>p</i> value
No. of patients	25	25	
Age (year)	45.2 \pm 17	43.6 \pm 14.9	0.738
Male/female	17/8	20/5	0.344
BMI (kg/m ²)	25.0 \pm 4.1	25.3 \pm 4.4	0.757
ASA (I/II/III)	12/13/0	15/9/1	0.608
<i>Type of surgery</i>			
Shoulder arthroscopic surgery	24	23	
Removal osteosynthesis	1	1	
Re-osteosynthesis	0	1	
MAC time (min)	89.0 \pm 38	85.8 \pm 31.4	0.747
Surgery time (min)	80.8 \pm 34.7	70.4 \pm 26.6	0.240
Time of discharge from the PACU	25.5 \pm 6.4	30.6 \pm 12.2	0.874

BMI body mass index, ASA Physical status classification system of the American Society of Anesthesiologists, MAC monitored anaesthesia care, PACU post anaesthesia care unit

groups (Tables 1 and 2). Pain intensity was lower and the mean Aldrete score at discharge was higher but without statistical significance in the I-group compared to the C-group (Table 2).

In the I-group and the C-group the mean \pm SD [range] of PtcCO₂ and PaCO₂ was 5.79 \pm 0.84 [4.37] and 5.44 \pm 0.59 [2.78] kPa, as well as 6.41 \pm 1.17 [6.29] and 6.01 \pm 0.96 [7.15] kPa; and for VsignSpO₂ and SaO₂ 97.2 \pm 2.4 [10] and 97.3 \pm 1.9 [7.2], as well as 97.8 \pm 1.8 [8] and 98.4 \pm 1.4 [6.1], respectively

(Table 3). Table 2 presents the significantly longer duration of hypercapnia in the C-group compared to the I-group. PtcCO₂/PaCO₂ > 6.0 kPa was detected in 15/10 patients of the I-group and in 22/18 of the C-group. Severe hypercapnia (PtcCO₂/PaCO₂ > 7.5 kPa) was detected in 3/0 patients of the I-group and in 10/3 patients of the C-group. No hypercapnia (PtcCO₂/PaCO₂ < 6.0 kPa) was found in 10/15 patients (40/60 %) of the I-group and in 3/7 patients (12/28 %) in the C-group. In both groups PtcCO₂ and PaCO₂ increased during the course (Fig. 2a, b).

In no patient SpO₂ or SaO₂ values less than 90 % were measured. FiO₂ supply during the process was not different between groups. The mean \pm SD PaO₂ in the I-group and the C-group was 17.4 \pm 6.8 and 20.1 \pm 6.9 kPa (*p* = 0.003), respectively (Table 3). The time course of the PaO₂ in both groups showed, that the statistically significant differences were found during the time points 1 (before placement the catheter), 2 (immediately after starting MAC) and 3 (15 min after starting MAC) (Fig. 2c).

For Bland–Altman analysis 233 data pairs of PtcCO₂ and PaCO₂, and for V-Sign SpO₂ and SaO₂ were available. PtcCO₂ and PaCO₂ showed a strong correlation (*r* = 0.78), but the agreement was only moderate with a mean bias (LOA) of -0.37 (-1.69 ; $+0.95$) kPa showing an overestimation the PaCO₂ (Table 4; Fig. 3a, b). Sensitivity and specificity of PtcCO₂ to detect changes of PaCO₂ were 0.94 and 0.56, respectively. VsignSpO₂ and SaO₂ were also strong correlated (*r* = 0.71). Bland–Altman analysis showed a good agreement with a mean bias (LOA) of $+1.2$ (-0.3 ; $+2.7$) % resulting in a slight underestimation the SaO₂ (Table 4). The strongest correlation (*r* = 0.95) showed V-sign PR with the electrocardiographic measured

Table 2 Results of procedural data, values are expressed as mean \pm SD [range] or as mean \pm SD (median [range])

	Intervention group	Control group	<i>p</i>
Midazolam (mg/kg)	0.105 \pm 0.024 [0.085]	0.097 \pm 0.019 [0.061]	0.178
Propofol (μ g/kg/min)	48.8 \pm 12.6 [47]	52.5 \pm 22.8 [90]	0.474
Remifentanyl (ng/kg/min)	60.2 \pm 42.3 [199]	48.0 \pm 35.0 [172]	0.273
Paracetamol (mg/kg)	12.7 \pm 4.8 [20.0]	8.0 \pm 7.0 [18.2]	0.007
Clonidine (μ g/kg)	1.9 \pm 0.7 [3.0]	1.7 \pm 1.0 [4.8]	0.509
Crystalloid (ml)	864 \pm 218 [900]	929 \pm 255 [1,300]	0.309
VAS	16 \pm 7 [20]	20 \pm 8 [20]	0.070
Aldrete score at discharge	9.9 \pm 0.3 [1]	9.7 \pm 0.5 [1]	0.091
PtcCO ₂ > 6.0 (min)	42.4 \pm 47.4 (30 [180]) ^a	63.6 \pm 40.2 (60 [165]) ^b	0.067
PtcCO ₂ > 6.5 (min)	21.0 \pm 35.7 (0 [150]) ^c	45.6 \pm 40.0 (45 [165]) ^d	0.026
PaCO ₂ > 6.0 (min)	9.6 \pm 20.3 (0 [90]) ^e	37.8 \pm 34.4 (30 [105]) ^f	0.001
PaCO ₂ > 6.5 (min)	1.2 \pm 4.2 (0 [15]) ^g	18.6 \pm 26.8 (15 [105]) ^h	0.002

VAS visual analog scale, Aldrete Aldrete postanaesthetic recovery score, PtcCO₂ > 6.0 duration of PtcCO₂ values >6.0 kPa, PtcCO₂ > 6.5 duration of PtcCO₂ values >6.5 kPa, PaCO₂ > 6.0 duration of PaCO₂ values >6.0 kPa, PaCO₂ > 6.5 duration of PaCO₂ values >6.5 kPa, *n* number of patients

^a *n* = 16; ^b *n* = 21; ^c *n* = 11; ^d *n* = 17; ^e *n* = 10; ^f *n* = 18; ^g *n* = 3; ^h *n* = 13

Table 3 Results of continuous data, values are expressed as mean ± SD [range]

	Intervention group	Control group	<i>p</i>
BIS	80.1 ± 10.6 [53]	81.0 ± 11.4 [48]	0.687
OAAS	4.2 ± 0.5 [3]	4.2 ± 0.5 [2]	0.543
PaO ₂ (kPa)	17.4 ± 6.8 [37.3]	20.1 ± 6.9 [36.6]	0.003
PaCO ₂ (kPa)	5.44 ± 0.59 [2.78]	6.01 ± 0.96 [7.15]	<0.001
PtcCO ₂ (kPa)	5.79 ± 0.84 [4.37]	6.41 ± 1.17 [6.29]	<0.001
SaO ₂ (%)	97.3 ± 1.9 [7.2]	98.4 ± 1.4 [6.1]	0.001
SpO ₂ (%)	96.5 ± 2.3 [10]	97.3 ± 1.9 [9]	0.009
VsignSpO ₂ (%)	97.2 ± 2.4 [12]	97.8 ± 1.8 [8]	0.098
PR (bpm)	71.1 ± 14 [61]	64.0 ± 10.7 [42]	<0.001
VsignPR (bpm)	71.7 ± 13 [56]	64.4 ± 10.4 [40]	<0.001
MAP (mmHg)	81.4 ± 15.5 [75]	80.4 ± 17.2 [81]	0.170

BIS Bispectral Index Electroencephalography, expressed as dimensionless count, *OAAS* Observer’s Assessment of Alertness and Sedation Scale, *PaO₂* partial arterial oxygen tension, *SaO₂* arterial oxygen saturation, *SpO₂* oxygen saturation, *VsignSpO₂* oxygen saturation detected by the V-Sign™ 2 sensor, *PR* pulse rate, *VsignPR* pulse rate detected by the V-Sign™ 2 sensor, *PaCO₂* partial arterial carbon dioxide tension, *PtcCO₂* transcutaneous continuous partial carbon dioxide tension detected by the V-Sign™ 2 sensor, *MAP* mean arterial pressure

PR, but the agreement was only moderate (Table 4). In forty-five of 50 patients the detection of the Vsign 2 sensor was again briefly disturbed by electro cautery (68 episodes), by mechanical compression of the sensor (7 episodes) and by air lock on the sensor membrane (27 episodes). No patient developed disorders of the peripheral skin perfusion or skin damage on the earlobes after the V-Sign 2 sensor was removed.

4 Discussion

The main findings of this study were (1) no significant disturbances of oxygenation were found in both groups, (2) PtcCO₂ detected significant states of hypoventilation, (3) the incidence, degree and length of hypoventilation episodes were significantly reduced in the PtcCO₂ monitored group, and (4) the agreement of PtcCO₂ and PaCO₂ was moderate with a overestimation of the PaCO₂, but the sensitivity of PtcCO₂ to detect changes of PaCO₂ was high.

Recently, De Oliveira et al. [16] compared transcutaneous and nasal end-tidal carbon dioxide measurements against PaCO₂ in deep sedated, spontaneous breathing patients undergoing ambulatory gynaecological hysteroscopy. They reported significant hypercapnic states in the patients during the procedure and demonstrated better agreement of PtcCO₂ with PaCO₂ compared to end-tidal measured CO₂. In their study in 8 of 12 Patients with PaCO₂ > 6.65 kPa the PtcCO₂ agreed and PtcCO₂ showed

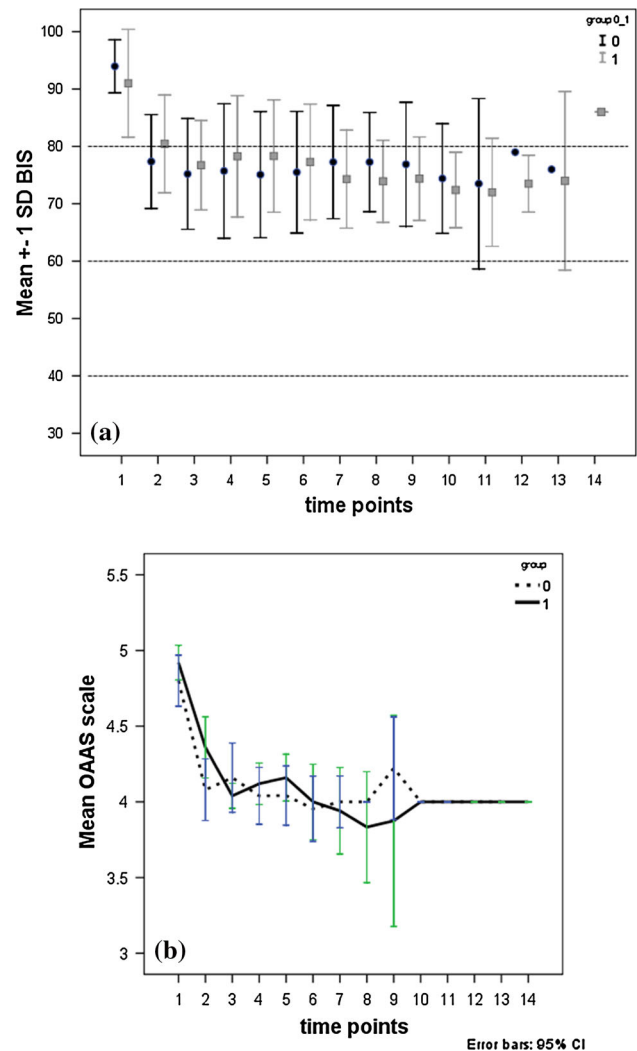


Fig. 1 **a** Bispectral Index EEG (BIS) and **b** Observer’s Assessment of Alertness/Sedation scale (OAAS) changes during the course of the procedure. Data are presented as mean and 95 % Confidence interval (error bar 95 %CI). *Definitions* Time points are: before placement of the interscalene catheter (1), after starting MAC (2), every 15 min during surgery until the end of surgery (3–14); group 0, control group; group 1, intervention group. By the time point 11 twenty-one and twenty-three operations were completed in the I-group and the C-group, respectively. Statistical analysis of the data at the remaining time points was omitted because of insufficient amount of data

a slight overestimation of the PaCO₂ with a mean bias of 0.23 kPa. In the current investigation episodes of hypercapnia were detected in 28 patients with the paCO₂ and in 37 patients with the PtcCO₂. Most patients suffered mild to moderate hypercapnia. Severe hypercapnia was detected in 13 of these patients with the PtcCO₂ but only in three patients with the PaCO₂. These findings suggest that PtcCO₂ considerably over-estimated the PaCO₂, resulting in displaying false high values. The episodes of hypercapnia were detected in both groups. However, incidence, degree and duration of hypercapnia measured by PaCO₂

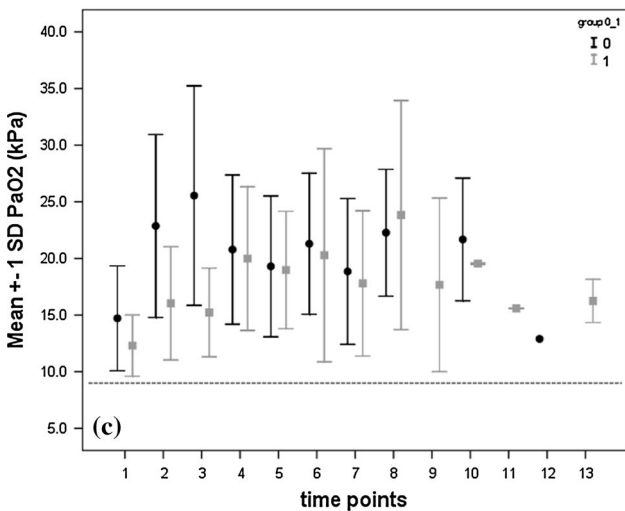
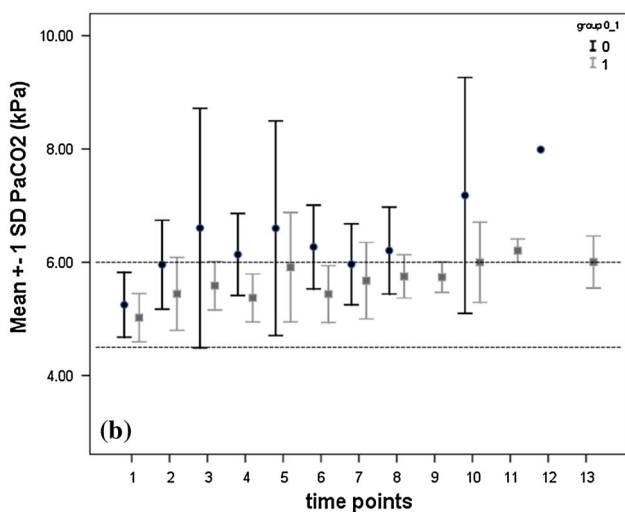
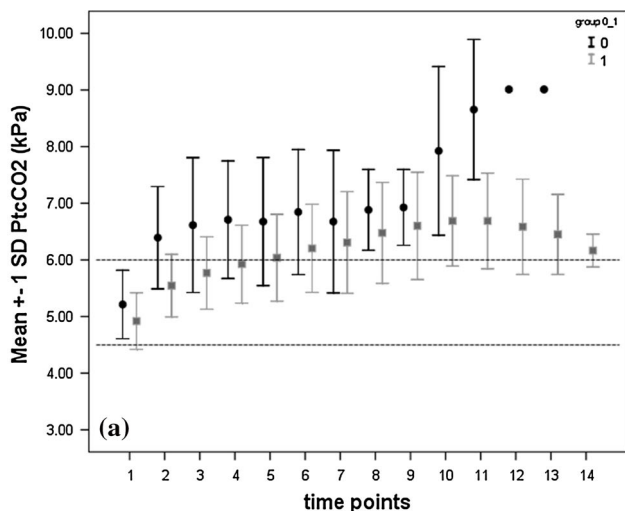


Fig. 2 a PtcCO₂, b PaCO₂ and c PaO₂ changes of the C-group (0) and the I-group (1) during the course of the procedure. Data are presented as mean ± SD. *Definitions* Time points are: before placement of the interscalene catheter (1), after starting MAC (2), every 15 min during surgery until the end of surgery (3–14); C-group, control group; I-group, intervention group. By the time point 11 twenty-one and twenty-three operations were completed in the I-group and the C-group, respectively. Statistical analysis of the data at the remaining time points was omitted because of insufficient amount of data

Table 4 Correlation and agreement of the SaO₂ and VsignSpO₂, PR and VsignPR, and PaCO₂ and PtcCO₂

	n	r	Mean bias	LOA
SaO ₂ -VsignSpO ₂ (%)	233	0.71	+1.2	-0.3/+2.7
PR-VsignPR (bpm)	390	0.95	-0.2	-8.2/7.8
PaCO ₂ -PtcCO ₂ (kPa)	233	0.78	-0.37	-1.69/+ 0.95

Mean bias mean difference between two methods of measurement, *LOA* limits of agreement (±2 SD of mean bias = 95 % confidence interval), *SaO₂-VsignSpO₂* difference between arterial oxygen saturation value and oxygen saturation detected by the V-Sign™ 2 sensor, *PR-VsignPR* difference between pulse rate value of the ECG and pulse rate detected by the V-Sign™ 2 sensor, *PaCO₂-PtcCO₂* difference between partial arterial carbon dioxide tension value and corresponding transcutaneous continuous carbon dioxide value detected by the V-Sign™ 2 sensor

and PtcCO₂ were significantly reduced in the I-group compared to the control group. Importantly, in both groups neither SpO₂ measured with the V-Sign 2 sensor nor SaO₂

showed values below 90 %. This result is mainly explained by the routine administration of oxygen during the MAC procedure, by the patient population included and the only mild to moderate sedation of the patients. Combined PtcCO₂ and SpO₂ measurement has been successfully used for continuous surveillance of spontaneous breathing patients after major abdominal surgery undergoing different postoperative pain treatments. In twenty-eight ASA I and II patients after elective major laparotomy, Kopka et al. [20] reported significant hypoventilation states in the patient-controlled analgesia group, whereas in the patients of the epidural anaesthesia group no hypoventilation states were observed. Similar results were found by McCormack et al. [21]. After major colorectal surgery PtcCO₂ values were significantly elevated in the patient controlled analgesia group compared to patients receiving epidural analgesia monitored for 24 h. As in the current investigation, in both studies no significant oxygenation disturbances measured by SpO₂ were found in any patients. However, in the I-group of this investigation PaO₂, SaO₂ and SpO₂ were statistically significant but not clinically relevant reduced compared to the C-group. Interestingly, these significant reduced oxygenation parameters were only found during the period between placement of the interscalene catheter and the 15 min sampling time point of surgery after starting MAC. In the further course of MAC no significant differences in PaO₂, SaO₂ and SpO₂ were found between the groups. This observation cannot be explained with the

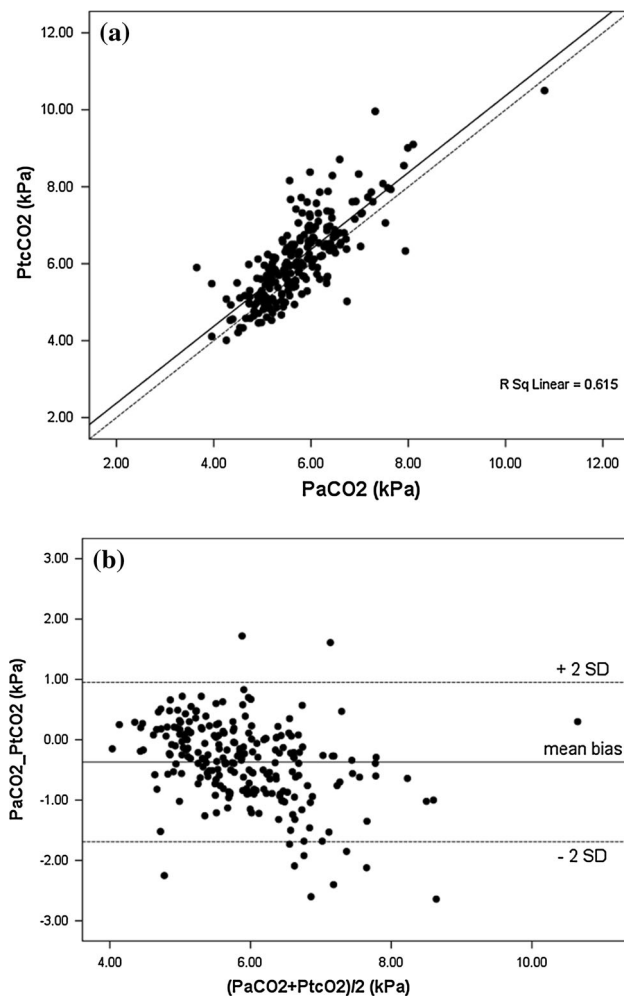


Fig. 3 **a** Linear correlation and **b** agreement of PaCO_2 and PtcCO_2 using the Bland–Altman analysis with r of 0.78 ($r^2 = 0.615$) and a mean bias and LOA of -0.37 and $-1.69/+0.95$ kPa. *Definition a* dashed line represents line of identity; *b* LOA Limits of agreement ($2 \text{ SD} = 95 \%$ CI)

only smooth and not significant modification of the MAC during the procedure. The application of less cumulative doses of propofol and higher cumulative doses of remifentanyl in the I-group compared to the C-group was not significantly different and showed only a trend. Post hoc analysis of the applied blood concentrations of propofol ($\mu\text{g/ml}$) and of remifentanyl (ng/ml) during the different time points of blood sampling have shown that no statistical significant difference was found between the blood concentrations of propofol and remifentanyl between both groups at all time points (data not shown). In particular at the interesting time points the propofol blood plasma concentrations showed only a trend to be lower in the I-group compared to the C-group, whereas the remifentanyl blood concentrations were similar in both groups. A possible reason for these findings might be a higher rate of possible recurrent laryngeal nerve palsy resulting in a

diaphragmatic high level on the site of catheter placement. However, no chest X-ray was performed to assess this hypothesis due to the uneventful post-operative recovery.

Though, this smooth modification seemed to have significant impact on the ventilation state of the patients. PtcCO_2 and PaCO_2 values were significantly higher and the duration of the hypercapnic episodes were significantly longer in the C-group compared to the I-group. Whereas hypercapnia occurred in about two-thirds of patients in the C-group, monitoring the PtcCO_2 led to a reduction the incidence of hypercapnia to one-third of the patients in the I-group. The trend to have used higher doses of analgesics and reduced doses of hypnotics during MAC in the I-group is supported by the significant higher dose of paracetamol in the I-group compared to C-group. The beach chair position is an uncomfortable and often painful patient positioning and sufficient analgesia during the process is necessary. Therefore it may be assumed that progressive increasing carbon dioxide values, which were only visible for the anaesthesiologist in the I-group, led to the decision rather carefully to increase the remifentanyl dose supported by the significant raised use of non-opioid analgesics accompanied by a concomitant reduction of the propofol dose. However, during the surgery no significant differences in the sedation level, measured with the OAA/S and the BIS, were observed in both groups. Interestingly, the postoperative detected VAS values were significantly lower in the I-group compared to the C-group and the Aldrete Score showed a trend to be higher in the I-group.

Although PtcCO_2 showed a strong correlation with PaCO_2 and the sensitivity of PtcCO_2 to detect a rise of PaCO_2 was high, the agreement of PtcCO_2 and PaCO_2 in this study with spontaneous breathing patients was only moderate with a mean overestimation the PaCO_2 of 0.39 kPa and limits of agreement of -1.69 and $+0.95$ kPa. In contrast to these results a good agreement of PtcCO_2 and PaCO_2 with a drift corrected mean bias and LOA of $+0.13$ kPa and $-0.63/+0.89$ kPa was reported in 24 patients who required nocturnal non-invasive ventilation [12], in patients after cardiac surgery [13] and in patients scheduled for lung function testing because of ventilator disturbances or the necessity of non-invasive ventilation [22]. Additionally, in spontaneously breathing deep sedated patients undergoing ambulatory gynaecological hysteroscopy [16] and in non-intubated dyspnoic patients in an emergency department good agreement of PaCO_2 and PtcCO_2 has also been reported [23]. Contrary to our results, in both previous studies with spontaneous breathing patients no repeated measurements were calculated. Using the previous sensor technique of the Sentec device, Fanelli et al. [24] reported an only moderate mean bias and wide limits of agreement of repeatedly measured PaCO_2 and PtcCO_2 in spontaneously breathing, non-intubated patients

in the early postoperative period after major abdominal, vascular, or thoracic surgery. They hypothesised that PtcCO₂ could be partially uncoupled from PaCO₂ during spontaneous, irregular breathing patterns, because failed re-equilibration of the central compartment with the carbon dioxide buffer systems and possible interindividual differences in terms of CO₂ buffering. Post hoc analysis the agreement of PaCO₂ and PtcCO₂ at each sampling time point of this study clearly demonstrated a good agreement with a mean bias (LOA) of -0.08 (-0.86 ; $+0.70$) kPa at the first and -0.11 (-0.83 ; $+0.66$) at the second sampling point (time point). At the following sampling points the agreement decreased to be only moderate. Additionally to the hypothesis of partially uncoupling the PtcCO₂ from PaCO₂ during spontaneous breathing, these findings rather support the hypothesis that procedural errors might be considerable reasons. The Vsign 2 sensor was fixed to earlobe, which was close to the surgical field. During surgery repetitive invasive access to the shoulder and its movement was often necessary to achieve good surgical conditions. These manoeuvres could have led to a more or less strong lateral inclination the head to the opposite side of surgery accompanied by mechanical disturbances of the ear sensor. Additionally, it cannot be completely excluded that irrigation solution, used during arthroscopic surgery diffused in the surrounding soft tissue. Both could have led to a swelling of subcutaneous and skin tissue with subsequently reduced tissue perfusion, resulting in increasing uncoupling the metabolism in peripheral tissue (PtcCO₂) from the central compartment (PaCO₂). Another reason for the only moderate agreement of PtcCO₂ and PaCO₂ might be the high rate of sensor disturbances by electro cautery, mechanical compression the sensor and by air lock on the sensor membrane. Although these disturbances lasted only briefly, their effect on the detection quality of the sensor may have been profound.

In addition to the PtcCO₂ measurement the V-sign 2 sensor detects partial oxygen saturation. In 20 patients with obstructive or restrictive lung disease needing long-term oxygen therapy Schaifroth Török and colleagues reported good agreement of SpO₂ measured with a previous version of the Vsign 2 sensor and SaO₂ [25]. In this investigation mean bias (LOA) of SaO₂ and Vsign SpO₂ was $+1.2$ (-0.3 ; $+2.7$) %, which corresponds to a slight underestimation of the SaO₂. However, the agreement was good.

In conclusion, regional anaesthesia combined with MAC led to mild and moderate hypercapnia without any significant disturbance the oxygenation in predominantly healthy patients undergoing shoulder surgery. Although, agreement between PaCO₂ and PtcCO₂ was only moderate in these spontaneous breathing patients, PtcCO₂ monitoring significantly reduced incidence, degree and duration of hypercapnia.

Conflict of interest None.

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