Evaluation & management of drooling; assessment tools, application of botulinum toxin

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이지인

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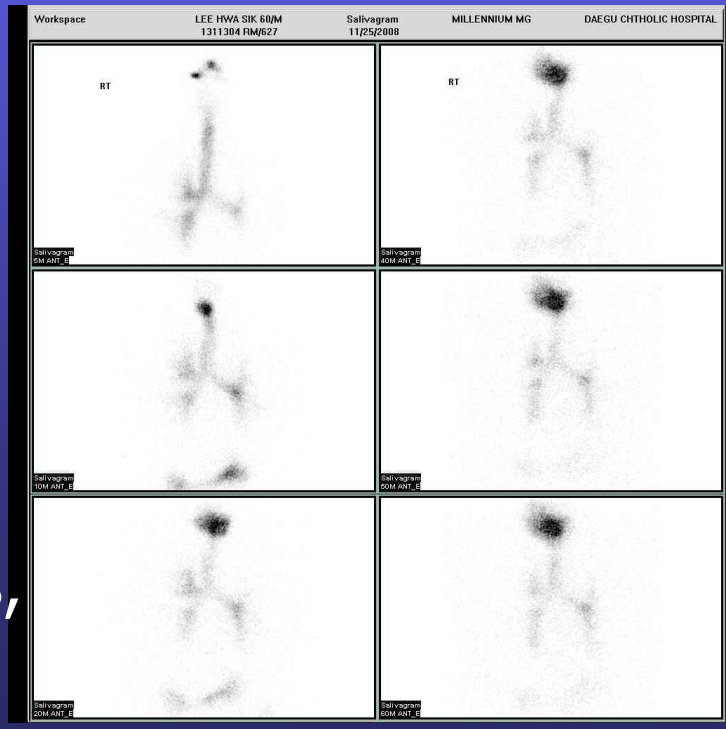
Case. 지 0 섭(M/11)

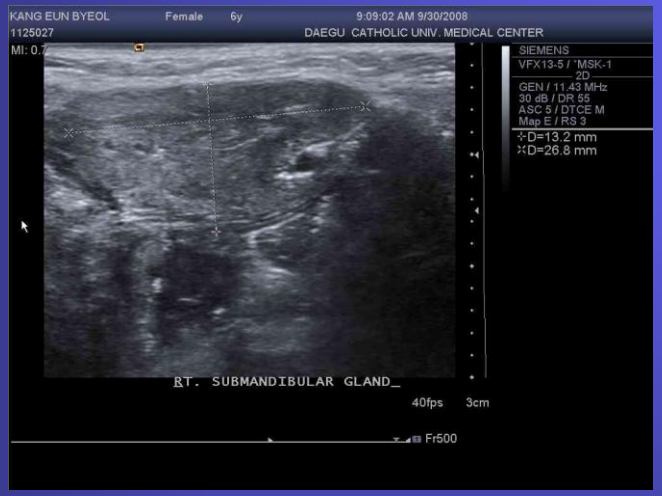
Cerebral palsy, Spastic Quadriplegia(GMFCS level V)
2004년 : PEG, tracheostomy
R/O aspiration pneumonia 입원
: 2004년 3회, 2005년 1회, 2006년 3회, 2007년 1회, 2008년 4회

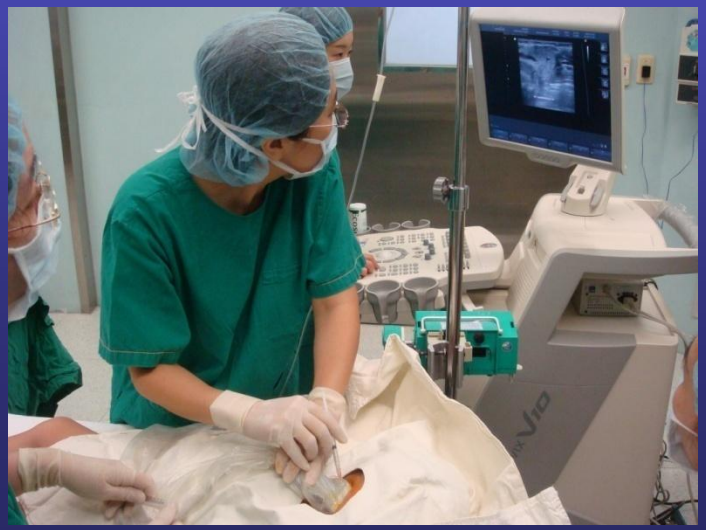
2008년 11월
Teacher drooling scale : grade 5/5
(grade5: constant drooling, always wet)
Drooling frequency and severity scale
(DSS grade 5/5; profuse drooling off the
body and onto objects;furniture,books,
DFS grade 4/4; constant drooling)



Sialogram (+)

⇒ Botulinum toxin A (one unit/kg/gland) injection
into bilateral parotid gl. and bilateral submandibular gl.
under the ultrasound- and EMG-guidance & conscious sedation





시술날짜	몸무게 (kg)	drooling 정도	시술부위	BoTN-A	용량
2010.07.07	10	TDS 4/5, PDS 4/4 DSS 5/5, DFS 4/4	both parotid(P) and submandibular(S) glands	dysport	117U(29.4x4)
2010.11.03	10	TDS 4/5, PDS 1/4 DSS 5/5, DFS 4/4	both P & S glands	dysport	117U(29.4x4)
2011.10.19	14	-	both P & S glands	meditoxin	60U(15x4)
2012.05.30	14	-	both P & S glands	meditoxin	70U(15x2,20x2)
2012.10.25	14	TDS 5/5, PDS 2/4 DSS 5/5, DFS 4/4	both P & S glands	dysport	205.8U (58.8x2, 44.1x2)
2013.04.04	14	TDS 5/5, PDS 2/4 DSS 5/5, DFS 4/4	both P & S glands	dysport	205.8U (58.8x2, 44.1x2)
2013.09.05	14	TDS 5/5, PDS 2/4 DSS 5/5, DFS 4/4	both P & S glands	dysport	205.8U (58.8x2, 44.1x2)
2014.02.26	14	TDS 5/5, PDS 2/4 DSS 5/5, DFS 4/4	both P & S glands	dysport	205.8U (58.8x2, 44.1x2)

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Posterior Drooling/Aspiration Scale (PDAS) :

0: no coughing and/or choking,
1: coughing and/or choking at night or on supine position without aspiration pneumonia history
2: coughing and/or chocking at any time regardless position without aspiration pneumonia history
3: one aspiration pneumonia history in the past 12 mo.
4: more than one aspiration pneumonia in the past 12 mo

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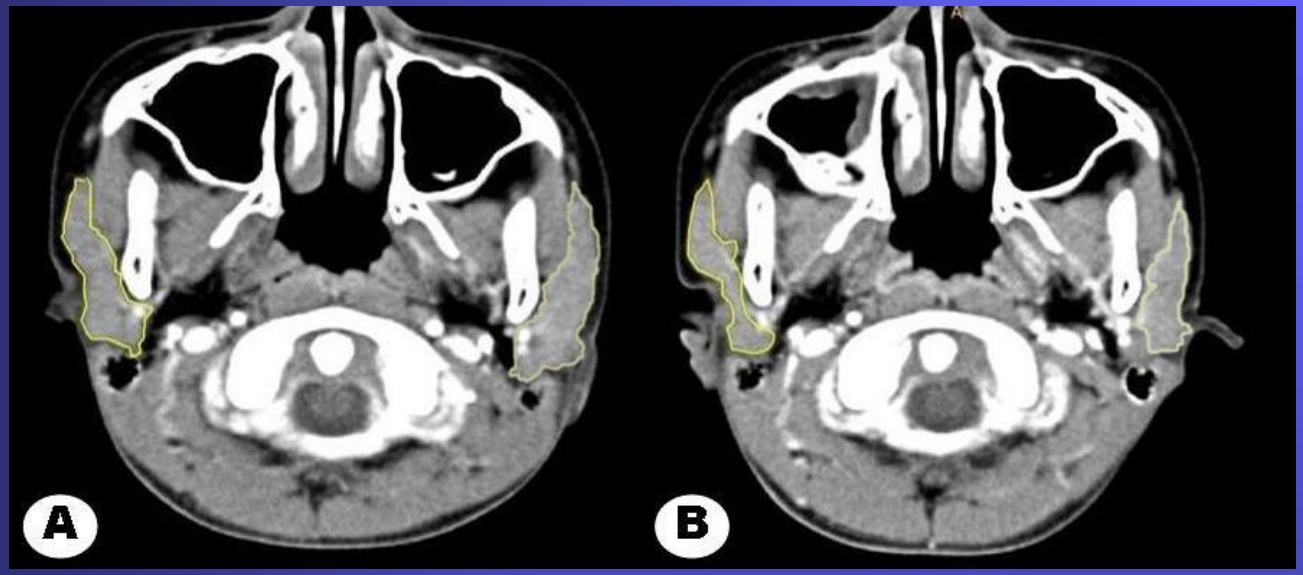
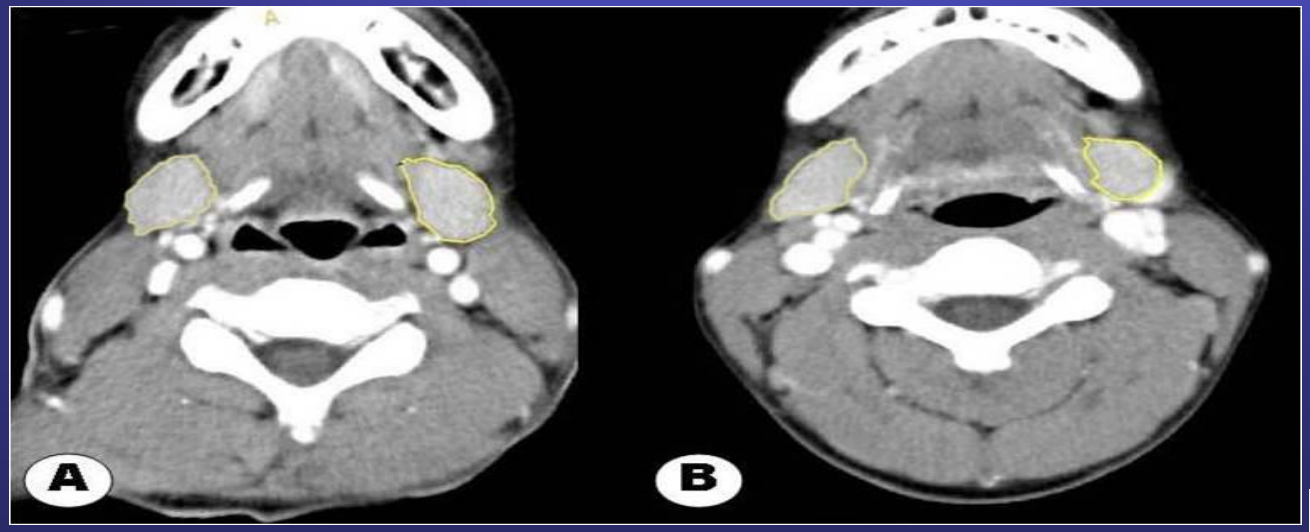
Outlines of salivary glands were drawn with yellow lines on this CT.
A. Before injection B. 3 weeks after injection





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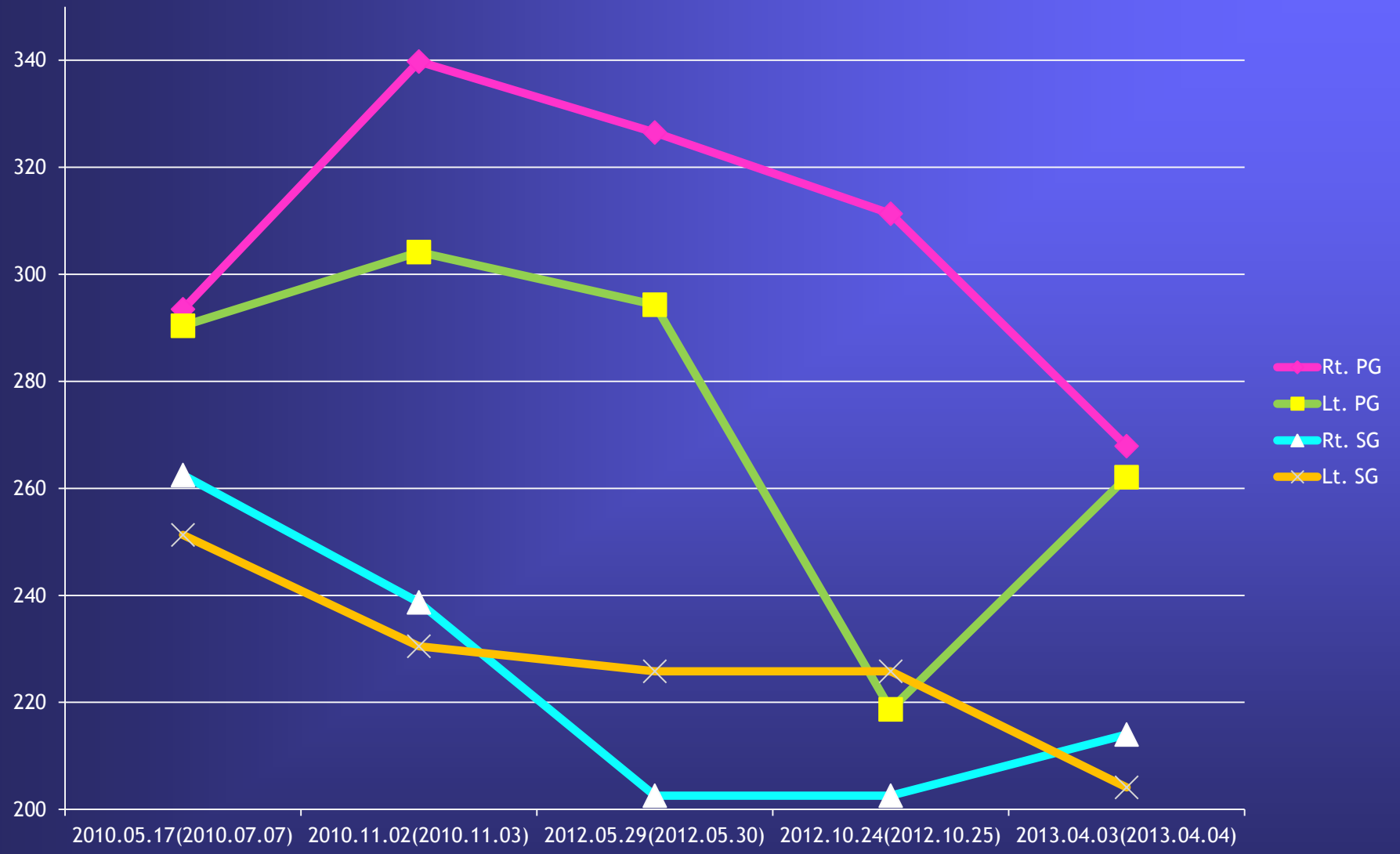

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- Overview of drooling
- Evaluation of drooling
  - assessment tools
- Management of drooling
  - application of botulinum toxin

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Definition

- Poling(1978): a visually evident presence of excessive saliva
- Lanconi(1989): saliva outside the lower lip
- Brodsky(1993): spilling of saliva from the mouth onto the lips, chin, neck and clothing
- Kay(2006): pools of saliva greater than one inch diameter
- Van der Burg(2009): saliva(either a drop or a string) present beneath the lower lip line or a string falling from the mouth for a period longer than two seconds without the individual leaning face and/or clothes

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Blasco 1992; Reddihough 2010

1) Anterior drooling
: the unintentional loss of saliva from the mouth

2) Posterior drooling
: saliva spilled over the tongue through the faucial isthmus

- normal phenomenon in children before the development of oral neuromuscular control at 18-24 months of age
  cf) pathological : drooling after age 4 years

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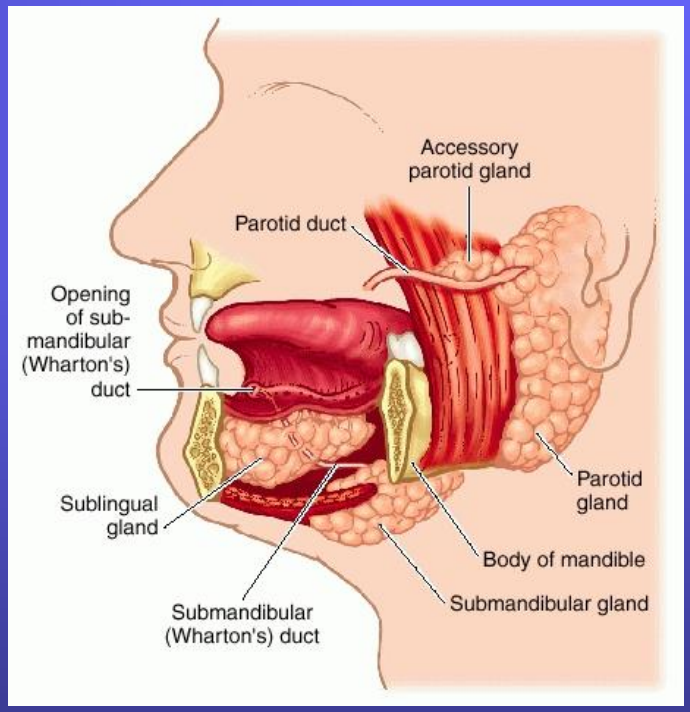
Salivary glands

- 3 major pairs of glands
  - Parotid
  - Submandibular
  - Sublingual

- several hundred minor glands located in upper aerodigestive tract (lips, cheeks, tongue et al.)



- Flow without stimulation: submandibular 65% parotid 23% sublingual 4%, others 8%
- Flow with stimulation: parotid 69% submandibular 26% sublingual 5%

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Microanatomy of the salivary gland

1. Secretory unit
   Acinus,
   Myoepithelial cells,
   Duct

2. Acini
   Parotid - purely serous(amylase)
   Submandibular - mixed but
   predominantly serous
   Sublingual - mixed but
   predominantly mucous(mucin)

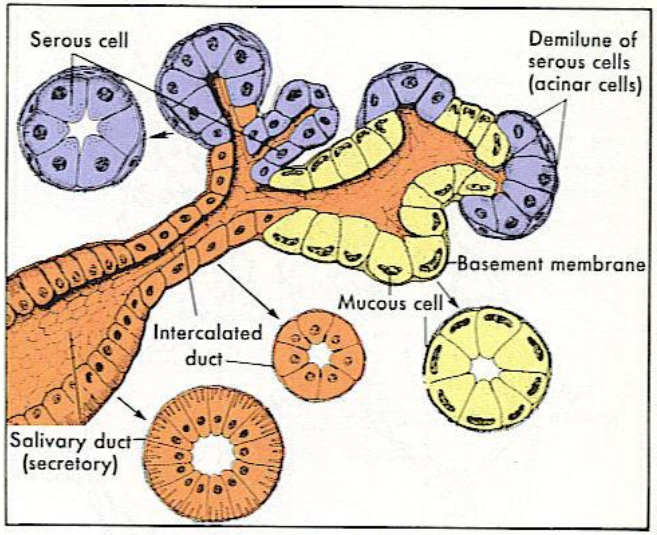

FIGURE 30-3 The structure of the human submandibular gland, as seen with the light microscope. (Redrawn from Braus H: Anatomie des Menschen, Berlin, 1934, Julius Springer.)

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Salivary secretion

- Both the sympathetic and parasympathetic systems play a role in the stimulation of salivary secretion.
  - Parasympathetic system directly stimulates submandibular, parotid and sublingual glands
  cf) Sympathetic system stimulates contraction of muscle fibres around salivary ducts.

- Normal amounts:
  adults: about 1 L/day (1cc/min)
  children: about 0.5-0.6 L/day (0.5 cc/min)

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- Drooling in children with cerebral palsy

1) secondary not to excessive production of saliva(sialorrhea)
but is the result of pooling of saliva

2) because of neurologic impairment such as spasticity
of the oropharyngeal and esophageal musculature
as well as oral sensory dysfunction and poor head control

3) G-E reflux in children with CP
: increase of salivary flow rate
-> exacerbate anterior and posterior drooling
cf) In healthy subjects, exposure of the distal esophagus to acid
-> result in an immediate increase of saliva secretion
-> the swallowed saliva play a role in the defense of
esophageal mucosa to acid-induced injury

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Assessment of drooling

- Severity and impact of drooling

1) Subjective scales : completed by patients or caregivers
   - Drooling rating scale
   - Drooling frequency and severity scale
   - Visual analogue scale
   - Drooling impact scale
   - Global impression of change

2) Objective measures
   - Salivary flow measures; weight of dental rolls
   - Direct observations of saliva loss; counts of saliva drops
   - Bibs(or tissues) used

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Teacher drooling scale

- Rate anterior drooling on a 5-point scale

Grade 1: No drooling
Grade 2: Infrequent drooling, small amount
Grade 3: Occasional drooling, intermittent all day
Grade 4: Frequent drooling, but not profuse
Grade 5: Constant drooling, always wet

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Drooling Frequency and Severity Scale

- Drooling Severity Scale
  - 1= Never drools, dry
  - 2= Mild drooling, only lips wet
  - 3= Moderate drool reaches the lips and chin
  - 4= Severe drool drips off chin & onto clothing
  - 5= Profuse drooling off the body and onto objects (furniture,books)
- Drooling Frequency Scale
  - 1= No drooling
  - 2= Occasionally drools
  - 3= Frequently drools
  - 4= Constant drooling

The Drooling impact scale

OVER THE PAST WEEK

1. How frequently did your child dribble?

Not at all 1 2 3 4 5 6 7 8 9 10 Constantly

2. How severe was the drooling?

Remained dry 1 2 3 4 5 6 7 8 9 10 Profuse

3. How many times a day did you have to change bibs or clothing due to drooling?

Once or not at all 1 2 3 4 5 6 7 8 9 10 10 or more

4. How offensive was the smell of the saliva on your child?

Not offensive 1 2 3 4 5 6 7 8 9 10 Very offensive

5. How much skin irritation has your child had due to drooling?

None 1 2 3 4 5 6 7 8 9 10 Severe rash

6. How frequently did your child's mouth need wiping?

Not at all 1 2 3 4 5 6 7 8 9 10 All the time

7. How embarrassed did your child seem to be about his/her dribbling?

Not at all 1 2 3 4 5 6 7 8 9 10 Very embarrassed

8. How much do you have to wipe or clean saliva from household items, e.g. toys, furniture, computers?

Not at all 1 2 3 4 5 6 7 8 9 10 All the time

9. To what extent did your child's drooling affect his or her life?

Not at all 1 2 3 4 5 6 7 8 9 10 Greatly

10. To what extent did your child's dribbling affect you and your family's life?

Not at all 1 2 3 4 5 6 7 8 9 10 Greatly

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Drooling quotient

- measuring percentage of time that a person drools
  in a specified time period
- Drooling was scored positive
  if during a 15-second interval new saliva was present
  on the lip margin or dropping form the mouth or chin area
- observed both at rest($DQ10^{R}$) and during an activity($DQ10^{A}$)

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Table 2 Recommended assessments

Assessment	Purpose	Who does it	ICF[a] domain measured	Properties	Clinical utility
Speech pathologist examination	Examination of positioning, oral functions, speech and swallowing	Speech pathologist	Body structure: nose, dental, mouth, pharynx (s310–S330) Structures of head and neck region) (s710) Body function: sucking, biting, chewing, manipulation of food, salivation, swallowing (b5100–5105) Body function: speech, voice, articulation (b310–399)	–	Expert opinion to support decision making on treatment/ intervention
Drooling Quotient	Quantitative scores of drooling	Nurse/speech pathologist/carer/ teacher	Body function: salivation (b5104)	Validated instrument to express the severity of drooling	Score on a numerical scale
Drooling Severity and Frequency Scale	Outcome on an ordinal scale	Nurse (practitioner)/ speech pathologist	-	Structured inventory, not validated, easy to use in clinical practice	Score which is indicative of the severity and frequency of drooling
Drooling Impact (DrI) Scale	Questionnaire to assess the effect of saliva control interventions on drooling in children with developmental disabilities	Individual, carer or person who knows the individual well	Participation	Valid, reliable (test–retest), responsive to change	Free, no training required, < 5 min to score, carer self-administered, over phone or in person
Salivary flow	Measure saliva secretion in ml/min or g/min	Speech pathologist or any other well-instructed team member	Body structure: salivary gland (s510)	Variable outcome with intra-and inter-individual variation, but reliable for research purposes with larger numbers of patients	Research purposes

[a]International Classification of Functioning, Disability and Health (ICF): valuable information can be found in the chapters about Body structures & Body Functions (S5, B5), Activity and participation (D7) and Environmental factors (E3). For children, the ICF-CY version should be reviewed.

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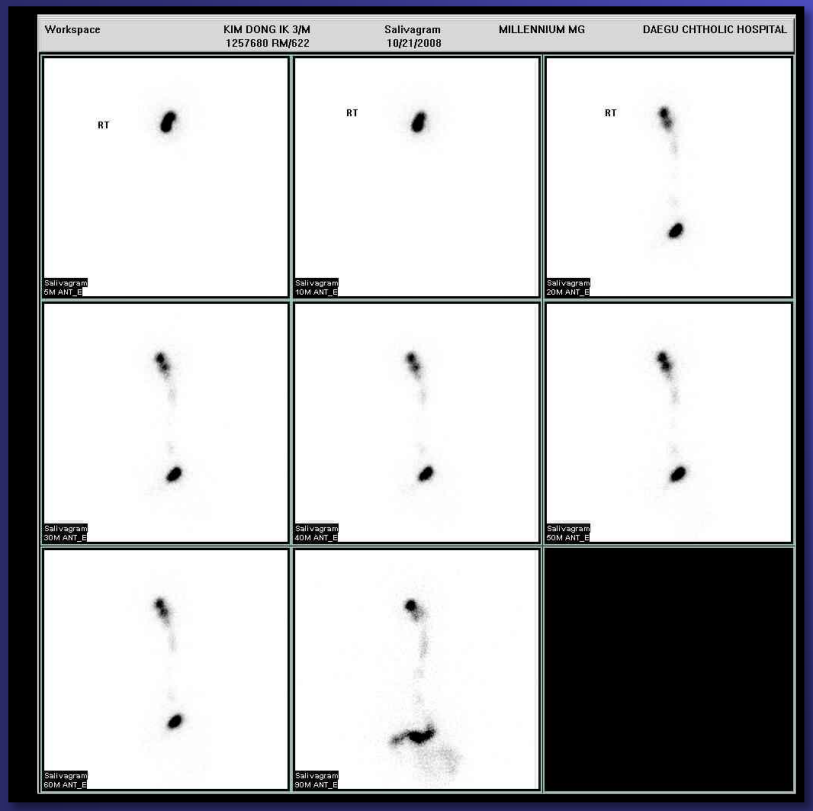
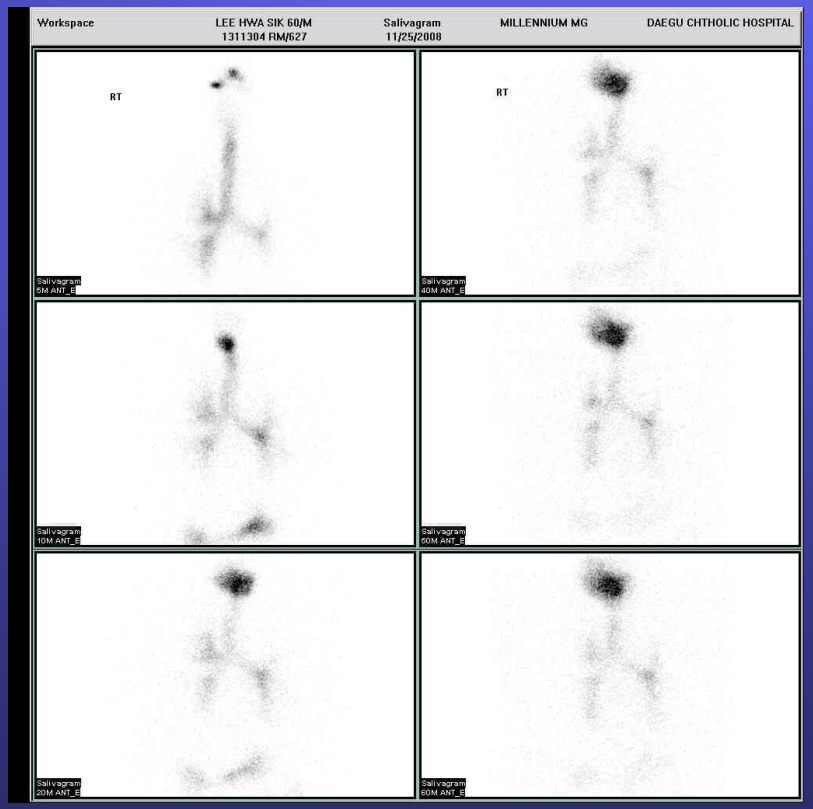
Sialogram(Salivagram)

100 microCi 99m-Tc-sulfur colloid in 0.1ml saline
; drop under the patient's tongue
-> 20sec/frame dynamic images over ten minutes





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History of Botulinum toxin A injection for drooling

- Justinus Kerner, a German poet and physician.
  : the first suggestion of idea using BTX to treat sialorrhoea
  : He had noted the severe dryness of mouth of patients with botulism and suggested that the toxin could be used to treat hypersalivation.

- Use in adults
  Since 1999, Parkinson's Ds, ALS, other neurologic ds.
- Use in children
  Since 2001, CP and other neuromuscular disorders

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Botulinum Toxin

Fig. 2 *Clostridium botulinum* type F, Langeland strain. Brain-heart culture medium. **a** Spore form. 48 hours growth time. **b** Vegetative form. 12 hours growth time. Figures by courtesy of Ms H King and Dr HS Tranter, Public Health Laboratory Service, Centre for Applied Microbiology & Research, Salisbury, Wiltshire, UK.

- Produced by *Costridium botulinum*, an obligate anaerobic, a rode shaped, gram positive organism found in soil and water
- **7** distinct serotypes: A, B, C, C, D, E, F, G

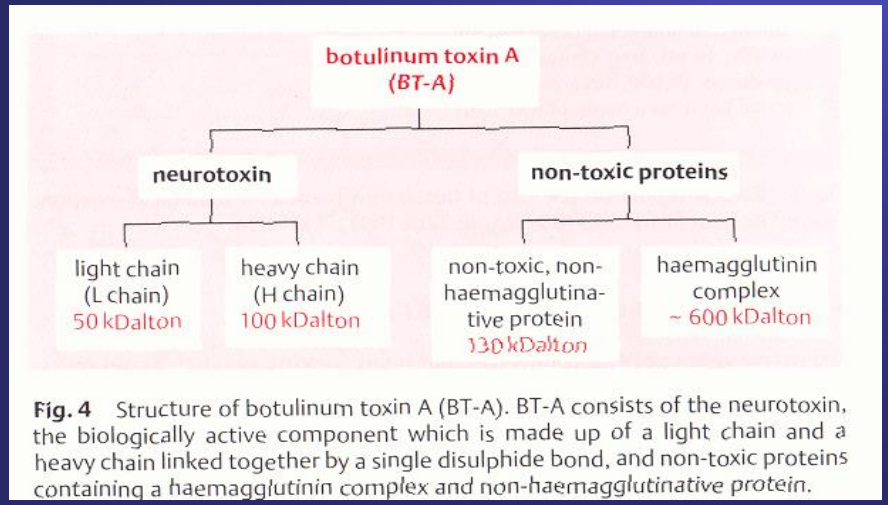

Fig. 4 Structure of botulinum toxin A (BT-A). BT-A consists of the neurotoxin, the biologically active component which is made up of a light chain and a heavy chain linked together by a single disulphide bond, and non-toxic proteins containing a haemagglutinin complex and non-haemagglutinative protein.

- Botulinum toxin A
: 150 kDa neurotoxin molecule
+ One or more nontoxin proteins (haemagglutinin)

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Commercially Available BoTN-A in Korea

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Mechanism of Action

- Effects on parasympathetic neurons
  - ACH is the neurotransmitter in postganglionic fibers of the parasympathetic division of the autonomic nervous system
  - Treatment of hyperhidrosis & hypersalivation

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Changes in acinar cell after botox injections to salivary glands- by Teymoortash et al., 2007

- Goal: To verify whether temporary acinar atrophy occurs simultaneously with chemical denervation of the glands.
- Methods:
  - Rt. SM: BTX A, BTXB, or both
  - Lt. SM: Saline
- Results: atrophy of the acini: more prominent on glands injected w/botulinum toxin A and B
- Reduction of the area of acinar cells after injection of BTX
- Significant decrease in amylase

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Botulinum toxin in the management of sialorrhoea: a systematic review

Lim, M.,* Mace, A.,* Reza Nouraei, S.A.,† & Sandhu, G.†

2006 Blackwell Publishing Limited, *Clinical Otolaryngology*, 31, 267–272

Injection of salivary glands with BTX is a minimally invasive, effective and potentially safe treatment for sialorrhoea. There is level 1b evidence for the efficacy and safety of BTX-A (Dysport) and BTX-B (Myobloc). There is no clear evidence on whether BTX-A or BTX-B is clinically superior or whether injection into parotid or submandibular gland may be more advantageous. Neither of the RCTs employed the use of ultrasound guidance but in taking into account lower level evidence, use of ultrasound does not appear to confer advantage in terms of efficacy or safety. BTX is rapidly gaining in popularity and has the potential to become the treatment of choice for sialorrhoea. A larger and better designed randomised double-blind placebo-controlled trial is required to evaluate this modality of treatment. Further studies could also directly compare BTX-A and BTX-B, different dosage of injection, ultrasound *versus* no ultrasound guidance or submandibular *versus* parotid gland injection. Comparison with surgery may prove difficult due to inability to adequately blind subjects and observers.

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Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review)

M. Naumann, MD

Objective: To perform an evidence-based review of the safety and efficacy of botulinum neurotoxin (BoNT) in the treatment of autonomic and urologic disorders and low back and head pain.

Methods: A literature search was performed including MEDLINE and Current Contents for therapeutic articles relevant to BoNT and the selected indications. Authors reviewed, abstracted, and classified articles based on the quality of the study (Class I–IV). Conclusions and recommendations were developed based on the highest level of evidence and put into current clinical context.

Results: The highest quality literature available for the respective indications was as follows: axillary hyperhidrosis (two Class I studies); palmar hyperhidrosis (two Class II studies); drooling (four Class II studies); gustatory sweating (five Class III studies); neurogenic detrusor overactivity (two Class I studies); sphincter detrusor dyssynergia in spinal cord injury (two Class II studies); chronic low back pain (one Class II study); episodic migraine (two Class I and two Class II studies); chronic daily headache (four Class II studies); and chronic tension-type headache (two Class I studies).

Recommendations: Botulinum neurotoxin (BoNT) should be offered as a treatment option for the treatment of axillary hyperhidrosis and detrusor overactivity (Level A), should be considered for palmar hyperhidrosis, drooling, and detrusor sphincter dyssynergia after spinal cord injury (Level B), and may be considered for gustatory sweating and low back pain (Level C). BoNT is probably ineffective in episodic migraine and chronic tension-type headache (Level B). There is presently no consistent or strong evidence to permit drawing conclusions on the efficacy of BoNT in chronic daily headache (mainly transformed migraine) (Level U). While clinicians' practice may suggest stronger recommendations in some of these indications, evidence-based conclusions are limited by the availability of data. **Neurology® 2008;70:1707–1714**

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Guidelines of Botulinum Toxin A Injection in salivary glands

- No specific guideline
  - Appropriate Dose
  - Duration of effect
  - Side effect
  - Either parotid glands or submandibular glands

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Salivary gland botulinum toxin injections for drooling in children with cerebral palsy and neurodevelopmental disability : a systemic reviews - *Rodwell K et al(Dev Med Child Neurol 2012)*

Table II: Characteristics of intervention

Study	Parotid gland	SMG	BoNT preparation	Dose (total per child)	Dose (total/gland or U/kg/gland)	Ultrasound guided (Y/N)	Dilution dose (total/gland)	Number of sites	Anaesthetic/sedation[a]
Randomized control trials									
Nordgarden et al.[22]	Bilateral: five participants	Bilateral: six participants	BoNT-A Botox	100U	25U	Y	25U/0.8ml	NS	GA
Basciani et al.[17b]	Bilateral	Bilateral	BoNT-B	High: 5000MU Medium: 3000MU Low: 1500MU	High: 1250MU Medium: 750MU Low: 375MU	Y	Total dose/gland in 0.25ml	NS	Topical anaesthetic
Alrefai et al.[19c]	Bilateral	No	BoNT-A Dysport	100U (first) 140U (second)	50U	N	50U/0.25ml	2/PG	NS
Lin et al.[20]	Unilateral	Unilateral	BoNT-A Botox	NS	2U/kg/gland	Y	NS	NS	NS
Reid et al.[21]	Bilateral	Bilateral	BoNT-A Botox	100U	25U (or 4u/kg/gland if <25kg)	Y	25U/1ml	SMG: 1 PG: 1	GA
Prospective studies									
Banerjee et al.[23]	Bilateral	Bilateral	BoNT-A Botox	70U	2U/kg total 1.4U/kg PG 0.6U/kg SMG	Y	50U/1ml	1/SMG 2/PG	Topical anaesthetic Sedation
Bothwell et al.[24]	Bilateral	No	BoNT-A Botox	10U	5U	N	NS	1/PG	Topical anaesthetic
Erasmus et al. 2011, 2012 [31,32d]	No	Bilateral	BoNT-A Botox	50U	NS	Y	33U/ml	NS	NS
Erasmus et al. 2010 (A)	No	Bilateral	BoNT-A Botox	30–50U	NS	Y	NS	NS	NS
Jongerius et al. 2004 (A and B)[26,27d]	No	Both	BoNT-A Botox	30–50U	15–25U	Y	15–25U/1ml	3/SMG	GA
Ong et al.[28]	Bilateral	Bilateral	BoNT-A Botox	50U	15–25U	Y	50U/1ml	1/SMG 1/PG	Sedation
Scheffer et al. 2010 (A)[29d]	No	Bilateral	BoNT-A Botox	50U	25U	Y	25U/1ml	3/SMG	GA
Scheffer et al. 2010 (B)[30d]	No	Bilateral	BoNT-A Botox	50U	15–25U	Y	15–25U/1ml	3/SMG	GA

[a]Sedation included midazolam alone, or midazolam combined with nitrous oxide gas. [b]Treatment was classified as low-, medium- or high-dose treatment. [c]Alrefai et al.[19] used an alternative brand of BoNT-A, Dysport. International units of Dysport are different from Botox. One unit of Botox is approximately equivalent in potency to 4U of Dysport.[62] The Alrefai et al.[19] study included a repeat set of injections 4 months after the first set of injections, with a total dose increase from 100U to 140U of Dysport. [d]Six studies reported on the same cohort of patients: Jongerius et al. (A) and (B) reported on two different outcome measures in the same cohort of patients; Scheffer et al. (B) later incorporated the Jongerius et al. patients as well as Scheffer et al. 2010 (A) patients; Erasmus et al.[25,31] performed secondary analyses on the Scheffer et al. (B) cohort of patients. SMG, submandibular gland; BoNT, botulinum toxin; NS, not specified; GA, general anaesthetic; MU, mouse units of BoNT-B; PG, parotid gland.

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Dosage

- 10 units divided between parotid glands (the lowest dose)
  ; 3 of 9 children as 'good responders' *Bothwell et al(2002)*

- Dose dependent on child's weight(30-50 units; higher dose)
  ; a 51-63% reduction in maximal salivary flow rate
  Jongerius et al(2001)

=> 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 pts.

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Duration of effect

- *Savarese et al(2004)*
  ; sustained significant reduction in severity, frequency of drooling, and number of bibs used for 2 mos but no significant difference by 3 mos.

- *Jongerius et al(2004)*
  ; 48% of patients continued to have a clinical response to botulinum toxin A, using the drooling quotient, at 24 wks, which was the duration of the study.

⇒ Most studies reported duration of beneficial effects to be present at least 12wks post injection.

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Side effect

- No significant side effects were reported following administration of botulinum toxin A,
  although minor effects such as local swelling,
  chewing difficulties, dry mouth, and transient weakness
  of mouth closure have been reported.

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Parotid glands vs Submandibular glands

- Savarese et al(2004)
  - 53% - marked response
    to parotid gl. Injection
- Suskind and Tilton(2002)
  - submandibular gland injection
    - only 33% responders
  - both submandibular and parotid glands injection
    - most effective (80%)

Fig. 1. Picture of the injection areas of BTX-A injections.

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Botulinum toxin A versus B injection

Mov Disord. 2011 Feb 1;26(2):313-9. doi: 10.1002/mds.23473. Epub 2011 Jan 21.

Botulinum toxin A versus B in sialorrhea: a prospective, randomized, double-blind, crossover pilot study in patients with amyotrophic lateral sclerosis or Parkinson's disease.

Guidubaldi A, Fasano A, Ialongo T, Piano C, Pompili M, Mascianà R, Siciliani L, Sabatelli M, Bentivoglio AR.

Istituto di Neurologia, Università Cattolica del Sacro Cuore, Roma, Italia.

Abstract

BACKGROUND: Either **botulinum toxins** (BoNTs) A and B have been used for improving **drooling** in different neurological conditions.

METHODS: Consecutive patients affected by Amyotrophic Lateral Sclerosis (ALS) or Parkinson's Disease (PD) accompanied by severe **drooling** were randomized to receive **botulinum** neurotoxin type A (BoNT-A) or B (BoNT-B) injections into the salivary glands. Following the first treatment, when **sialorrhea** returned to baseline (at least three months after the first injection), subjects were re-treated with the other serotype. Ultrasound-guided injections into parotid and submandibular glands were bilaterally performed: total doses were 250 U BoNT-A (Dysport) and 2500 U BoNT-B (Neurobloc). Objective (cotton roll weight) and subjective (ad hoc clinical scales) evaluations were performed at baseline, after 1 and 4 weeks, and every 4 weeks until **drooling** returned to baseline.

RESULTS: Twenty-seven patients (15 ALS and 12 PD) were enrolled, fourteen completed the study. BoNT-A and BoNT-B treatments gave both subjective and objective improvements in all patients. The latency was significantly shorter after BoNT-B treatments (3.2 ± 3.7 days) compared to BoNT-A (6.6 ± 4.1 days; P = 0.002). The mean benefit duration was similar at 75 and 90 days for BoNT-A and BoNT-B, respectively (P = NS). The only **toxin**-related side effect was a change to saliva thickness.

CONCLUSIONS: Either 250 U Dysport or 2500 U Neurobloc have similar effectiveness and safety in controlling **sialorrhea**. BoNT-B has a shorter latency and comparable duration. Cost analysis, considering the doses used in this study protocol favored BoNT-B treatment.

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Repeat Botox injection into the submandibular glands

Jongerius PH. et al
(J Pediatr Gastroenterol Nutr. 2005)

1) A marked decrease in submandibular salivary flow, anterior drooling and posterior drooling after the first injection was achieved.

2) A striking finding was the long lasting effect after the second BoNT injection. The interval between treatments ranged 7 to 12 months

->It is hypothesized that hypotrophy of the injected salivary glands may be induced due to long lasting denervation.

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Eur J Neurol. 2010 Aug;17 Suppl 2:109-21.

Botulinum toxin assessment, intervention and aftercare for paediatric and adult drooling: international consensus statement.

Reddihough D, Erasmus CE, Johnson H, McKellar GM, Jongerius PH; Cereral Palsy Institute.

Definition

Recommendation 1

In summary, the following is recommended:*

- To define the term 'drooling' as: the unintentional loss of saliva from the mouth
- That the terms anterior and posterior drooling should be distinguished

*Expert opinion.

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Assessment

Recommendation 2

A. A thorough assessment is recommended, and therapy based on:*

- A thorough evaluation of the medical and social–emotional history of the patient
- Examination of the oral region by the speech pathologist
- A dental examination in individuals greater than 3 years of age
- Questionnaires with good content and construct validity such as the Drooling Impact Scale

B. Assessment for research purposes may include additional measures, for example, the Drooling Quotient or the measurement of salivary flow.

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Indications

Recommendation 3

It is recommended that BoNT-A should not be administered:*

- If BoNT-A has been given for any reason in the previous 3 months
- If the patient has antibodies against BoNT-A
- If the patient is unfit for sedation or anaesthesia (this mainly relates to children as adults may have treatment without anaesthesia)

In the presence of dysphagia and CP with GMFCS level V, careful assessment should take place prior to injection.

Acquired resistance to BoNT therapy is a well-recognized phenomenon, marked by lack of beneficial effect. It is recommended that BoNT-B be tried after treatment failure with BoNT-A or vice versa.

*Expert opinion.

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Optimal botulinum toxin intervention regimen

Recommendation 4

The following is recommended:

- Injection of BoNT-A into the salivary glands (parotid and submandibular) ideally under ultrasound guidance*

*Expert opinion.

Table 3 Injection site, dose and injection procedures[a]

Injection Site	BOTOX® U	Dysport® U	Myobloc® U	Injection Procedures
Submandibular gland	10–50	15–75	250–1000	Percutaneous injections, ventral approach, one injection/side, use of US, general anaesthesia (mainly in children)
Parotid gland	10–50	15–75	400–1000	Idem

[a]Different preparations are available e.g. BOTOX®, Dysport®, Myobloc®. All data reported here are from the published literature. BOTOX® and Dysport® are not exchangeable. Research suggests (level 3) that 1 Unit of BOTOX® equates to approximately 3- 4 Units of Dysport® but since the units are not interchangeable, to improve safety it is recommended that professionals follow manufacturer's dosing guidelines and do not use approximate conversions.

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Adverse effects

Recommendation 5

The following is recommended to avoid or limit adverse events with the use of BoNT therapy:*

- The use of ultrasound guidance during injections
- Observation of the patients for at least 2 hours following injection
- Regular contact with the patients or caregivers in the week following injection to evaluate swallowing problems
- Being aware of the possibility that thickening of saliva over time may occur which leads to swallowing and respiratory problems
- Moist or pureed food in the first week following injection

*Expert opinion.

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Summary

- When choosing a treatment for drooling, it is essential to balance out the benefits and the risks and to closely monitor the patient to identify any unwanted side effects.

- Initially the management approach is conservative and then progress to more invasive procedures if appropriate.

- The majority of available evidence for saliva management in neurological conditions focuses on botulinum toxin injections, but, there are no robust guidelines for their administration.

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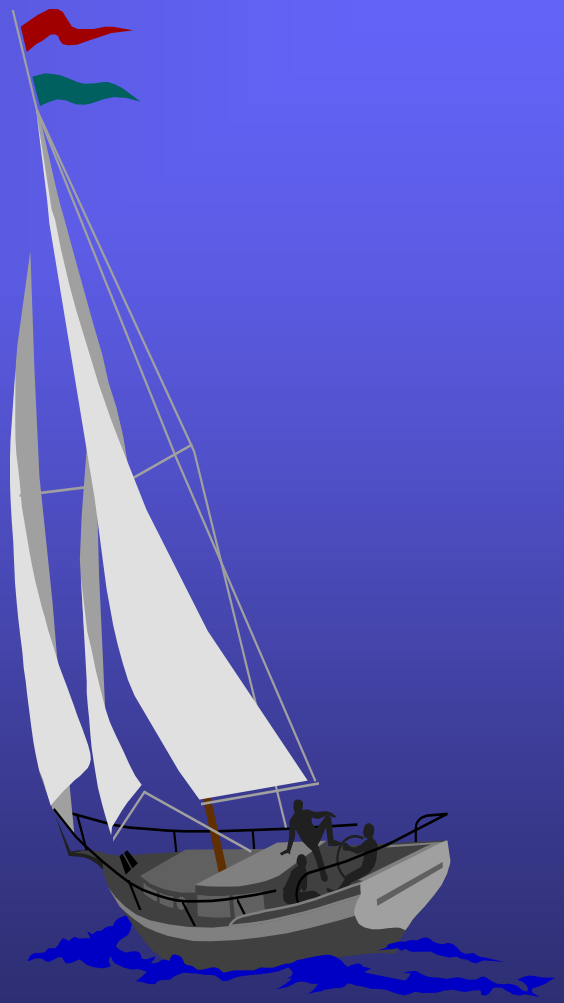

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