Avaliação da Cetamina Racêmica e do Isômero S(+), Associados ou Não a Baixas Doses de Fentanil, na Balneoterapia do Grande Queimado *

Assessment of the Use of Racemic Ketamine and Its S(+)Isomer, Associated or Not with Low Doses of Fentanyl, in Balneotherapy for Major Burn Patients

Fernando Antônio de Freitas Cantinho, TSA¹, Antonio Carlos Pereira da Silva, TSA²

RESUMO

Cantinho FAF, Silva ACP - Avaliação da Cetamina Racêmica e do lsômero S(+), Associados ou Não a Baixas Doses de Fentanil, na Balneoterapia do Grande Queimado.

JUSTIFICATIVA E OBJETIVOS: O cuidado da ferida do grandequeimado desencadeia estímulo doloroso muito intenso. Este estudo teve por objetivo avaliar a segurança e efetividade de diferentes combinações de fármacos na anestesia para balneoterapia.

MÉTODO: Com a aprovação do Comitê de Ética, foram estudados 200 procedimentos de balneoterapia em 87 grandes queimados adultos. Em todos os casos foi empregado o midazolam. Foram utilizados frascos numerados da cetamina, não se conhecendo no momento do uso se era racêmica ou S(+). A cada manhã era sorteado se os procedimentos daquele dia seriam conduzidos com ou sem fentanil. Formaram-se quatro grupos: ISO/sf (isômero S(+) sem o fentanil), ISO/cf (isômero S(+) com o fentanil), RAC/sf (cetamina racêmica sem o fentanil) e RAC/cf (cetamina racêmica com o fentanil). As doses iniciais propostas foram: midazolam 0,06 mg.kg¹, cetamina 1,0 a 1,1 mg.kg¹, fentanil 0,8 µg.kg¹; as doses adicionais eram administradas conforme necessário.

RESULTADOS: Em apenas um caso houve lembrança de dor durante a balneoterapia. No grupo que recebeu a cetamina S(+), o acréscimo do fentanil não evidenciou vantagens; associado à forma racêmica, o fentanil reduziu a dose total e o número de bolus da cetamina. A extensão da superfície corporal queimada foi a principal determinante da intensidade de dor pós-procedimento. A menor intensidade de dor pós-procedimento foi o principal fator considerado pelo paciente para sua satisfação pela anestesia recebida.

CONCLUSÕES: As quatro diferentes combinações de fármacos mostraram-se seguras e permitiram ausência de dor durante a balneoterapia. Características não ligadas diretamente aos anestésicos mostraram-se de maior importância na definição da dor pós-proce-

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Endereço para correspondência (**Correspondence to**): Dr. Fernando Antônio de Freitas Cantinho Rua Professor Fernando Raja Gabaglia, 182/casa 1 Freguesia – Jacarepaguá 22750-660 Rio de Janeiro, RJ E-mail: fhbmcantinho@terra.com.br dimento, que foi a principal característica considerada pelo grande queimado para definir sua satisfação com a anestesia recebida.

Unitermos: ANALGÉSICOS: cetamina; DOENÇAS: queimadura; TE-RAPÊUTICA: balneoterapia

SUMMARY

Cantinho FAF, Silva ACP – Assessment of the Use of Racemic Ketamine and its S(+)isomer, Associated or Not with Low Doses of Fentanyl, in Balneotherapy for Major Burn Patients.

BACKGROUND AND OBJECTIVES: The care of the wounds of major burn patients triggers severe painful stimuli. The objective of this study was to assess the safety and efficacy of different drug combinations in anesthesia for balneotherapy.

METHODS: After approval by the Ethics Commission, 200 procedures of balneotherapy in 87 major burn adult patients were evaluated. Midazolam was used in all cases. The vials of ketamine were numbered and, therefore, at the time of the use, one did not know whether racemic or S(+)ketamine was being used. Each morning it was decided by drawing lots whether fentanyl would be used or not in the procedures of that day. Patients were included in one of four groups: ISO/sf (S(+) isomer without fentanyl), ISO/cf (S(+) isomer with fentanyl), RAC/sf (racemic ketamine without fentanyl), and RAC/cf (racemic ketamine with fentanyl). The initial doses proposed were as follows: midazolam, 0.06 mg.kg¹; ketamine, 1.0 to 1.1 mg.kg¹; and fentanyl, 0.8 µg.kg¹⁻¹; additional doses were administered as needed.

RESULTS: Only one patient recalled the pain of balneotherapy. In the group that received S(+)ketamine, the use of fentanyl did not bring additional advantages; however, when associated with racemic ketamine, fentanyl reduced the total dose and the number of ketamine boluses. The extension of body surface burned was the main determinant of the severity of post-procedure pain. Reduced pain severity was the main factor considered by patients when grading their satisfaction with the anesthesia.

CONCLUSIONS: The four different drug combinations proved to be safe and guaranteed the absence of pain during balneotherapy. Characteristics not directly related to the anesthetics proved to be more important in the incidence of post-procedure pain, which was the main factor considered by major burn patient to define their satisfaction with the anesthesia used.

Keywords: ANALGESICS: ketamine; DISEASES: burns; THERAPY: balneotherapy.

with different variables. Advanced age, larger extension and depth of the thermal lesion, and burns of the airways are some of the characteristics that increase mortality ^{1,2}. Patients with the worse prognosis develop severe dysfunctions of one or more organs and systems ³.

Effective treatment of major burn patients requires multi- and interdisciplinary work, preferentially in a Burn Unit (BU). The inclusion of Anesthesiology among those disciplines is useful and fundamentally important in several steps of treatment. Besides the variability of response to pain among humans, it is especially difficult to estimate its severity in burn patients ⁴. Pain varies according to the degree of the dermal lesion, and it may even be absent in areas of deeper damage due to the destruction of nociceptive receptors ⁵. It is well known that the proper approach to pain can reduce the incidence of post-traumatic stress disorder in those patients ⁶.

The balneotherapy performed in the study patients goes beyond the simple change of dressings and cleaning of the wound: anesthesia is administered at the moment of the daily bath of major burn patients. With the patient lying on a steel bunk, the entire body surface, burned or not, is cleaned with running water and cleaning solution. The wounds are also frequently debrided. The use of anesthesia allows the staff to carry out other procedures that would otherwise be painful, such as physical therapy, drainage of abscesses, skin biopsy, and removal of stitches.

The intensity of the painful stimulus caused by treating a burn wound is comparable to that of surgical procedures. Consequently, techniques based just on hypnotics and opioids that do not require ventilatory support do not provide adequate analgesia in different treatment phases and circumstances. Since burn wounds require almost daily care, the expectation of pain is a greater problem than the pain itself ^{7,8}.

The objective of the present study was to complement a prior study⁹ and to assess: 1) the efficacy and safety of four different drug combinations in balneotherapy of major burn patients; 2) pain severity during and after the procedures, as well as to identify the most important variables that affect its severity; 3) the degree of satisfaction of major burn patients with the anesthesia and to identify the variables patients considered more important in the determination of their satisfaction.

METHODS

After approval by the Ethics on Research Committee, 234 anesthetic procedures for balneotherapy in 87 patients awake and oriented, ages 18 to 64 years admitted to the Burn Unit (BU), were evaluated in this prospective double-blind study. Thirty-four cases were excluded due to irregularities in post-anesthetic records; therefore, the results refer to 200 cases. Both genders were included in this study, and burns were caused by different agents and circumstances and were of different depths and extension. The procedures were

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INTRODUCTION

The daily treatment of major burn patients is challenging. Burn accidents affect different population groups regarding age, gender, race, social group, and associated diseases. When studying and treating burn patients, one has to deal performed in the morning, in the bathroom located in the BU, and patients were fasting for at least six hours. Exclusion criteria included cardiovascular instability requiring vasoactive drugs, respiratory failure with mechanical ventilation, and incapacity of the patient to provide the information required by the post-anesthetic evaluation.

While the patient was brought to the bathroom and prepared by the nursing staff, the anesthesiologist and the BU physician exchanged information regarding the patient clinical condition. The patient was observed in order to determine whether a venous access was present or if a new one was necessary for administration of fluids and drugs. The pulse oximeter (SpO₂) was the only electronic monitor used regularly.

Only intravenous drugs were used in anesthesia for balneotherapy. The initial doses of those drugs were based on a prior study⁹. Midazolam was administered to all patients at an initial dose of 0.06 mg.kg⁻¹. Each morning it was decided by drawing lots whether fentanyl would be used in the procedures carried out that day; when used, the initial dose of fentanyl was 0.8 µg.kg⁻¹. Ketamine was provided in numbered vials, in concentrations of 50 mg.mL⁻¹, and, therefore, the chemical form used - racemic or the S(+) isomer - was unknown. The initial dose of ketamine was 1.0 mg.kg⁻¹ when used along with fentanyl, and 1.1 mg.kg⁻¹ when the opioid was not used. During anesthesia maintenance, boluses of midazolam and/or ketamine were administered according to the manifestations of agitation or pain, respectively. Whenever the total dose of midazolam reached 0.1 mg.kg⁻¹, and if the patient remained agitated, which was attributed to ketamine, propofol at an initial dose of 0.4 mg.kg⁻¹ was used, and further doses were equal or lower than the initial dose, according to the response of the patient.

Since midazolam was used in all patients, they were divided in four groups according to the chemical form of ketamine used and whether it was associated with fentanyl or not: ISO/ sf (S(+) isomer without fentanyl), ISO/cf (S(+) isomer with fentanyl), RAC/sf (racemic ketamine without fentanyl), and RAC/cf (racemic ketamine with fentanyl).

Afterwards, to identify among two variables which one had greater influence on pain severity after balneotherapy the same sample of 200 cases was further divided in two new groups, regardless of the drugs used. The balneotherapy group (n = 156) included patients who underwent daily cleaning of their wounds and bath. In the balneotherapy + surgery group (n = 44), small surgical procedures, such as debridement (n = 39), drainage of abscesses, and removal of autografts stitches were performed.

Dypirone 30 mg.kg⁻¹ was administered to all patients during balneotherapy for post-anesthetic analgesia. Post-anesthetic evaluation was carried out in the afternoon by a physician who did not participate in the anesthesia and, therefore, was unaware of the drugs used in the morning.

Age, weight, gender, burned surface area (BSA), length of hospitalization, duration of the procedure, doses of anesthe-

tic agents used, and the need to use propofol were the parameters evaluated. The following parameters were investigated in the post-anesthetic evaluation: recollection of the pain during balneotherapy, pain severity after the procedure (VAS – visual analogue scale), recollection of dreams or hallucinations experienced during anesthesia, and patient satisfaction (on a 1 to 10 scale) with the anesthesia received that day.

The study protocol did not determine parameters to be suggested to the patient to grade their satisfaction; they answered freely when questioned about their degree of satisfaction with the anesthesia received each day during the study. Afterwards, the investigators compared patient satisfaction with the other parameters to identify which one of them better correlated with the definition of satisfaction by the patient.

Printed records were transcribed to the data bank developed in the Epi Info 6 software, the same software version 3.5 (June 2008) was used to analyze the data. Parametric data are presented as mean \pm standard deviation and Analysis of Variance (ANOVA) was used to compare them; whenever the Bartlett test indicated that variances were not homogeneous, the Kruskal-Wallis test was used. The Chi-square test was used for non-parametric data. A p < 0.05 was considered as statistically significant.

RESULTS

Table I shows the data regarding gender, age, weight, SAB, duration of the procedures, length of hospitalization, percentage of patients who reported hallucinations, and patient satisfaction with the anesthesia. Table II shows the total dose of midazolam and ketamine, the number of boluses of those drugs, and the percentage of cases that required propofol and the total dose used.

By comparing both groups, RAC/sf and RAC/cf, it was evident that the use of fentanyl decreased the number of boluses and the total dose of racemic ketamine. When the S(+) isomer was used, fentanyl did not reduce the total dose and the number of boluses of ketamine, it did not decrease pain severity after the procedure, and it decreased patient satisfaction with the anesthesia.

All four different anesthetic combinations proved to be safe and effective. A reduction in SpO₂ below 90% or respiratory depression requiring ventilatory support with positive pressure was not observed. Cardiovascular instability or any other systemic imbalance related to anesthesia was not observed either. Only one patient recalled the pain during balneotherapy: a 28 years old patient in the RAC/sf group with 50% SAB, who had been hospitalized for nine days said during the post-anesthetic evaluation that during balneotherapy he experienced, for a short while, pain grade 10 in the VAS. He also noticed that more anesthetic was administered, which was followed by immediate loss of consciousness; according to him, the VAS after balneotherapy was equal to four and patient satisfaction equal to seven.

	ISO/sf (n = 44)	ISO/cf (n = 56)	RAC/sf (n = 56)	RAC/cf (n = 44)
Gender (M/F)	19/25	26/30	28/28	21/23
Age (years)	33.3 ± 12.5	33.5 ± 10.7	33.2 ± 13.5	35.4 ± 10.9
Weight (kg)	67.9 ± 14.1	66.9 ± 15.9	70.3 ± 15.9	66.9 ± 12.9
SAB (%)	27.6 ± 17.1	28.8 ± 16.9	33.2 ± 14.1	26.6 ± 16.3
Duration of the Procedures (minutes)	30.4 ± 12.5	28.0 ± 9.0	31.2 ± 10.4	30.2 ± 12.9
Length of Hospitalization (days)	18.8 ± 16.1	17.0 ± 15.5	20.3 ± 16.5	17.6 ± 15.7
Report of Hallucinations (%)	27.3	23.2	33.9	36.4
Satisfaction	9.7 ± 0.9 *	9.2 ± 1.2 *	8.9 ± 1.7	9.6 ± 0.6

Table I – Gender, Age, Weight, Burned Surface Area (BSA), Duration of the Procedures, Length of Hospitalization, Hallucinations, and Patient Satisfaction with the Anesthesia Used in Each of the four Study Groups.

^{*} Kruskal-Wallis, p = 0.01

Table II – Total Dose and Number of Boluses of Midazolam and Ketamine; Percentage of Cases That Required the Use of
Propofol to Attenuate the Agitation Attributed to Ketamine and Total Dose Used.

	ISO/sf (n = 44)	ISO/cf (n = 56)	RAC/sf (n = 56)	RAC/cf (n = 44)
Midazolam				
Dose (mg.kg ⁻¹)	0.06 ± 0.02	0.07 ± 0.01	0.07 ± 0.01	0.07 ± 0.01
N°. of boluses	1.21 ± 0.47	1.30 ± 0.50	1.50 ± 0.59 1	$1.27\pm0.45\overset{*}{}$
Ketamine				
Dose (mg.kg ⁻¹)	1.78 ± 0.58	1.58 ± 0.68	2.33 ± 0.83 $^{\rm 2}$	1.65 ± 0.68 **
N°. of boluses	2.78 ± 1.38	2.66 ± 1.57	3.57 ± 1.46 $^{\rm 3}$	2.63 ± 1.49 $^{\text{\#}}$
Propofol				
Dose (mg.kg ⁻¹)	0.76 ± 0.74	0.43 ± 0.20	0.65 ± 0.14	14.3
Percentage of use	7.3	9.1	14.3	7.0

* ANOVA: p = 0.04; ** ANOVA: p = 0.0001; ** ANOVA: p = 0.0044

Pain severity after balneotherapy varied considerably among the patients (Figure 1); differences among the four study groups were not observed. Greater SAB is associated with larger wound area and, therefore, balneotherapy tends to last longer. This tendency was confirmed in the study population (Figure 2).

It was observed that longer procedures (Figure 3A) and larger SAB (Figure 3B) were associated with higher degrees of pain after the procedure. We tried to identify which of the two parameters was more important in determining an increase in pain severity. For such, the same 200 cases were divided again, regardless of the drugs used, in two groups specifically for this assessment (Table III). The procedure lasted longer in the bath + surgery group than in the bath group, but pain severity after the procedure was similar in both groups. Therefore, it was evident that the extension of SAB was a greater determinant of pain severity after the procedure. The length of hospitalization, a reflection of the time and stage of wound evolution (Figure 4), was another parameter related with pain severity after the procedure.

Patient satisfaction with the anesthesia was 9.3 ± 1.2 , the 25^{th} percentile 9, and median of 10, and for the most part reflected pain severity after the procedure (Figure 5).

Hallucinations were more frequent when racemic ketamine was used: 35% versus 25% with the S(+) isomer; however, considering the limitations of the study population, this was not statistically significant (Table I). The presence of hallucinations don't cause an adverse effect on patient satisfaction.

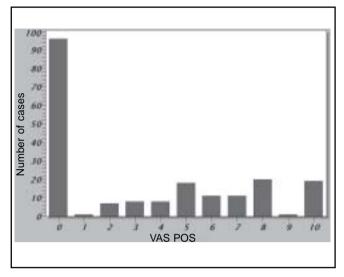


Figure 1 – Distribution of the Different Degrees of Pain after the Procedure (VAS POS), Evaluated by the Visual Analogue Scale (n = 200).

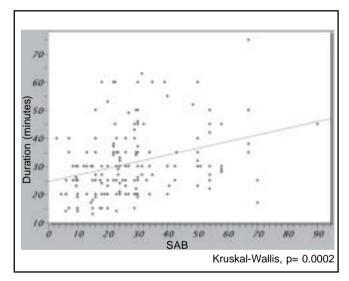


Figure 2 – Dispersion and Regression Line Demonstrating the Positive correlation between the Extension of Surface Area Burned (SAB) and the Duration of the Procedure.

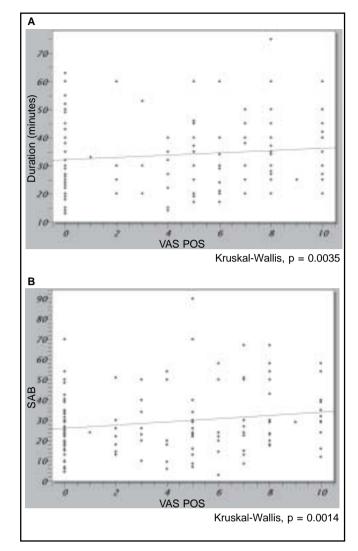


Figure 3 – Dispersion and Regression Line Indicating a Positive Correlation between Pain Severity after the Procedure (VAS POS) with the Duration of the Procedure (3A), as well as the Surface Area Burned (SAB) (3B).

Table III - Comparison Between the Bath/Wound Cleaning/Dressing Change Group (Bath Group) and the Group in which
Cleaning was Associated with Other, More Painful, Procedures (Bath + Surgery Group).

	Bath (n = 156)	Bath + surgery $(n = 44)$	p (ANOVA)
Duration (minutes)	28.3 ± 10.3	40.0 ± 12.8	< 0.000001
SAB (%)	29.2 ± 16.5	29.7 ± 15.2	0.85
VAS POS	3.1 ± 3.5	3.8 ± 4.0	0.27

SAB - surface area burned; VAS POS - pain severity determined by the Visual Analogue Scale after the procedure.

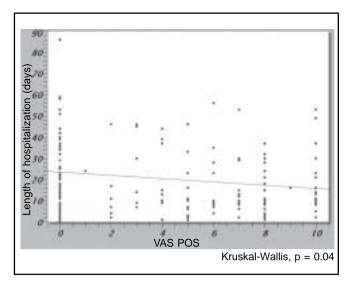


Figure 4 – Dispersion and Regression Line Demonstrating the Negative Correlation between the Length of Hospitalization and Severity of Pain after the Procedure According to the Visual Analogue Scale (VAS POS).

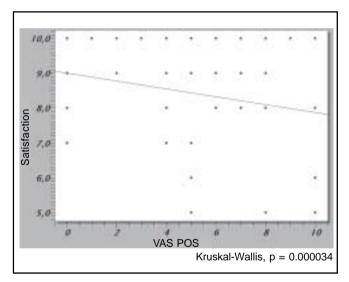


Figure 5 – Dispersion and Regression Line Demonstrating the Negative Correlation between Pain Severity after the Procedure, According to the Visual Analogue Scale (VAS POS), and Patient Satisfaction with the Anesthesia.

DISCUSSION

According to the objectives of the study, important characteristics were defined:

- All four different drug combinations allowed the safe and effective cleaning of the wounds of major burn patients. Adding fentanyl to midazolam and S(+)ketamine did not bring further benefits;
- 2) With only one exception among 200 cases, pain during the procedure was completely eliminated. Pain after the

3) Patients showed a high degree of satisfaction with the anesthesia received. Since pain recollection was almost completely absent, reduced pain severity after balneotherapy was the main factor to determine patient satisfaction. The addition of fentanyl to midazolam and S(+)ketamine had a negative influence in patient satisfaction.

A review of the literature indicated that descriptions of analgesic or anesthetic techniques employed for wound cleaning and dressing changes in major burn patients are rare. Among the alternatives described we can mention acupuncture ¹⁰, massage ¹¹, virtual reality games ¹², and hypnosis or other psychological approaches ¹³⁻¹⁶. Among the drugs used more often, and almost always in associations ²⁵, we can mention alfentanil ¹⁷, fentanyl ¹⁸, midazolam ¹⁹, propofol ^{20.21}, sevoflurane ²², and, especially, ketamine ²³⁻²⁴.

Clinically important respiratory depression was not observed in the study population; however, it should be emphasized that, despite the low incidence, it does happen and, therefore, all monitoring and resuscitation equipment should be readily available. Balneotherapy has a peculiar characteristic: the patient is invariably naked, facilitating direct observation of the thorax and respiratory movements. Irregular thoracic movements frequently precede a reduction in oxygenation, which helps to identify respiratory problems.

The pulse oximeter is constantly affected by interferences caused by patient mobilization during the bath; and peripheral vasoconstriction leads to incorrect pulse readings and consequently the numeric value of oximetry shown does not reflect the status of the patient. For those reasons, the use of other electronic monitors is not impossible; however, regular and reliable cardioscope and non-invasive blood pressure readings, for example, can only be obtained with a delay in the dynamics of balneotherapy. All monitoring apparatuses foreseen in the resolution of the Federal Medical Board should be strictly observed and should, therefore, be readily available; the effective use of said apparatus during the bath of major burn patients depends on several circumstances.

It is well known that μ opioid agonists have agonist activity in NMDA receptors ²⁶, characterizing an opposite effect to that of ketamine in those receptors. This question was not resolved in the references consulted; however, it seems possible that, in balneotherapy for major burn patients, fentanyl interferes with the actions of S(+)ketamine on NMDA receptors with a negative interaction. Such interaction could explain the higher patient satisfaction (Kruskal-Wallis, p = 0.01) observed in the ISO/sf group when compared with the ISO/cf group. Those two groups were homogeneous regarding other parameters studied that could influence postanesthetic evaluation. The use of propofol when the psychomotor agitation attributed to ketamine persisted and the total dose of midazolam reached 0.1 mg.kg⁻¹ proved to be a good choice. Excessive post-anesthetic somnolence caused by higher doses of midazolam, which can delay the return to regular feeding, should be avoided.

The severity of pain after the procedure decreased as a function of the length of hospitalization. This is possibly due to the decreased stimulation of nociceptors as the wound develops granulation tissue and new epithelium, i.e., the size of the crude area is reduced; this represents a reduction of SAB and a smaller wound area to be cleaned.

The anesthesia used allowed better wound care without promoting the development of pain. Thus, the professionals involved can concentrate in the wound to be treated, providing adequate wound care ²⁷.

Studying populations of burn patients means to study a diverse group of patients even when they are homogeneously divided according to age, gender, SAB, length of hospitalization, use of drugs, and etc. Major burn patients typically present dynamic evolution in which a short interval, of a few days, can be associated with marked clinical and emotional changes; the pathophysiological dynamics ²⁸ most certainly influences the pharmacokinetics and pharmacodynamics of the drugs used ^{5,29}. Therefore, it is very difficult to obtain similar groups of burn patients in which only the drugs vary. Considering the lack of similar studies in the database consulted (Medline, LILACS, Cochrane Library), one should use caution when evaluating the results described here; further clinical studies are necessary. More specifically, it would be premature to state that there is a possible negative interaction between fentanyl and S(+)ketamine. However, regarding the anesthesia in the bathroom, the degree of post-procedure analgesia, and patient satisfaction with the anesthesia, one can say that the addition of fentanyl to midazolam and S(+)ketamine does not offer further advantage.

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RESUMEN:

Cantinho FAF, Silva ACP - Evaluación de la Cetamina Racémica y del Isómero S(+), Asociados o No a Bajas Dosis de Fentanil, en la Balneoterapia del Gran Quemado.

JUSTIFICATIVA Y OBJETIVOS: El cuidado de la herida del gran quemado desencadena un estímulo doloroso muy intenso. Este estudio tuvo el objetivo de evaluar la seguridad y la eficacia de diferentes combinaciones de fármacos en la anestesia para balneoterapia.

MÉTODO: Con la aprobación del Comité de Ética, fueron estudiados 200 procedimientos de balneoterapia en 87 grandes quemados adul-

tos. En todos los casos se usó el midazolam. Se utilizaron frascos numerados de la cetamina, y cuando se usaron no se sabía si era racémica o S (+). Todas las mañanas, se hacía el sorteo para saber si los procedimientos de ese día serían comandados por el fentanil o no. Quedaron establecidos cuatro grupos: ISO/sf (isómero S(+) sin el fentanil), ISO/cf (isómero S(+) con el fentanil), RAC/sf (cetamina racémica sin el fentanil) y RAC/cf (cetamina racémica con el fentanil). Las dosis iniciales propuestas fueron: midazolam 0,06 mg.kg¹, cetamina 1,0 a 1,1 mg.kg¹, fentanil 0,8 µg.kg¹; las dosis adicionales se administraban conforme a lo necesario.

RESULTADOS: En solo un caso hubo recuerdo de dolor durante la balneoterapia. En el grupo que recibió la cetamina S(+), la añadidura del fentanil no mostró ventajas. Asociado a la forma racémica, el fentanil redujo la dosis total y el número de bolo de la cetamina. La extensión de la superficie corporal quemada fue el principal determinante de la intensidad de dolor posprocedimiento. La menor intensidad de dolor posprocedimiento, fue el principal factor considerado por el paciente para su satisfacción por la anestesia recibida.

CONCLUSIONES: Las cuatro diferentes combinaciones de fármacos fueron seguras y permitieron la ausencia de dolor durante la balneoterapia. Las características no vinculadas directamente a los anestésicos, tuvieron una mayor importancia en la definición del dolor posprocedimiento, que fue la principal característica considerada por el gran quemado para definir su satisfacción con la anestesia recibida.