



ORIGINAL ARTICLE

Pre-anaesthetic medication with intranasal dexmedetomidine and oral midazolam as an anxiolytic. A clinical trial[☆]



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KEYWORDS

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Abstract

Introduction: Dexmedetomidine is a pharmacological option for sedation in children. In this study, the efficacy of intranasal dexmedetomidine to reduce preoperative anxiety in paediatric patients is compared with that of oral midazolam.

Materials and methods: A prospective, randomized, double-blind, controlled trial was conducted on children 2–12 years of age, randomly assigned to one of the following two groups: group A received premedication with oral midazolam and intranasal placebo, group B received intranasal dexmedetomidine and oral placebo. Anxiety was assessed with the modified Yale scale, and a risk analysis and number needed to treat was performed.

Results: A total of 108 patients were included, 52 (48.1%) treated with dexmedetomidine, and 56 (51.9%) with midazolam. Anxiety was less frequent in the dexmedetomidine group at 60 min ($P = .001$), induction ($P = .04$), and recovery ($P = .0001$). Risk analysis showed that dexmedetomidine reduced the risk of anxiety by 28% (RAR = 0.28, 95% CI: 0.12–0.43) and to prevent one case of anxiety, four patients need to be treated with intranasal dexmedetomidine (NNT = 4, 95% CI: 3–9). Changes in heart rate, mean arterial pressure, and oxygen saturation were statistically significant in the dexmedetomidine group, with no clinical consequences. There were no cases of bradycardia, hypotension or oxygen desaturation.

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PALABRAS CLAVE

Ansiedad;
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Conclusiones: Intranasal dexmedetomidine premedication is more effective than oral midazolam to reduce preoperative anxiety in paediatric patients.

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Medicación preanestésica con dexmedetomidina intranasal y midazolam oral como ansiolítico. Un ensayo clínico

Resumen

Introducción: La dexmedetomidina es una opción farmacológica en la sedación del paciente pediátrico. En este estudio, se compara la eficacia de la dexmedetomidina intranasal versus midazolam por vía oral para disminuir la ansiedad preoperatoria en pacientes pediátricos.

Material y métodos: Se realizó un ensayo clínico, doble ciego, en niños de 2 a 12 años de edad, asignados aleatoriamente a uno de los siguientes dos grupos: a) recibió medicación preanestésica con midazolam por vía oral y placebo intranasal; b) recibió dexmedetomidina intranasal y placebo por vía oral. Se evaluó la ansiedad con la escala de Yale modificada y realizamos el análisis de reducción de riesgo y un número necesario a tratar.

Resultados: Se estudió a 108 pacientes, 52 (48,1%) tratados con dexmedetomidina y 56 (51,9%) con midazolam. La ansiedad fue menos frecuente en el grupo de dexmedetomidina a los 60 min ($p=0,001$), en la inducción ($p=0,04$) y en la recuperación ($p=0,0001$). El análisis de riesgo mostró que la dexmedetomidina redujo el riesgo de ansiedad en un 28% (RAR = 0,28, IC del 95%, 0,12 a 0,43) y que para prevenir un caso de ansiedad es necesario tratar con dexmedetomidina intranasal a 4 pacientes (NNT = 4, IC del 95%, 3 a 9). En el grupo de dexmedetomidina se registraron cambios estadísticamente significativos en la frecuencia cardiaca, la presión arterial media y la saturación de oxígeno, sin repercusión clínica; no se registraron casos de bradicardia, hipotensión ni desaturación de oxígeno.

Conclusiones: La premedicación con dexmedetomidina intranasal es más eficaz que el midazolam por vía oral para disminuir la ansiedad preoperatoria en pacientes pediátricos.

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Introduction

In a surgical procedure, the high anxiety levels that children experience during the preoperative period may be associated to negative medical, psychological, and social consequences. To reduce the distress of children and to facilitate the induction of anaesthesia, the child is given a sedative before going into the operating room.

The main goals of premedication in children are to facilitate a smooth separation from the parents and ease the induction of anaesthesia. Other effects that can be achieved with the pharmacological preparation of the patient are: amnesia, anxiolysis, prevention of psychological stress, and a reduction in the total anaesthetic requirements. The groups of patients that benefit most from premedication are toddlers and preschoolers, in whom separation anxiety is paramount; and also adolescents, who are sensitive about their body image and loss of control, patients with previous unpleasant hospital experiences, and patients who are unable to communicate or cooperate.¹

Midazolam is the premedication most frequently used in children.² It has been demonstrated that midazolam administered orally at 0.5 mg/kg is efficacious in reducing anxiety and improving the conditions for induction of anaesthesia, but it has been associated with adverse effects such

as agitation, paradoxical reaction, and negative postoperative behaviour changes.³ For this reason, other drugs and delivery routes are being explored. One of those drugs is dexmedetomidine.

Dexmedetomidine is a highly specific α_2 -adrenergic receptor agonist with sedative, anxiolytic, and analgesic properties, and a considerable sympatholytic effect. Its bioavailability when administered via the buccal route is 81.8%.⁴ In 1999 dexmedetomidine was approved in the United States by the Food and Drug Administration to be used in human patients as a short-term (<24 h) sedative and analgesic in intensive care units.⁵ In healthy volunteers, intravenous dexmedetomidine has an action onset of 15 min; it can also have systemic effects when administered by the transdermal, buccal, or intramuscular routes, with the latter two routes having showed bioavailabilities of 82% and 104%, respectively.⁶

It has been shown that in adult patients, intranasal administration of 1–1.5 $\mu\text{g}/\text{kg}$ of dexmedetomidine produces sedation within 45–60 min, and has its peak effect at 90–105 min. This is accompanied by mild to moderate changes in heart rate and arterial blood pressure.⁷

Recent studies in paediatric patients have shown that intranasal dexmedetomidine produces more sedation than oral midazolam.⁸ It has been used successfully in diagnostic

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