

## THE EFFECT OF BOTULINUM TOXIN IN THE TREATMENT OF INCONTINENCE IN CHILDREN AND ADOLESCENTS WITH MYELOMENINGOCELE AND NEUROGENIC BLADDER DYSFUNCTION

Botulinumtoxin injections in the bladder wall is an established treatment for both adults and children with overactive bladder and incontinence. The effect is expected to be 1/2 - 1 year and treatment can be repeated as needed.

### Hypothesis / aims of study

The aim of the study was to examine the effect of botulinumtoxin in the treatment of urinary incontinence in children and adolescents with neurogenic bladder dysfunction.

### Study design, materials and methods

Eighteen children/young people, all but one with myelomeningocele, 10 boys and 8 girls (8 - 20 years, md10.8), have been treated of which 6 had a second treatment and 2 had 3 treatments. All participants had neurogenic bladder dysfunction and fulfilled the criteria for participation: overactive bladder, incontinence and to use clean intermittent catheterisation (CIC) for bladder emptying. All but 4 were treated with anticholinergics prior to treatment. Botulinumtoxin (Botox®) was injected into the bladder wall via cystoscopy under general anaesthesia or analgesia. Evaluation was performed by cystometry and micturition/CIC-charts (frequency, volume, leakage during 3 days) before, at 3 months and 1 year after start of treatment. Questionnaire about current bladder and bowel function and psychosocial influences were answered before and at 3 months after start.

### Results

At 3 months follow-up there was a significant increase in bladder volume (p 0.03) and decrease in bladder pressure (p 0.004). After treatments the bladder volume was larger before leakage occurred (p 0.03). Children and parents rated the incontinence from 0 (no leakage) to 5 (wet, almost every day). After 28 treatments decreased leakage was reported (p 0.003), where 46% reported from 0-1 which means dry or almost dry. An additional individual was dry using anticholinergic drugs before treatment with Botox® and remained so after even without medication. The effect of treatment was 5.4 months (m) measured from when anticholinergics were reinserted, alternatively when leakage increased again. Four young people had a good effect in 12 months or longer. No side effects were noted.

### Interpretation of results

Botulinumtoxin given intramurally in the detrusor wall has effect on detrusor overactivity, bladder volume, detrusor pressure and incontinence but the effect is transient. For most children the leakages decreased but only a few became completely continent. One explanation could be that the majority of children in the study had overactive bladder in combination with a weak/non functioning urethra sphincter while botulinumtoxin is expected to have effect mainly on the detrusor overactivity.

### Concluding message

Botulinumtoxin has effect on incontinence in children and adolescents with myelomeningocele and neurogenic bladder dysfunction but the effect is relatively short-lived. No side effects reported.

<b>Specify source of funding or grant</b>	<b>None</b>
<b>Is this a clinical trial?</b>	<b>Yes</b>
<b>Is this study registered in a public clinical trials registry?</b>	<b>No</b>
<b>Is this a Randomised Controlled Trial (RCT)?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>The Regional Ethical Committee at Linköping University</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>