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# Pain during injections of botulinum toxin in children: Influence of the localization technique

## *Douleur lors des injections de toxine botulique chez l'enfant : influence de la technique de repérage*

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**Abstract**

*Objective.* – In this study, we consider two localization techniques used in injections of botulinium toxin in children: electrical stimulation and ultrasound. The hypothesis of this work was that injections performed without stimulation would be less painful.
*Patients and methods.* – Monocentric prospective study, with 107 sessions of lower limb injections. Two groups of children were compared: localization by ultrasound only (60 children), detection by stimulation only or by stimulation combined with ultrasound (47 children). Pain assessment was performed by the child or an accompanying party using the Visual Analog Scale (VAS) and by a health care team using the Face, Legs, Activity, Cry, Consolability (FLACC).
*Results.* – A significant difference between the two groups was found in both self-report and by means of the behavioral observational pain scale. Indeed, VAS average and FLACC average were significantly higher with detection by stimulation than with ultrasound alone: 4.5 cm $\pm$ 2.54 versus 2.7 cm $\pm$ 2.27; $P < 0.001$ for VAS scale and 3.7 $\pm$ 2.1 versus 2.7 $\pm$ 2.3; $P < 0.05$ for FLACC scale.
*Conclusion.* – When compared to ultrasound detection, localization by electrostimulation appears to increase the overall pain caused during injections of botulinum toxin in children.


*Keywords:* Botulinum toxin; Pain; Children; Localization technique; Ultrasound

**Résumé**

*Introduction.* – L'objectif de cette étude était d'évaluer la douleur lors des injections de toxine botulique chez l'enfant en fonction de la technique de repérage utilisée. L'hypothèse était qu'en l'absence d'électrostimulation, le geste était moins douloureux.
*Patients et méthodes.* – Étude prospective monocentrique, portant sur 107 séances d'injections des membres inférieurs. Deux groupes de patients ont été comparés : repérage par échographie seule (60 enfants) et repérage par stimulation seule ou stimulation associée à l'échographie (47 enfants). L'évaluation de la douleur a été effectuée avec l'échelle visuelle analogique (EVA) par l'enfant ou son entourage et avec la Face, Legs, Activity, Cry, Consolability (FLACC) par l'équipe soignante.
*Résultats.* – Il existait une différence significative entre les groupes que ce soit pour l'échelle d'auto- ou d'hétéro-évaluation. En effet, l'EVA moyenne et la FLACC moyenne étaient significativement plus élevées dans le groupe électrostimulation que dans le groupe échographie seule : 4,5 cm $\pm$ 2,54 versus 2,7 cm $\pm$ 2,27 ; $p < 0{,}001$ pour l'EVA et 3,7 $\pm$ 2,1 versus 2,7 $\pm$ 2,3 ; $p < 0{,}05$ pour la FLACC.

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*Conclusion.* – Le repérage par électrostimulation semble augmenter la douleur globale du geste par rapport à l'utilisation de l'échographie.


*Mots clés :* Toxine botulique ; Douleur ; Enfants ; Repérage ; Échographie

## 1. English version

### 1.1. Introduction

Botulinum toxin is a treatment of spasticity that has been more and more widely used over the past twenty years. Since 2009 in France, it has become an indicated symptomatic treatment of spasticity of the upper and/or lower limbs in children aged more than 2 years [1]. Scientific proof of its effectiveness in reducing localized spasticity has been provided repeatedly [2,3] in terms of improved active function of the upper and lower limbs (level of evidence 2) and as a means of attenuating the painful implications of spasticity (level of evidence 2) [3]. As a result, botulinum toxin is now the standard treatment for children with cerebral palsy [4]. Unfortunately, intramuscular injections are at times painful and consequently difficult to carry out in children.

Accurate targeting of a spastic muscle requires localization prior to product injection. Several localization techniques can be applied. More often than not in France, as counseled in official recommendations (Accord Professionnel) [3], localization is carried out by electrical stimulation [5], which is nonetheless at once painful and possibly time-consuming [6]. As an alternative, localization by ultrasound has been developing over the last few years. Recent studies have shown its interest as concerns the intramuscular injections performed in treatment of spasticity in children. One of the advantages of localization by ultrasound consists of its rapidity [7]. Moreover, a study by Py et al. [8] shows that in comparison with anatomical localization, ultrasound techniques produces more significant improvement from an analytical as well as a functional standpoint. By the same token, clinical experience has shown that localization by ultrasound appears less painful than localization by electrostimulation. However, scarcely any studies have objectified this clinical fact, and we have found no published work comparing the different localization techniques in terms of the pain they may cause. Our hypothesis is that when electrostimulation is not applied, intramuscular injection is perceived as less painful. The objective of this study has consequently consisted of assessing the levels of pain occasioned by injections of botulinum toxin in children according to the localization technique employed, namely electrostimulation or ultrasound.

### 1.2. Material and methods

#### 1.2.1. Patients

This is an open monocentric prospective study covering the period from May 2011 to October 2012. The inclusion criteria were: any child less than 18 years of age undergoing a botulinum toxin injection as treatment for spasticity of the lower limbs. The exclusion criteria were: more than 18 years of age, anatomical localization, insufficient data, injection at the level of the upper limbs.

We only included injections carried out on the lower limbs; injections carried out on the upper limbs were excluded so as to obtain localization of targeted muscles presenting as much homogeneity as possible and thereby avoid introducing a bias through which muscle localization would depend on perception of the injection as painful.

For each child treated, an assessment sheet was filled out. The recorded data included: mode of pain assessment (self-evaluation or hetero-evaluation) and demography, as well as the localization technique applied, the type of toxin used, the concentration, the total dose, the number of muscles, the number of injection sites, and the methods of distraction and premedication.

The localization technique was chosen independently of clinical context according to the availability of the ultrasound apparatus on the day of injection.

The ethics committee of the Angers university hospital gave its approval to this observational study.

#### 1.2.2. Course of a session

Local analgesia with EMLA® cream, a mixture of lidocaine and prilocaine, was systematically applied at the sites of the planned injections, not less than 40 minutes before the latter were carried out. Analgesia by an equimolar mix of oxygen and nitrous oxide was conjointly applied, initially at a rate of 9 L/min, and secondarily at a rate adjusted according to the respiratory volume of the child. The injection was started subsequent to at least 3 minutes of inhalation aimed at achieving optimal sedation.

Antalgic medication by paracetamol at a dose of 15 mg/kg could accompany the above-mentioned analgesia prior to the injection, as could anxiolytic treatment by hydroxyzine at a dose of 0.5 mg/kg or of midazolam at a dose of 0.3 mg/kg. Use of these means of treatment was decided upon according to the age of the child and the degree to which the physician was familiar with him or her. The different medical procedures, methods of distraction and therapeutic drugs were all indicated in the patient's medical records.

#### 1.2.3. Techniques of injection and localization

Injections were performed by an experienced injector accustomed to applying the two localization techniques. The products used were the botulinum toxin Dysport® (Ipsen Ltd) or Botox® (Allergan Inc.). The doses administered were generally 20 units Allergan®(UA)/kg for Botox® and 30 units Speywood (US)/kg for Dysport®.