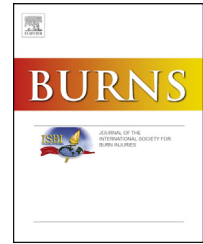


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Clonidine for reduction of hemodynamic and psychological effects of S+ ketamine anesthesia for dressing changes in patients with major burns: An RCT

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ABSTRACT

Clonidine has anesthetic-sparing properties and it may reduce the hemodynamic and psychological effects of S+ ketamine. The objectives of this study were to evaluate the interactions between clonidine and ketamine in hemodynamic and the psychological effects. Psychological effects were evaluated in a very detailed way.

Method: A prospective, double-blind, placebo-controlled study designed for 48 patients with major burns, aged 18–60 years, ASA II or III, who were scheduled for dressing changes was conducted. Midazolam, S+ ketamine, placebo, or clonidine was used for the anesthesia. Intraoperative hemodynamic alterations over time were assessed. The psychological effects were evaluated in detail using 13 variables, the return of conscience, and analgesia during the first 2 h after the procedures.

Results: The clonidine group had low arterial pressure during the procedure. At the 30-min evaluation of the psychological variables, five out of 13 were lower in the clonidine group. At the 2-h evaluation, only the Anxious variable was lower in the clonidine group. Cardiac frequency, postoperative analgesia, delirium, and dreaming were not different between both groups. There was no difference in complication rates between both groups.

Conclusion: Clonidine in S+ ketamine plus midazolam anesthesia reduces the arterial pressures and the postoperative psychological effects.

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1. Introduction

The management of patients with severe burns has improved all over the world. Major advances in several areas have been associated with lower morbidity and mortality rates [1,2]. Burns

produce an intense inflammatory response, and in major burns this response becomes systemic, and it may damage other organs. After the initial management, wound excision, graft preparation, pain control, and rehabilitation will be the next steps [3–5]. The patient's management in this phase is very complex and there is no consensus about the best treatment.

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Ketamine is a drug used in many countries for pain from burns, dressing changes, and for surgical procedures in burn patients, despite good evidence of efficacy. Ketamine has some side effects, in a dose-dependent manner that limits its use (dreaming, hallucinations, delirium, mood alterations, and the emergence phenomena) [6,7].

Although it has been used for decades, ketamine's psychological effects are little understood and they were not evaluated in detail or divided into groups of somatosensitive alterations when used in anesthetic dosage.

The association of clonidine in ketamine-based anesthesia can reduce some of the undesirable side effects and improve analgesia. Clonidine is an alpha-2 adrenoceptor agonist that reduces sympathetic tone and produces analgesia, anxiolysis, sedation, and the anesthetic-sparing effect [2]. There is no clear evidence that clonidine decreases the psychological effects of ketamine.

The possibility of whether the association with the clonidine reduces ketamine's psychological effects beyond the maximum reduction obtained with midazolam alone has not been researched yet.

Considering the possible interaction with clonidine and ketamine, we designed this study to evaluate the effects of clonidine in the midazolam and ketamine anesthesia for dressing changes and wound debridements in patients with major burns.

We evaluated in detail the somatosensitive and psychological effects after anesthetic doses of ketamine and the safety of the clonidine association in these patients.

2. Materials and methods

2.1. Design

A prospective, double-blind, randomized, and placebo-controlled study was conducted. The protocol was approved by the Ethics Committee of the São José Municipal Hospital and by the Ethics and Research Committee by Medical School of São Paulo University – Research Protocol no. 136/10, registered according to Brazilian laws. All patients signed informed consent before going to the surgery room and after randomization.

The primary end point was hemodynamic effects. The secondary end points were psychological alterations, analgesia, dreaming, delirium, and need for ventilator assistance.

2.2. Subjects

The study was performed by including 48 patients with major burns, hospitalized in our burn center, ASA physical status class II or III, aged 18–60 years, who needed dressing changes and wound debridements with general anesthesia.

Major burns were defined by Brazilian recommendations (supplementary materials) [9], stratified by Garcés's Index in class II or III (supplementary materials) [10], and the burned corporeal area was classified by the Lund–Browder system (supplementary materials) [5,11].

Patients were excluded from the protocol if they had <72 h of trauma, need of vasoactive drugs, severe arterial hypertension, ischemic heart disease, mechanic ventilation, renal or hepatic insufficiency, intracranial hypertension, cranial

trauma, glaucoma, psychiatric disease, epilepsy, pregnancy or breastfeeding, use of epidural catheter or patient-controlled analgesia, known allergy for any drug used in the study, impossibility of basic hemodynamic monitoring, or previous participation in this study.

2.3. Protocol procedures

All patients were monitored with a peripheral pulse oximeter, a continuous cardioscope, and a noninvasive measure of arterial pressure. The Datex-Ohmeda CardiCap/5TM monitor was used for all patients and calibrated according to the manufacturer's recommendations. Preanesthetic medication was not used and all patients fasted for 6–8 h. The same surgeons and the same anesthesiologist carried out all procedures. Ketoprofen 1 mg/kg and metamizol 30 mg/kg were used for analgesia. Oxygen 3 L/min was delivered by nasal catheter during the whole procedure, and for hydration, 10 ml/kg of sodium chloride was used plus reposition of blood loss.

The anesthesiologist received a 20-ml syringe identified with the label “protocol solution,” with 15 ml of solution that contained sodium chloride or clonidine 10 mcg/ml diluted in sodium chloride. Patients were randomized into two groups: “clonidine group” (CG) and “placebo group” (PG). The syringes were prepared by an anesthesiologist who was not involved either in the surgical or anesthetic procedure or in the postoperative evaluation.

Midazolam 0.07 mg/kg and 0.2 ml/kg of the protocol solution (placebo or clonidine 2 mcg/kg) were used for all patients in the beginning of the anesthesia. After 5 and 10 min, intravenous S+ ketamine 1 mg/kg was used. Each dose of S+ ketamine was diluted in 20 ml of sodium chloride and manually infused in 1 ml per second.

Additional intravenous doses of S+ ketamine 0.5 mg/kg combined with protocol solution 0.05 ml/kg (placebo or clonidine 0.5 mcg/kg) were used if the appropriate level of surgical anesthesia was not obtained (pain evidence during the procedures or reflexes movements with surgical stimulation). It was the anesthesiologist's subjective decision.

Patients were excluded from the study if they needed more than four additional doses in 1 h. Any measure of systolic pressure >200 mmHg or diastolic pressure >120 mmHg during the procedure excluded the patients from the study.

A dose of intravenous morphine 40 mcg/kg was defined for rescue analgesia if the pain Visual Analog Scale (VAS) was >4, every 20 min until the pain VAS was <4.

After 2 h, the patients were discharged to the burn center room for the postanesthesia care unit (PACU) if the pain VAS was <4, there was no bleeding or vomiting, and the Aldrete–Kroulik index was ≥8. For analgesia in the first 24 h, rescue with intravenous morphine 40 mcg/kg if VAS was >4 was carried out, every hour if necessary. All non-opioid analgesic drugs were maintained, and ketamine or clonidine was not used during the first 24 h after the procedure.

In the surgery room, the total doses of S+ ketamine, the number of the additional doses, the number of patients excluded from the protocol, and delirium occurrence (yes, not, and not conclusive) were evaluated. The cardiac frequency, diastolic and systolic pressure, peripheral oxygen saturation, and the need for ventilator assistance were registered every 5 min.

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