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Rev Chil Pediatr. 2019;90(6):649-656
DOI: 10.32641/rchped.v90i6.1169

ORIGINAL ARTICLE

Results after implementation of a sedoanalgesia protocol for procedures in hospital environment

Resultados tras implantación de un protocolo de sedoanalgesia para procedimientos en ámbito hospitalario

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Received: 01-4-2019; Approved: 13-8-2019

Abstract

We analyze the effectiveness and safety of a specific analgosedation protocol for procedures, and evaluate the satisfaction of the health personnel with each procedure. **Patients and Method:** Prospective study of an analgosedation protocol for hospital procedures in children under 18 years of age, with an individualized strategy based on the patient's baseline situation, the type of procedure and the experience of the pediatrician responsible for the sedation. The following variables were recorded: diagnosis motivating the procedure, type of procedure, anthropometric data, allergies, medication, ASA status and baseline disease, fasting time, lung auscultation, temperature, oxygen saturation, respiratory rate, heart rate, blood pressure, sedation location, type of drug, dose, route of administration, Ramsay sedation scale, duration of sedation, type and treatment of adverse effects, presence of family members throughout the procedure, and patient satisfaction. **Results:** 279 sedations were performed. The most commonly used drugs were nitrous oxide (62.7%) and midazolam (16.5%); the most commonly used routes of administration were the inhaled one (62.4%) and the intravenous one (15.8%). The satisfaction was high for the pediatrician (92.5%), the nurse (94.3%), the family (96.8%), and patients (93.6%), with a good correlation between them, and it was significantly lower when using midazolam and the nasal and oral routes. The adverse effects rate was 3.2%, and none was severe. **Conclusions:** The implementation of a specific analgosedation protocol for procedures in the hospital environment achieves high levels of effectiveness and safety, as well as a high level of satisfaction, both in family members and in health personnel.

Keywords:
Sedation;
Technique;
Security;
Satisfaction

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How to cite this article: Rev Chil Pediatr. 2010;90(6):649-656. DOI: 10.32641/rchped.v90i6.1169

Introduction

Sedation and analgesia for procedures are the set of techniques and drugs used to minimize the pain and anxiety produced by these interventions which are more relevant in pediatric age[1]. In recent years, diagnostic procedures (imaging tests, lumbar puncture, etc.) and therapeutic ones (suture, reduction fracture, etc.) have increased in children[2] and it has been demonstrated that good sedation and analgesia minimize the appearance of undesirable effects derived from pain and fear, and allows performing procedures more safely[3].

For many years, sedation and analgesia in a hospital setting were carried out mainly by anesthesiologists, especially in the operating room. However, other specialists have progressively assumed responsibility for sedation and analgesia for these procedures that are performed in many other hospital areas[4].

It has been proven that sedation and analgesia performed by trained pediatric intensive care specialists, emergency physicians, and pediatricians are effective and safe[5], however, a good prior assessment and adequate monitoring are necessary in order to ensure that sedation and analgesia are adequate and safe as this allows early detection of the occurrence of adverse effects in real time.

The development of protocols and guidelines for sedation and analgesia has improved its state and minimized complications[2,6]. Despite this, there is great variability among hospitals in the monitoring and strategy choice of sedation and analgesia for procedures in children[7].

The hypothesis of our study is that a protocol implementation with a strategy of individualized sedation and analgesia for procedures in children will allow obtaining high effectiveness with minimum adverse effects.

The main objective of this study is to analyze the effectiveness of a sedation and analgesia protocol, and the safety it provides for the procedures.

Patients and Method

Prospective quasi-experimental study carried out between September 2013 and March 2015, previously approved by the hospital's ethics committee, so that the data and patients confidentiality was respected at all times, and due to they are part of the study, they did not require further tests, administration of any additional medication or increasing the number of visits required for regular follow-up.

A specific protocol of sedation and analgesia for pediatric procedures was previously implemented in a secondary care hospital. In order to carry out this protocol, an updated bibliographic review was conducted on the subject, including different clinical guidelines, and it was written by a pediatrician team. To write this protocol, several pediatric intensivists were included, as well as emergency physicians and the head of emergency medical services, all of them with several years of experience in sedation procedures. The different opinions that arose were resolved with a specific search to resolve the doubts. This protocol was implemented after presenting it and reaching consensus with the rest of the professionals involved in the performance or indication of sedation and analgesia in procedures (pediatricians, surgeons, and nurses) through clinical sessions.

The protocol included the following steps:

1. Definition of the human team needed to perform the sedation and analgesia in a procedure so that the drug choice and supervision of its effects are carried out by an experienced pediatrician, different from the professional who performs the procedure. In addition, at least one nurse from the pediatric service must always be present, who prepares and administers the drugs and monitors the patient at all times.
2. To carry out a previous evaluation of the patients' basal situation through an anamnesis that includes allergies, current medication, basic illnesses, previous experiences with sedation and fasting time, and vital signs before sedation (oxygen saturation, heart and respiratory rate, pulmonary auscultation, temperature, and blood pressure).
3. To inform patients and family members of the procedure and strategy of sedation and analgesia, and sign informed consent.
4. To check the material and equipment necessary to carry out sedation and analgesia, monitoring and treatment of possible complications.
5. Continuous monitoring.
6. Drug choice by the pediatrician in charge, considering the basal situation of the patients, the procedure to be performed, and the physician's own experience. The protocol differentiated the types of procedures according to the pain intensity they might cause (painless, mildly painful, or moderately-intensely painful), and suggested the drugs of choice for each type of procedure, distinguishing between exclusively sedative drugs (propofol, Chloral hydrate, and midazolam), which can be administered alone or as adjuvants to an analgesic, and others with sedative and analgesic effects (nitrous oxide, ketamine, and fentanyl) with the possibility of combining them with each other or with local anesthetics (Table 1). The final drug choice is made by the pediatrician in charge based on his or

her own clinical experience, but always within the options included in the protocol.

7. Data recording every 5 minutes from the time of drug administration to the disappearance of the last drugs effects, including the sedation degree according to the scale. All family members were also present during the induction of sedation.

Any event potentially harmful to the patient occurring during the time of sedation was considered an adverse effect.

All children aged between one month and 18 years with a physical status classification lower than 4 according to the American Society of Anesthesia (ASA) criteria were included in the study: ASA I (previously healthy patient), ASA II (patient with some disease without functional limitation), or ASA III (patient with limiting disease), who underwent a diagnostic or therapeutic procedure that could generate pain or anxiety and who received sedation or analgesia. Patients with ASA IV, V or VI were not included since they are those with an important underlying pathology and, therefore, with a high risk to administer sedatives by non-anesthesiologists physicians. Allergy to any of the drugs included in the protocol and patients or relatives who refused to participate in the study were considered as other exclusion criteria.

The following variables were recorded: diagnosis motivating the procedure, type of procedure, anthropometric data (age, weight), allergies, medication, ASA status and underlying disease, fasting time, pulmonary auscultation, temperature, oxygen saturation, respiratory and heart rate, blood pressure, sedation point, drug type, dose, route type, Ramsay sedation scale (validated ordinal scale, where 1 is an agitated patient and 6 is an asleep one without response to stimuli), sedation duration, type and treatment of adverse effects, presence of relatives throughout the procedure, and patient satisfaction (aged over 3 years, without cognitive pathology), family present, pediatrician in charge and nurse (yes/no answer to the question: 'Are you satisfied with the sedation and analgesia performed in this procedure?' 5 minutes after the end of the sedative effect). The effectiveness of sedation and analgesia for a procedure was measured according to this satisfaction, considering it effective when it is a positive satisfaction response of at least two of the four subjects. The satisfaction of pediatricians in charge was expressed through the level of sedation achieved according to the Ramsay sedation scale score (at least 2).

A results statistical study was carried out with SPSS software version 15.0.1 (SPSS Inc. Chicago, IL, USA). Quantitative variables were expressed as median and interquartile range (IR) since they did not follow normal distribution. Qualitative variables were expressed in frequencies and percentages. The Chi-square test and Fisher's exact test were used to compare the different variables. For the analysis of the association degree of interpersonal satisfaction, a tetrachoric correlation test was used. The Kruskal-Wallis test was used to analyze the sedation duration according to the drug administered. A $p < 0.05$ value was considered statistically significant.

Table 1. Pharmacological options according to the procedure type

	No pain	Mild pain	Moderate-severe pain
Procedure Type	Diagnostic imaging	Laceration suture, lumbar puncture, abscess drainage, foreign body extraction	Fracture reduction, thoracic drainage, venous line cateheterization, burns
Local anesthesia	Not required	EMLA patch or subcutaneous lidocaine / mepivacaine	EMLA patch or subcutaneous lidocaine / mepivacaine
Types of drugs, routes and doses	Midazolam Intranasal: 0.3-0.5 mg/Kg IV/IM: 0.2-0,3 mg/Kg Oral: 0.5 mg/Kg Buccal: 0.5 mg/Kg	Nitrous Oxide Inhaled: 6-15 lpm	Ketamine IV 1 mg/Kg + Midazolam IV 0.1 mg/Kg (adyuvant) Fentanyl IV: 1-2 mcg/Kg + Midazolam IV: 0.1 mg/Kg (adjuvant)
	Chloral hydrate Oral: 75 mg/Kg Propofol IV: 0.5-1 mg/Kg	Midazolam (adjuvant) Intranasal: 0.3-0.5 mg/Kg IV: 0.2-0.3 mg/Kg Oral: 0.5 mg/Kg Buccal: 0.5 mg/Kg	Fentanyl IV: 1-2 mcg/Kg Propofol IV: 0,5-1 mg/Kg (adjuvant) + Fentanyl IV: 1-2 mcg/Kg

IV: intravenous; IM: intramuscular; lpm: liters per minute.

Results

During the 19 months of study, 279 procedural sedation and analgesia were studied which were administered to 260 patients. The mean age was 5.1 years (SD 4.1), with a median of 4 (IR 2-7). No patient had allergies. According to the ASA classification, 83.9% of patients were previously healthy, 11.5% had a disease without functional limitation, and 4.7% had a limiting disease such as global psychomotor retardation, infantile spasms, bacterial meningitis, or acute pneumonia with pleural effusion. Before the drug administration, all patients had normal temperature, oxygen saturation, and blood pressure, and 5 of them presented hypoventilation and tachycardia related to pneumothorax or pleural effusion. No patient required respiratory or inotropic support or had presented adverse effects in previous sedations. Family members were present in 79.9% of cases.

Table 2 lists the drugs and routes used in each procedure. Up to 15% of the sedations registered in the study did not follow the established protocol, administering in 12 sedations a powerful sedative-analgesic drug (intravenous ketamine and midazolam) for minor painful procedures, and in 31 sedations administering a mild analgesic (nitrous oxide), or a sedative without analgesics (intranasal midazolam) in moderately-severely painful procedures. The most frequent diagnoses and procedures were wound and suture (54.5%), most of them in limbs and face, and closed fracture and reduction (12.2%), located mainly in wrists and arms. Most sedations were performed in the emergency department (ED) (78.9%), followed by the hospital ward (12.2%), the pediatric ICU (8.2%), and Radiology (0.7%). The most commonly used drugs were nitrous oxide (62.7%) and midazolam (16.5%). The most frequently used administration routes were inhalation (62.4%) and intravenous (15.8%), where the mean age of intranasal administration was 2.07 years, i.e., a younger age for intranasal administration compared with the use of other routes, which is not statistically significant ($p = 0.515$).

Table 3 shows the satisfaction of professionals, family members, and patients. Overall satisfaction of the pediatrician in charge (92.5%) and nursing staff (94.3%) was high but significantly lower when using midazolam versus other drugs, and when using the nasal or oral route versus other routes, with no significant differences regarding age, ASA classification, type of diagnosis, type of procedure or sedation area. Family members' satisfaction was 96.8%, with no significant variation when compared with each of the previous variables. Patient satisfaction with the sedation and analgesia strategy could not be assessed in 45.9% of them, due to their younger age. Out of those who were able to assess it (considered from the age of 3 onwards), it was satisfactory by 93.6%, and it was lower when drugs were administered through nasal route. The correlation degree of interpersonal satisfaction (pediatrician, nurse, relatives, and patient) was close to 1, with a 0.95 minimum of correlation between physician and relatives, and a 0.99 maximum between physician and patient, physician and nurse, and patient and nurse, with a p-value lower than 0.002 in all cases.

The overall rate of adverse effects was 3.2% (9 sedations), none of which was serious. The only ones requiring treatment were a case of mild oxygen desaturation after midazolam administration via nasal route, which was normalized after reintubation and oxygen administration through nasal cannula for 2 minutes; and another case of hypotension with no other complication after fentanyl and propofol administration through intravenous route, which was also resolved in a few minutes after increasing in 10ml/Kg of saline solution, with good subsequent evolution in both cases (table 4).

Table 2. Drugs and routes of administration according to the procedure type

	No pain		Mild pain		Moderate-severe pain	
Procedure type	Diagnostic imaging		Laceration suture, lumbar puncture, abscess drainage, foreign body extraction		Fracture reduction, thoracic drainage, venous duct canalization, burns	
Types of drugs, routes and doses	MIDAZOLAM		NITROUS OXIDE		KETAMINE + MIDAZOLAM	
	Intranasal	5	Inhaled	151	Intravenous	14
	Intravenous	2			FENTANYL + MIDAZOLAM	
	Oral	-			Intravenous	7
	Buccal	2	MIDAZOLAM		FENTANYL	
	CHLORAL HIDRATE		Intranasal	15	Intravenosa	8
	Oral	16	Intravenous	2	PROPOFOL + FENTANYL	
	PROPOFOL		Oral	2	Intravenous	1
	Intravenous	-	Buccal	11		

Table 3. Satisfaction percentage according to each variable and comparison of satisfaction among pediatricians, nurses, family and patients

Variable	Group	Pediatrician		Nurse		Family		Patient	
		%*	p	%*	p	%*	p	%*	p
Age	< 2 years	91	0.422	92.9	0.42	97.4	0.514	na	na
	> 2 years	94.3		95.9		95.9		95	
ASA	I	91.5	0.535	93.6	0.864	96.6	1.00	93.7	1.00
	II	96.9		96.9		96.9		100	
	III	100		100		100		100	
Diagnosis	Laceration	90.8	0.44	92.8	0.422	91.1	0.533	90.9	0.635
	Fractures	91.4		97.1		100		100	
	Abscess	100		100		100		100	
	Foreign body	83.3		83.3		91.7		100	
	Pleural effusion / Pneumothorax	94.1		94.1		94.1		100	
	Others	97.9		97.9		97.9		93.8	
Sedation site	Emergency	91.4	0.46	93.6	0.615	96.8	0.469	94	0.691
	Hospitalized	94.1		94.1		94.1		90	
	PICU	100		100		100		100	
	Radiology	100		100		100		100	
Drugs	Nitrous oxide	93.7	0.029	96	0.02	97.1	0.482	94.7	0.425
	Midazolam	78.3		80.4		91.3		82.4	
	Ketamine and midazolam	100		100		100		100	
	Chloral hydrate	100		100		100		100	
	Fentanyl and propofol	100		100		100		100	
	Midazolam and fentanyl	100		100		100		100	
	Others	100		100		100		100	
Administration routes	Inhaled	93.7	0.002	96	0.002	97.1	0.075	94.7	0.044
	Intranasal	80.8		80.8		92.3		60	
	Intravenous	100		100		100		100	
	Oral	95		95		100		100	
	Buccal	83.3		83.3		86.7		85.7	
Procedure	Laceration suture	90.8	0.385	92.8	0.153	96.1	0.182	90.9	0.47
	Fracture reduction	94.1		100		100		100	
	Abscess drainage	100		100		100		100	
	Foreign body extraction	83.3		83.3		91.7		100	
	Lumbar puncture	86.7		86.7		86.7		83.3	
	Thoracic drainage	100		100		100		100	
	Others	97.2		97.2		100		100	
Adverse effects	Yes	66.7	0.002	55.6	0.001	66.7	0.002	50	0.003
	No	97.8		95.6		97.8		95.9	

* Satisfaction percentage. na: not applicable.

Table 4. Adverse effects in relation to the type of drug, the route of administration and the procedure

Drug	Adverse effects n (%)	Route	Procedure	Adverse effect type
Nitrous oxide	3 (1.7)	Inhaled	Laceration suture	Vomiting
		Inhaled	Laceration suture	Vomiting
		Inhaled	Laceration suture	Vomiting
Midazolam	2 (4.3)	Intranasal	Lumbar puncture	Hypoxia
		Oral	Laceration suture	Paradoxical reaction
Ketamine and midazolam	1 (5.3)	Intravenous	Central venous duct canalization	Sialorrhea
Chloral hydrate	0	-	-	-
Fentanyl and propofol	1 (50%)	Intravenous	Bone marrow aspiration	Arterial hypotension
Midazolam and fentanyl	2 (18.2%)	Intravenous	Resonance	Hiccup
		Intravenous	Fracture reduction	Diplopia
Others	0	-	-	-

There were no significant differences in the occurrence of adverse effects regarding age, ASA classification, diagnosis, administered drug, the route used, and type of procedure, or the satisfaction degree of health staff, family members, and patients. There was a higher adverse effects incidence with sedations performed in Radiology (p = 0.007) compared with other areas, and with the administration of midazolam, both isolated and associated with ketamine (p = 0.014) (Table 5).

The overall mean duration of the sedation and analgesia procedures performed was 12.2 minutes, with a 10 minutes median (IR 5-15). Depending on the type of drug (figure 1), the minimum median duration was 10 minutes when using nitrous oxide, midazolam, among others, and the maximum was 32.5 minutes when using a fentanyl-propofol combination, and the differences were statistically significant (p = 0.001) after comparing them with the Kruskal-Wallis test.

Table 5. Emergence of adverse effects comparing the elements of each

Variable	Group	p
Age	≤ 2 years, > 2 years	0.514
ASA	I, II, III	0.185
Diagnosis	Laceration, fracture, abscess, foreign body, pleural effusion / pneumothorax, others	0.323
Sedation site	Emergency, Hospitalized, PICU, Radiology	0.007
Drugs	Nitrous oxide, midazolam, ketamine and midazolam, chloral hydrate, fentanyl and propofol, midazolam and fentanyl, others	0.014
Administration routes	Inhaled, intranasal, intravenous, oral, others	0.079
Procedure	Suture, fracture reduction, abscess drainage, foreign body extraction, Thoracic drainage, others	0.630

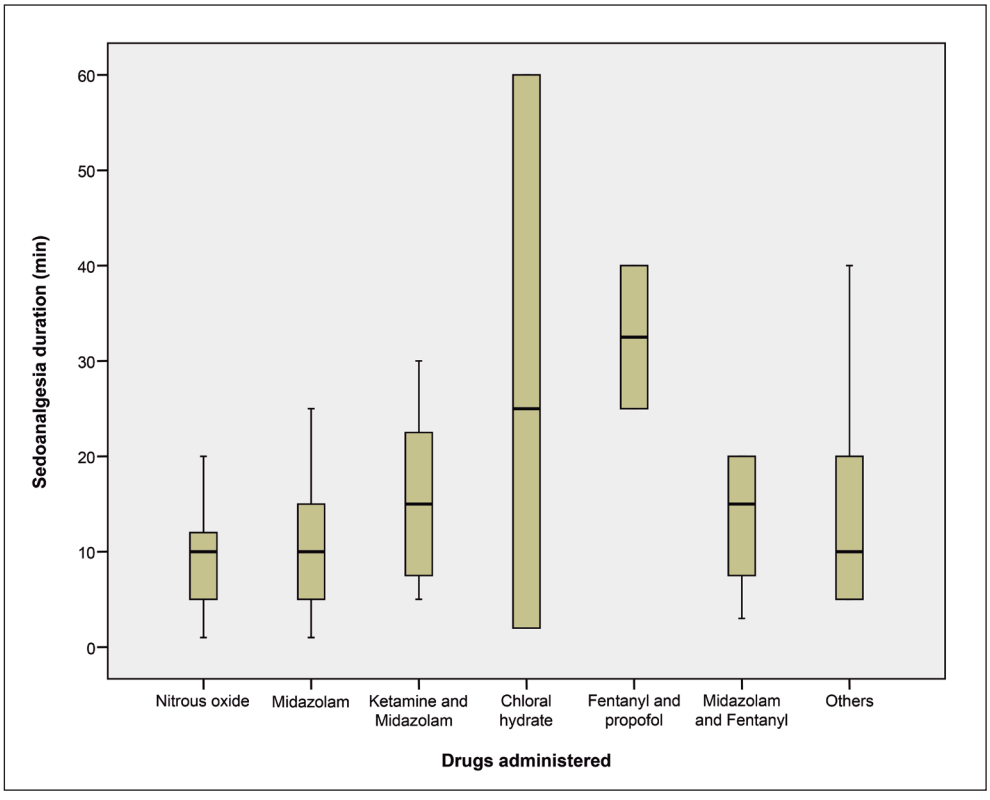

Figure 1. Relationship between type of drug and duration of sedoanalgesia. In rectangular boxes, the longer sides represent the interquartile range, the horizontal line that crosses them shows the median, and the vertical lines (whiskers) represent the total range.

Discussion

Our study shows a high protocol effectiveness of sedation and analgesia for procedures, since it presents a high satisfaction level in pediatricians, nurses, relatives, and patients, and a very high correlation between them, despite the subjectivity degree to which these personal impressions are subject to, which increases the internal validity of this sample.

Satisfaction has been the same with nitrous oxide, ketamine, chloral hydrate, fentanyl, or propofol. However, although other studies have found that nasal administration of midazolam is an effective treatment in sedation and analgesia for procedures in children[8,9], in our study, nasal and oral administration of midazolam was associated with lower health staff satisfaction. This may be because the dose administered may have been insufficient[10] or because the group of patients in whom midazolam was administered via nasal route was younger than the one in which nitrous oxide was administered, as sedation in young children is more difficult than in older children since they have higher levels of anxiety about performing techniques.

One of the factors associated with this high satisfaction is the scarce adverse effects, coinciding with that described in other studies[11,12], where, logically, there is a lower satisfaction when they appear. The presence of relatives during the procedure did not diminish the satisfaction degree of the healthcare personnel.

The safety of the sedation and analgesia strategies performed has been measured according to the rate of adverse effects and their severity, considering as severe effects respiratory depression, hemodynamic alteration with clinical relevance and anaphylactic reaction to drugs. Adverse effects have been few and mild, where vomiting was the most common, unlike other series where hypoxemia is the most common adverse effect (13). A higher rate of adverse effects has been observed in those procedures performed in Radiology as opposed to those performed in the ED, hospital ward, or pediatric ICU. This may be due to that vomiting appeared because of the inhaled administration of nitrous oxide, which represents 1.7% of the patients in whom this drug was administered, a lower incidence than that described in other studies, where it reaches up to 4-8%[14]. Close monitoring of patients before and during the procedure reduces the risk of adverse effects[2].

The duration of sedation and analgesia performed was significantly longer when the fentanyl-propofol combination was administered intravenously than other drugs, surely because the optimal sedation time with propofol is reached gradually, and fentanyl is a potent sedative with a longer recovery time, even so, this combination is highly effective and we believe it is a good alternative when the procedure is going to be long and painful, as in the central venous catheter placement. The duration of sedation with chloral hydrate does not differ significantly regarding other drugs, however, there is a very long time of sedation, probably because of the more erratic and unpredictable absorption when it is administered orally.

Our study has several limitations. Despite that several clinical sessions were held in the pediatric service in order to achieve correct awareness and learning in the use of the protocol drugs for sedation and analgesia, in some cases, the drug choice recommendations as established in the protocol were not followed. This may be due to the difficulty that appears whenever new work routines are introduced in a pediatric service, as reported by other authors[15]. On the one hand, only 45.9% of the patients were able to answer the question related to satisfaction due to their young age or cognitive capacity, which explains why satisfaction in this group is less measurable. On the other hand, the changes in satisfaction and adverse effects over time have not been analyzed which may occur with the protocol development and experience with these sedation and analgesia strategies, as has been pointed out in some studies[16].

In conclusion, the implementation of a specific sedation and analgesia protocol for pediatric procedures in the hospital setting allows, by a good prior evaluation, the selection of low-risk patients to administer sedative drugs, which minimizes the number of adverse effects, and through continuous monitoring, the early detection of these adverse effects. Also, in addition to the selection of a proper drug, a high effectiveness degree is achieved in relation to the satisfaction degree of health professionals, relatives, and patients.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

Financial Disclosure

Authors state that no economic support has been associated with the present study.

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