HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL

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Abstract:

Recently, there has been an increase in the popularity of minimally invasive surgical techniques, including arthroscopic surgeries for shoulder procedures. Interscalene block is currently the gold standard technique for these surgeries, combined or not with general anesthesia. The last, when used in patients positioned in a beach chair can lead to serious hemodynamic and cerebral changes in the patients. Continuous non-invasive monitoring of the patient's cardiac output can provide data for better hemodynamics management compared to standard monitoring. Therefore, the aim of the study is to compare hemodynamic changes (cardiac output, blood pressure, heart rate, oxygen saturation) and intraoperative cerebral oxygenation using peripheral cerebral saturation monitoring with continuous measurement of cardiac output or standard hemodynamic between two anesthetic techniques for shoulder surgery: interscalene block with sedation versus interscalene block with general anesthesia. The groups will be evaluated as follows: group 1 general anesthesia plus interscalene brachial plexus block and group 2 sedation plus interscalene brachial plexus block. Additionally, each group will be subdivided into two more groups, one with continuous hemodynamic monitoring and the other with standard hemodynamic monitoring, that is, a total of 4 groups in the study. The analyzed variables will include gender, age, ASA, medications in use, comorbidities. Furthermore, duration of procedure and in the anesthetic recovery room, blood pressure, heart rate, cardiac output, peripheral oxygen saturation, cerebral oxygen saturation, BIS value, cardiac index, etCO2 will be evaluated. Besides, length of hospital stay, delirium, behavioral status and postoperative complication will also be assessed.

Keywords: Orthopedic surgery; General anesthesia; Nervous Blockage; Deep Sedation; Hemodynamic monitoring, cerebral oxygen saturation

1. INTRODUCTION

Recently, there has been an increase in the popularity of minimally invasive surgical techniques, including arthroscopic surgeries, especially those performed on an outpatient basis (1). Arthroscopic orthopedic surgeries were initially proposed for the knee. In 1931, Burman et al performed the first shoulder arthroscopic orthopedic surgeries in a cadaver. Since then, arthroscopic shoulder surgery has been increasingly improved. The indication for shoulder arthroscopy can be both for therapeutic and diagnostic procedures, such as hemiarthroplasty, total shoulder arthroplasty, subacromial decompression, rotator cuff injuries, shoulder instability, degenerative diseases of the acromioclavicular and glenohumeral joint, adhesive capsulitis, biceps pathologies and labrum, infection, among others (2); (3).

Shoulder surgeries can be performed in lateral decubitus, semi lateral decubitus, beach chair and semi beach chair position (1);(3);(4). The lateral decubitus position was the first position described for performing orthopedic shoulder surgery. The patient is set up in lateral decubitus with the arm pulled 35º to 70º in abduction and 15º in forward flexion. The traction rope is attached to a rope and pulley system (1). This positioning made the procedure difficult, as it makes it difficult to view the lower third of the shoulder joint. In 1985, Gross and Fitzgibbons modified the lateral position 30 to 40º posteriorly, leaving the glenohumeral joint with an axial axis parallel to the floor. A traction is performed at the midpoint of the humerus, perpendicular along the axial axis with slight abduction of the arm, with the arm being held by a rod placed at the bottom of the table (5). That change in position facilitated the visualization of structures and instrumentation, became it more efficient. Even with the modification of the lateral position, there are some disadvantages, such as non-anatomical position, the arm must be rotated for more anterior access, if conversion to open surgery is needed, it must be repositioned, patients do not tolerate only regional anesthesia, traction can cause neurovascular injury such as peroneal nerve and brachial plexus injury with an incidence of 10 to 30%, decreased limb perfusion. In addition, there is an increased risk of injury to the axillary and musculocutaneous nerve with the use of the portal in the antero-inferior region. Despite this, there are some advantages over the lateral decubitus position, as traction increases the space in the joint, and in the subacromial region and accentuates the labrum, the patient's head and operating table are not in the posterior and superior path of the shoulder and has less risk of hypotension/bradycardia, having better cerebral perfusion (4);(6).

The beach chair position was suggested in 1988 by Skybar to avoid complications from the lateral decubitus position. The patient is set up in a sitting position with at least 60°, the patient's shoulder is brought slightly off the table with a sheet under the scapula (3). This position makes it possible to prevent neurological complications, such as neuropathies of the brachial plexus, peroneal nerve, axillary and musculocutaneous nerve, and facilitates the visualization of structures. In addition to these advantages, a more anatomical position can also be inferred, facilitates the examination under anesthesia, hanging arm does not hinder the visualization of the anterior portals, does not need repositioning for conversion to open surgery, can be performed only with regional anesthesia, arm mobility during the surgery. There are some disadvantages, such as increased risk of hypotension and bradycardia with cardiovascular and neurological complications, dark band in the visualization of the subacromial space, fluid under the camera making visualization difficult, increased risk of air embolism and expensive surgical table equipment (3);(4);(6). The beach semi-deck position is a position that reduces the chair angle to 30º to try to reduce hemodynamic complications (7). These changes can be enhanced by the anesthetic technique used, such as general anesthesia, especially in elderly and hypertensive patients, and when controlled hypotension methods are used for better visualization of the surgical field (8). No technique is totally risk free; however, the most used technique today is the beach chair position. There are several hemodynamic monitoring techniques for intraoperative evaluation, such as invasive and non-invasive monitoring. Non-invasive hemodynamic monitoring can be the standard (heart rate and blood pressure) or continuous monitoring of cardiac output plus heart rate and blood pressure. In addition, there is also monitoring of cerebral oxygenation continuously. The use of continuous monitoring of cardiac output and monitoring of cerebral oxygenation can minimize complications in patients undergoing surgery in a beach chair position through early detection of cerebral hypoperfusion and hypotension, thus, complications are early reversed (9);(10);(11);(12);(13).

Anesthesia for shoulder orthopedic surgery can be performed with general anesthesia, interscalene brachial plexus block associated with sedation, and general anesthesia associated with interscalene brachial plexus block. The anesthetic technique chosen will depend on the type of shoulder surgery and patient acceptance. Prolonged surgeries, analgesia complementation and patient failure or refusal of regional anesthesia is indicative of general anesthesia use (14);(15). General anesthesia is associated with a decreased in the sympathetic effect, systemic vascular resistance and, consequently, a

decreased in mean arterial pressure, cardiac output, and cerebral blood flow. Interscalene block is the gold standard technique and most often used for shoulder procedures, this technique favors shorter anesthetic recovery time, less postoperative pain, use of narcotics and incidence of nausea/vomiting (16);(17);(18).

Literature (18);(19);(20) has shown superiority of sedation in conjunction with interscalene brachial plexus block in relation to general anesthesia (GA) and interscalene brachial plexus block, however there are few studies comparing cerebral and hemodynamic behavior and the type of anesthesia.

The prospective study by Gillespie et al (21) with 52 patients undergoing interscalene blockade associated with laryngeal masking or orotracheal intubation demonstrated at least one hypotension event in all patients. In addition, three patients had ischemic events. However, the patients did not show changes in the mini mental state examination. The study by Soeding et al (22) evaluated 40 patients, who were divided into two groups: interscalene block with sedation versus interscalene block with laryngeal mask in spontaneous ventilation. Cerebral blood flow, MAP (mean arterial pressure) and HR (heart rate) were evaluated. The group using a laryngeal mask had a significant decrease of approximately 32% in MAP. Regarding cerebral blood flow, there was no significant difference.

These data were similar to those found in the study by Agirre et al (23) , which prospectively evaluated 52 patients undergoing orotracheal intubation with interscalene block. There was a decrease in MAP both in patients who had ischemic events and patients who did not have ischemic events. Regarding neurobehavioral tests, there was no significant difference. The prospective study by Vincent et al (24) evaluated 140 patients with interscalene blockade associated with controlled target sedation and detected an incidence of hypotension/bradycardia of 5.7% and a lower incidence of the Bezold-Jarisch reflex. The study by Ozzeybek et al 2010 (19) evaluated the use of interscalene blockade with sedation versus interscalene blockade and general anesthesia. Intraoperatively, MAP, heart rate, oxygen saturation and pain score were evaluated using the visual analogue pain scale. A significant decrease in mean arterial pressure was detected when positioned in a beach chair in the general anesthesia group, not requiring the use of ephedrine. Regarding the pain score, it was similar between groups.

Meidert et al 2017 (25) compared the use of continuous monitoring of cardiac output with standard monitoring in orthopedic surgeries and observed a significantly lower MAP and SBP (systolic blood pressure) in the group that used standard monitoring

compared to the group that used continuous non-invasive monitoring. The use of a beach chair position significantly decreases brain saturation in approximately 20% and it was correlated with the level of etCO2 as demonstrated in the study by Moerman et al 2012 (26) .

Therefore, there are few studies comparing the perioperative hemodynamic and neurological effects of these two techniques. There is no randomized, controlled study in the literature evaluating perioperative hemodynamic effects and neurological changes through the use of standard and continuous monitoring of cardiac output between these two techniques. So, the aim of the study is to compare intraoperative hemodynamic changes and cerebral oxygenation using peripheral and hemodynamic cerebral saturation monitoring with continuous measurement of cardiac output or standard hemodynamics between two anesthetic techniques for shoulder surgery: interscalene block with sedation versus interscalene block with general anesthesia.

2. OBJECTIVES

2.1. General:

Compare intraoperative hemodynamic changes (cardiac output, blood pressure, heart rate, oxygen saturation) and cerebral oxygenation using peripheral cerebral saturation monitoring and continuous hemodynamic measurement of cardiac output or standard hemodynamics monitoring between two anesthetic techniques for shoulder surgery: interscalene block with sedation versus interscalene block with general anesthesia.

2.2. Specifics:

- Compare changes in cerebral tissue saturation between groups;

- Assess delirium and behavioral changes;

- Verify the superiority of continuous hemodynamic non-invasive monitoring of cardiac output compared to standard hemodynamic monitoring (only heart rate and blood pressure);

- Verify the relationship between standard hemodynamic monitoring (only heart rate and blood pressure) and continuous hemodynamic monitoring of cardiac output plus heart rate and blood pressure and the use of vasopressors, blood transfusion, infused volume;

- Evaluate complications of the anesthetic blockade technique with sedation over the blockade technique and general anesthesia;

- Assess postoperative pain, length of stay post anesthetic recovery and length of hospital stay between groups;

3. MATERIALS AND METHODS

3.1. Design of study

This is a prospective, randomized controlled trial comparing two anesthetic techniques using a standard and continuous hemodynamic monitoring device for cardiac output: sedation and interscalene block with general anesthesia and interscalene block for arthroscopic shoulder surgery.

3.2. Study Local

The research will be carried out in three tertiary hospital in the São Paulo city

3.3. Study Population

This Study was approved by the Ethics Committee for the Analysis of Research of the Hospital Sepaco by opnion number: 5.283.169 and CAAE: 54549221.0.1001.0086; of the Hospital das Clínicas, Faculty of Medicine, University of São Paulo – USP by opnion number: 5.103.355 and CAAE: 46436721.4.0000.0068 and of the Institute of Medical Assistance to the State Public Servant of São Paulo by opnion number: 5.189.754 and CAAE: 52984221.5.1001.5463. All patients submitted to arthroscopic shoulder surgeries in a beach chair position at this institutions who meet the inclusion criteria listed will be included.

3.4. Inclusion criteria

- Patients of both genders, over 18 years of age;

- Patients undergoing arthroscopic shoulder surgery in a beach chair position.

3.5. Exclusion Criteria

- Patients classified as emergency,

- Blood dyscrasia

- Refusal of the procedure

- Infection at the puncture site

- Allergy to the medication used

- Previous cerebrovascular disease

- History of orthostatic hypotension

- Pulmonary disease

- Chronic use of opioids

- Performance of arthroscopic surgeries on both shoulders

- Refusal to participate in the study and/or not to sign an informed consent form

3.6. Calculation of the sample size

Based on the sample calculation, the study by Soeding PF et al, 2011 (22) , which observed a drop in MAP under general anesthesia of approximately 30%, the study by Vincent S et al, 2005 (24) , which observed a decrease in MAP under sedation of 5.6%, and the study by Meidert et al 2017 (25) , which observed a decrease in SBP of 18 mmHg and 12 mmHg of MAP in the group with intermittent monitoring in relation to the group with continuous monitoring. Based on these data, a difference in mean total MAP between groups of 12 mmHg was used and therefore, considering the study power of 80% and alpha error of 0.025 by Bonferroni correction due to be divided into 4 groups, a total sample of 92 patients will be need, with standard deviation of the group with continuous monitoring of cardiac output of 10 mmHg and in the group standard monitoring of 15 mmHg. However, estimating that we may have losses, the final sample will reach 100 patients, so there will be 25 patients in each of the 04 groups.

3.7. Technician

The selected patients will be divided into two groups: group 1 general anesthesia + interscalene brachial plexus block and group 2 sedation + interscalene brachial plexus block. Each group will be divided into two groups, one with hemodynamic continuous monitoring and one with standard hemodynamic monitoring, totaling 4 groups in total in the study. Group 1A general anesthesia + interscalene brachial plexus block with continuous monitoring; group 1B general anesthesia + interscalene brachial plexus block with standard monitoring; group 2A sedation + interscalene brachial plexus block with continuous monitoring; group 2B sedation + interscalene brachial plexus block with standard monitoring (figure 1).

General anesthesia will be done with Propofol (1-3mg/kg), Fentanyl (1-6 mcg/kg) and Rocuronium (0.3-0.6mg/kg) and maintenance of anesthesia will be with Sevoflurane

and Remifentanil. The patient will be maintained on volume-controlled mechanical ventilation (tidal volume 6-8ml/kg, PEEP=5 mmHg, RR=12 ipm, FiO2=50%) during the procedure. Parameters will be adjusted as assessed by the responsible anesthesiologist.

The technique of interscalene level brachial plexus block will be the same in both groups. The patient will be initially positioned in horizontal dorsal decubitus with the head slightly turned to the opposite side with slight elevation, with palpation of the interscalene groove and introduction of the needle in a slightly dorsal and caudal medial direction. The block will use a short Stimuloplex A50 needle (22G x 2") and the aid of Ultrasonography and peripheral nerve stimulator. The local anesthetic will be 0.5% ropivacaine 15-20 ml.

Sedation will be done with Propofol in a controlled target infusion pump.

The procedure should start about 15 minutes after the end of anesthesia.

Continuous monitoring will be done with clearsight continuously assessing blood pressure, cardiac output and heart rate; NIRS electrode to assess cerebral O2 saturation, peripheral O2 saturation, BIS value and axillary temperature.

Standard monitoring will be done with non-invasive blood pressure, heart rate, NIRS electrode to assess cerebral O2 saturation, peripheral O2 saturation, axillary temperature, BIS value. In addition, patients will use Clearsight, but the device will be blind to the anesthesiologist. Pressure monitoring will be every 5 min.

Hypotension will be considered with MAP lower than 65mmHg or a drop of 20% of the initial mean arterial pressure value based on the articles: Soeding PF et al 2011 (22) , Vincent S et al 2005 (24) and Meidert et al 2017 (25) . Cerebral O2 saturation (rScO2) was considered decreased when less than 60% or 20% lower than the baseline value, based on the article Moerman et 2012 (26) .

In the patient with continuous monitoring, decreased cardiac index (CI <2.6) or decreased cerebral saturation will be initially reversed with administration of 250ml fluid for 5 – 10min, if there is reversal of the picture, 20% increase in rScO2 or rScO2> 60% and/or CO>15%, the continuous monitoring is maintained. If there is no reversal, ephedrine 5mg is administered if hypotension remains, assess the hemoglobin (Hb) level. If Hb<9, perform 1CH transfusion, if Hb greater than or equal to 9, perform dobutamine infusion (titrate dose of dobutamine), maintaining monitoring (figure 2). In addition, a patient with hypotension is initially reversed with 250ml fluid for 5 to 10min, if there is a reversal of the condition, monitoring is maintained. If there is no improvement, administer ephedrine 5mg. If you maintain hypotension, check your hemoglobin level. If

hb<9, perform 1CH infusion. If hb greater than or equal to 9, perform norepinephrine infusion (titrate dose of norepinephrine), maintaining monitoring (figure 2).
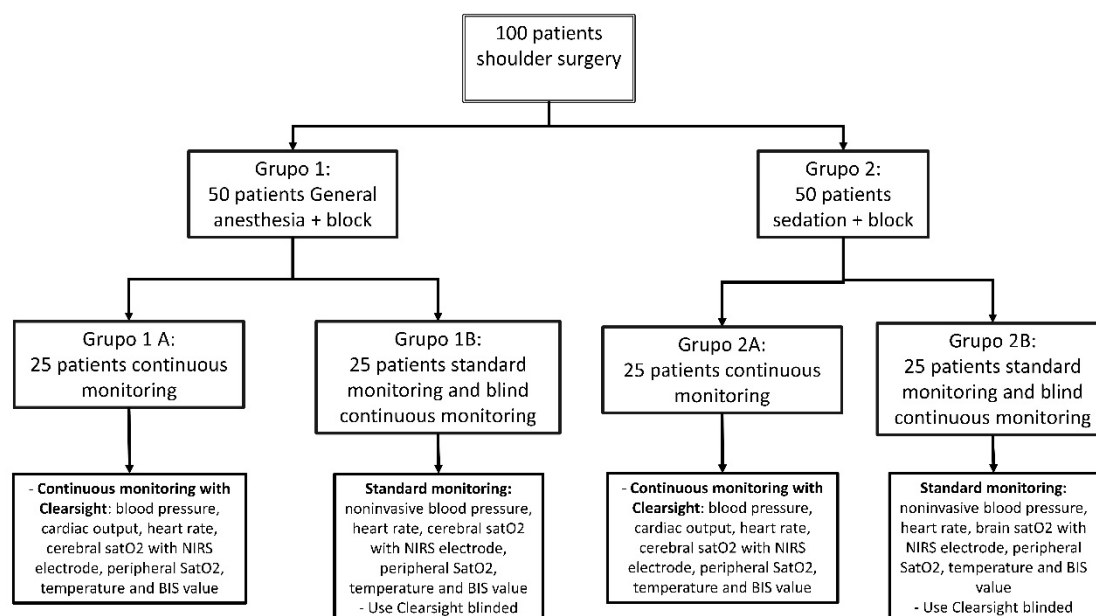
In the patient with standard monitoring, if hypotension, administer 250ml fluid for 5 – 10min, if there is a reversal of the condition, maintain monitoring. If there is no improvement, administer ephedrine 5mg. If you maintain hypotension, check your hemoglobin level. If hb<9, perform 1CH infusion. If hb greater than or equal to 9, perform norepinephrine infusion (titrate dose of norepinephrine). If there is a decrease in rScO2, evaluate the MAP. If hypotension, follow the hypotension flowchart detailed above. If you do not have hypotension and the patient is on OTI, evaluate capnography, O2 flow (FiO2), hypovolemia and anemia. If there is no hypotension and the patient is under sedation, it assesses level of consciousness, O2 flow (FiO2), hypovolemia and anemia (figure 3 and 4).

The anesthetic management of patients will be the responsibility of anesthesiologists.

BIS will be considered normal value between 40 and 60.

3.9. Project flowchart

The project flowchart according to CONSORT, follows below:

3.10. Data collect

After receiving an explanation about the procedures to be performed and signing the consent form, patients will be allocated into 4 groups as explained above using a table of random numbers. Data collected will be age, weight, height, race, gender, ASA, comorbidities, medications in use. During the surgical procedure, the analyzed data will be medications, infusion volume, blood components, vasopressor, anesthetic and surgical complications, anesthesia and surgery time.

In addition, systolic, diastolic and mean blood pressure, heart rate, cerebral O_2 saturation, peripheral O_2 saturation, axillary temperature, BIS value, cardiac index (in patients who will use clearsight) and et CO_2 (in patients will be collected who will be intubated) every 5 min intraoperatively and during post-anesthetic recovery (PAR) [27].

Postoperatively, the data analyzed will be: anesthetic recovery time, hospital stay, need to be referred to the intensive care unit (ICU), length of stay in the ICU and if the patient died. In addition, the visual numerical pain scale and the descriptive verbal pain scale will also be evaluated in the PVR and 24 hours after the procedure [28].

Sedation assessment will be performed using the intraoperative RASS scale for patients who are allocated to the sedation + interscalene brachial plexus block group and postoperatively for all groups. The values of the RASS scale are shown in table 1. The Confusion Management Method in the ICU (CAM-ICU) scale will be used to assess delirium, the table with the parameters used will be shown in figure 5 [29];[30].

3.11. Study blinding

The study will be covered in the assessment of cardiac output during intraoperative data analysis for standard monitoring group. In addition, data analysis will be covered, and they will just be identifying groups by numbers.

3.12. Randomization

Randomization will be done in blocks, the randomization list will be a random sequence of blocks of participants. Blocks will have the same predetermined size with 8 participants in a block, with four possible intervention and control sequences.

3.13. Data analysis

Categorical variables will be presented as absolute and relative frequencies.

Quantitative variables will be presented as mean and standard deviation or as median and interquartile range when appropriate. We will use the Kolmogorov-Smirnov test to assess the distribution pattern of continuous numerical variables.

Comparisons between general anesthesia + block and block + sedation will be performed, as well as comparisons between standard and continuous monitoring. Proportions will be compared using the Chi-square test or Fisher's exact test, if the assumptions for using the Chi-square are violated. Quantitative variables will be compared using the Mann-Whitney test or irregularly distributed Anova when appropriate.

Variables with repeated measurements will be analyzed by linear general multiple model (GLM) with Bonferroni correction for P values.

The association between explanatory variables and response will be evaluated using logistic regression models. Variables selected in the bivariate analyzes ($p<0.0.5$) and those considered clinically relevant will be submitted to multiple logistic regression analyses. Variables with substantial collinearity will be excluded. The result of logistic regression analyzes will be expressed as odds ratios and respective 95% confidence intervals.

All significance probabilities (P values) presented will be two-tailed. P values will be considered statistically significant when less than 0.05. *The Statistical Package for Social Sciences* software version 26.0 (SPSS Inc.®; Chicago, IL, USA) will be used to perform the analyses.

3.14. Ethical aspects

This study will follow the ethical principles of research involving human beings of Resolution 196/96 of the National Health Council (BRASIL, 1996). Respecting the fundamental principles of autonomy, beneficence, non-maleficence, justice and equity. Research participants will sign the informed consent form (IC) for authorization. The project will only be executed after approval by the ethics and research committee (CEP).

5. SCHEDULE

ACTIVITY	DURATION	START	END
Literature review	24 months	Month 1	Month 24
Submission to CEP	6 months	Month 1	Month 6
Data collect	9 months	Month 7	Month 16
Data analysis	12months	Month 7	Month 19
Final writing	5 months	Month 19	Month 24

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6. ANNEX OF FIGURES AND TABLES

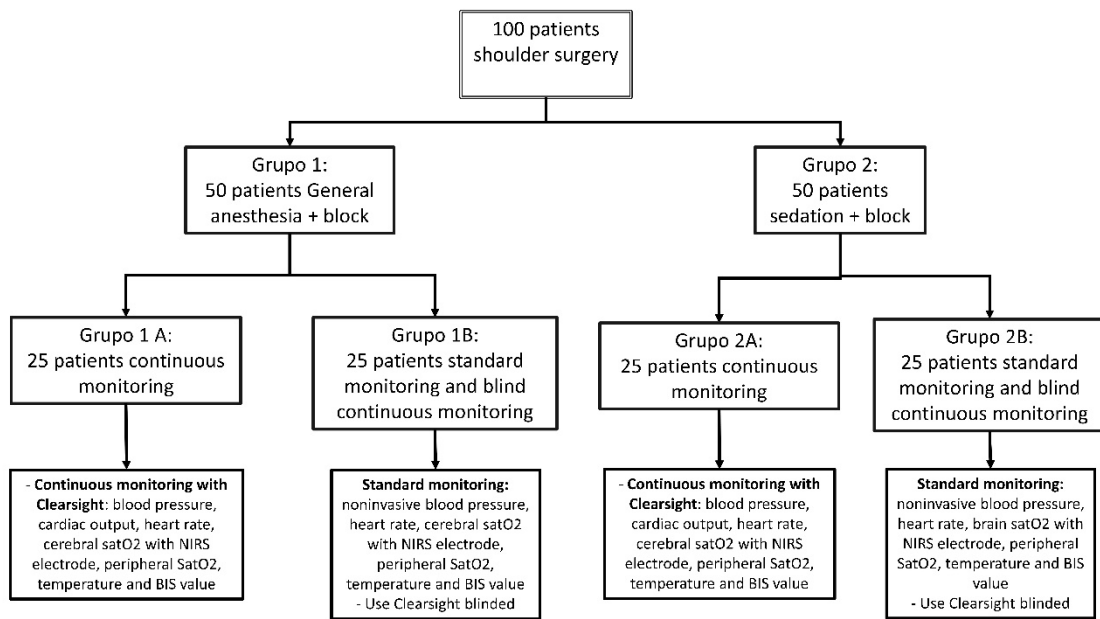|	Target of RASS Values	RASS Description
+4	Combative	Combative, violent, imminent danger
+3	Very Busy	Pulls or removes tubes and catheters, aggressive
+2	Hectic	Frequent unintentional movements, struggling with the fan
+1	Restless	Anxious, apprehensive, but no aggressive or sudden movements
0	Alert and Calm	
-1	Sleepy	Not fully alert but keeps awake with voice (eyes open and in contact more than 10s)
-2	Light sedation	Briefly wakes up with voice (eyes open and in contact for less than 10s)
-3	Moderate sedation	Movements or eye opening with voice (but does not maintain eye contact)
-4	Deep sedation	Does not respond to voice but has eye movements or eye opening with physical stimulation
-5	Unresponsive	Does not respond to voice or physical stimulation

Table 1: RASS scale values
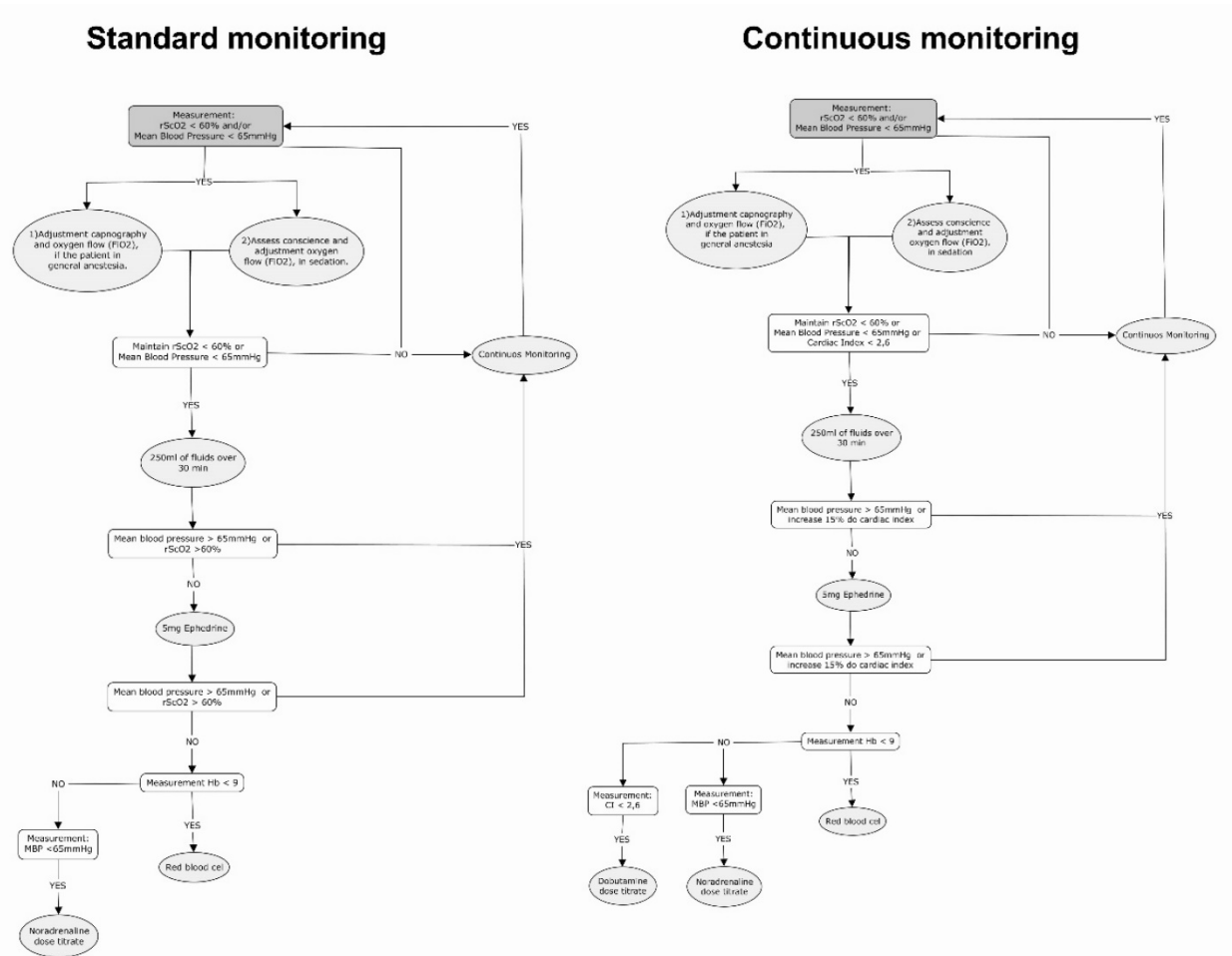
Figure 1: Flowchart of patient distribution.

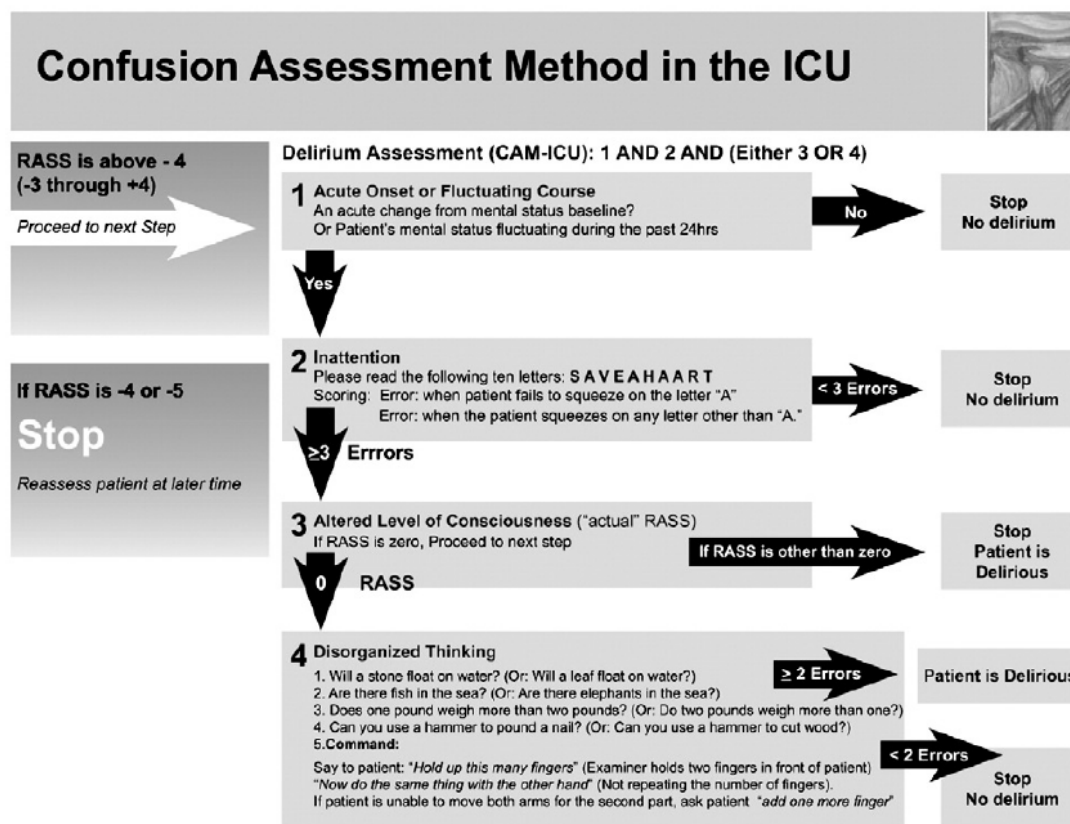Figure 2: Flowchart of monitoring groups

Figure 3: Evaluation of the CAM-ICU scale. Figure taken from the study by Guenther et al 2010 (30).