Focus Cerebralparese
l. Interdisziplinärer Kongress
Neuropädiatrie
Sozialpädiatrie
Kinderorthopädie
18.-20.06.200 in Freiburg
Störungen der Mundmotorik
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Autoren	Titel	Journal	Ort
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Is injection of botulinum toxin type A effective in the treatment of drooling in children with cerebral palsy? = http://www.bestbets.org/bets/bet.php?id=1303

Report By: L Vaile, F Finlay, - *Specialist Registrars in Paediatrics.* Institution: Community Child Health, NHS House, Newbridge Hill, Bath. Last Modified: 29th September 2006

Relevant Paper(s)

Author, date and country	Patient group	Study type (level of evidence)	Outcomes	Key results	Study Weaknesses
Jongerius et al, 2001	3 children (11–13 years) CP and severe drooling Treatment with single dose BTX-A into submandibular glands. Total dosage: 40 u if 15–25 kg 50 u if >25 kg	Case series.	Saliva secretion Quality of life questionnaire	Maximal salivary flow rate of sublingual and submandibular glands reduced by 51–63%	16 week study period: 1 child did not drool, the 2nd had reduced drooling, the 3rd had decreased drooling initially but not sustained Conclusion: duration of effect variable
Jongerius et al 2004(1)	45 children (3–18 years) CP and severe drooling Treatment with scopolamine patches, then with BTX-A into submandibular glands. Total dosage: 30 u if <15 kg 40 u if 15–25 kg 50 u if >25 kg	Controlled, open label, clinical trial.	Saliva secretion (measured by DQ drooling quotient, TDS teacher drooling scale and VAS visual analogue scale)	DQ: 53% responded to scopolamine and 64% responded to BTX-A at 2 weeks and 49% at 24 weeks TDS: 61.5% good responders 8 weeks post BTX-A and 36% at 24 weeks VA: reduced drooling throughout study	71% patients experienced moderate–severe side effects with scopolamine With BTX-A only non-severe side effects
Jongerius et al, 2004(2)	45 children (3–18 years) CP and severe drooling Treatment with scopolamine patches, then with BTX-A into submandibular glands. Total dosage: 30 u if <15 kg 40 u if 15–25 kg 50 u if > 25 kg	Controlled, open label, clinical trial.	Salivary flow rate	Submandibular flow rate decreased 25% with scopolamine and 42% 2 weeks after BTX-A Significant reduction with BTX-A compared with scopolamine at 4 and 8 weeks but between 8	Although BTX-A resulted in a greater reduction to submandibular flow than scopolamine overall 95% responded to scopolamine with significantly lower response rates to BTX-

Author, date and country	Patient group	Study type (level of evidence)	Outcomes	Key results	Study Weaknesses
				and 16 weeks significance disappeared	A (varying from 69% at 2 weeks to 49% at 24 weeks)
Bothwell et al, 2002	9 children (4–17 years) severe drooling and moderate or severe retardation (6 had CP) Single injection of BTX-A 10 u divided between parotid glands	Case series.	Saliva secretion (measured using dental bibs and DQ) Caregiver rating scales	For saliva secretion 33% good responders, 22% moderate responders, 11% poor responders and 33% non-responders 55% of parents thought improvement at 4 weeks and 22% at 16 weeks	16 week study period. BTX-A not as successful compared with other therapies e.g. surgery, anticholinergic therapy
Suskind et al, 2002	22 subjects (8–21 years) CP and significant drooling 2 groups: Group 1 (12 subjects): injection of 10, 20 or 30 u in escalating doses into submandibular glands Group 2 (10 subjects) injection of 30 u into submandibular glands and 20, 30 or 40 u into the parotid glands	Prospective, open label, dose escalation study.	Saliva secretion (measured using dental roll weights, DQ) Quality of life questionnaire Evaluation of swallowing	Submandibular gland only 33% response Submandibular and parotid glands 80% response from caretaker evaluation No adverse effects on swallowing	Varying length of response Results difficult to interpret as recycling of patients within groups and no comment on optimum dosage within groups
Savarese et al, 2004	21 patients (5–18 years) with CP and problematic drooling 15 u BTX-A into each parotid gland	Open label, non blinded, prospective study.	Saliva secretion (measured using VAS, number of bibs used/day, weight of dental rolls)	53% marked improvement in drooling, 21% moderate improvement, 15% slight improvement, 11% no response	79% parents said they would have their child undergo treatment again

Comment(s)

Drooling is a significant problem in many children with cerebral palsy. In addition to the physical effects, drooling causes psychosocial morbidity by detracting from physical appearance and inhibiting others initiating close contact. The management of drooling may be problematic as **anticholinergic drugs cause significant side** effects, surgical treatments have associated complications, and behavioural modification techniques have limited use in children with moderate or severe cognitive problems. Recently botulinum toxin A has emerged as a potential treatment for the management of drooling. Botulinum toxin A blocks the neuromuscular junction by inhibiting the release of presynaptic acetylcholine and this prevents the secretion of saliva. The first trial results, published in 2000 (Pal) in adults with Parkinson's disease showed botulinum toxin to be an effective treatment for drooling; subsequently trials have looked at its use in the management of children with cerebral palsy. Studies involved injection into the submandibular glands, the parotid glands, or both. The **submandibular glands produce 60–70% of secreted saliva when not eating** or drinking. Outcome measures in the studies were either a reduction in saliva secretion or an improvement in quality of life for the child as a consequence of reduced drooling. In the study by Jongerius et al, 2004 injection into the **submandibular** glands resulted in 64% of children showing a response at 2 weeks, decreasing to 49% at week 24. The **parotid** glands are more superficial and therefore easier to inject under local anaesthetic; and Savarese et al found that 53% patients showed a marked response to injection. Suskind and Tilton found that treatment was most effective (80%) when **both the submandibular and parotid** glands were injected. Studies used different doses of botulinum toxin A with differing response rates. Bothwell et al used the lowest dose (10 units divided between parotid glands); 3 of 9 children were described as "good responders". Savarese et al injected 15 units into each parotid gland; 53% of children showed a "marked improvement in drooling". Higher

doses were used in the studies by Jongerius et al; a 51–63% reduction in maximal salivary flow rate was achieved in the 2001 study, although the paper does not state whether this reduction in flow rate led to clinical benefit. The studies therefore suggest that the effect of **botulinum toxin A may be dose related**, with 50 units being the maximum dose used in the study patients. The duration of effect of botulinum toxin A was variable between individuals and between studies and varied according to the outcome measurement. Savarese et al showed a sustained significant reduction in severity, frequency of drooling, and number of bibs used for 2 months but no significant difference by 3 months. Jongerius et al, 2004 found that 48% of patients continued to have a clinical response to botulinum toxin A, using the drooling quotient, at 24 weeks, which was the duration of the study. The length of follow up in these studies may have been too short to determine the true duration of effect of treatment in some patients. Jongerius et al found that 40% patients experienced severe **side effects with scopolamine**. No significant side effects were reported following administration of botulinum toxin A in this or other studies, although minor effects such as **local swelling, chewing difficulties, dry mouth, and transient weakness of mouth closure** have previously been reported. Injection of botulinum toxin A is an invasive procedure and may require a general anaesthetic or sedation in children, depending on their anticipated ability to tolerate the procedure. It is generally performed by oral surgeons who may locate the glands by palpation, but other trained professionals may administer the injections under ultrasound localisation.

Clinical Bottom Line

Intrasalivary gland injection of botulinum toxin A shows benefit beyond scopolamine patches in many children with cerebral palsy and drooling in non-randomised studies. (Grade C) General anaesthesia may be required to administer botulinum toxin A; its effects are time limited. (Grade C)