Switching botulinum toxin formulations from onabotulinumtoxinA (Botox®) to incobotulinumtoxinA (Xeomin®): experience from a spasticity outpatient clinic

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Background

- Spasticity related to neurologic disease is relatively common and can be troublesome to affected individuals.¹
- Botulinum toxin type A (BoNT-A) injections are a recommended treatment option for limb spasticity due to various neurologic conditions.^{2–4}
- IncobotulinumtoxinA (Xeomin®, Merz Pharmaceuticals GmbH) treatment resulted in significant improvements in spasticity-associated disability and muscle tone, and was well tolerated in previous randomized, placebo-controlled clinical trials with open-label extension periods.^{5–7}
- In 2009, the Mid Yorkshire Hospitals NHS Trust made the decision to switch from onabotulinumtoxinA (Botox®, Allergan Inc.) to incobotulinumtoxinA for the management of spasticity related to neurologic conditions.
- In order to assess the clinical impact of this switch in BoNT-A treatment, a retrospective case-file review was performed to examine dose requirements, treatment intervals, and tolerability of onabotulinumtoxinA and incobotulinumtoxinA.

Methods

Study design and setting

Retrospective case-file review of consecutive patients in an outpatient spasticity-management clinic.

Inclusion and exclusion criteria

Patients with spasticity related to any neurologic condition, who had previously been treated with onabotulinumtoxinA and were switched to incobotulinumtoxinA (**Table 1**).

Table 1. Inclusion and exclusion criteria		
Inclusion criteria	Exclusion criteria	
Any patient switched from onabotulinumtoxinA to incobotulinumtoxinA within the last 7 years	Any patient not switched from onabotulinumtoxinA to incobotulinumtoxinA within the last 7 years	
Age ≥18 years	Age <18 years	
Diagnosis of spasticity in upper or lower limbs	Insertion of intrathecal baclofen pump during study period Initiation of oral antispasmodic medication during study period Limb fractures during the study period Limb surgery for spasticity and/or contracture during the study period	

Interventions

- BoNT-A was injected into the affected muscles of the upper and/or lower limb.
- For each treatment, dosing, injection sites, and treatment intervals were adjusted based on clinical need and previous treatment outcomes.
- Switching from onabotulinumtoxinA to incobotulinumtoxinA was generally initiated at a unit dose ratio of 1:1. Both products were reconstituted to the same volume. Electromyography, electrostimulation or ultrasound were occasionally used to guide injections. No change in practice took place during the study period.

Main outcome measures

Patient records were used to document treatment intervals, doses, muscles treated, injection technique, and adverse reactions.

Results

Study population and baseline characteristics

- Records from 254 consecutive patient records were reviewed; 93 patients fulfilled the inclusion criteria. A total of 161 patient records were excluded from the review (Table 2).
- Patients included were 16–82 years of age (mean 46.5 years) at the start of treatment, and 59% were male (**Table 3**).
- Spasticity was mainly due to stroke (40.9%), cerebral palsy (25.8%) or multiple sclerosis (18.3%; **Table 3**).
- Patients had been treated with onabotulinumtoxinA for 3–55 months (mean 16 months) before receiving incobotulinumtoxinA for 7–73 months (mean 39 months) (**Table 3**).

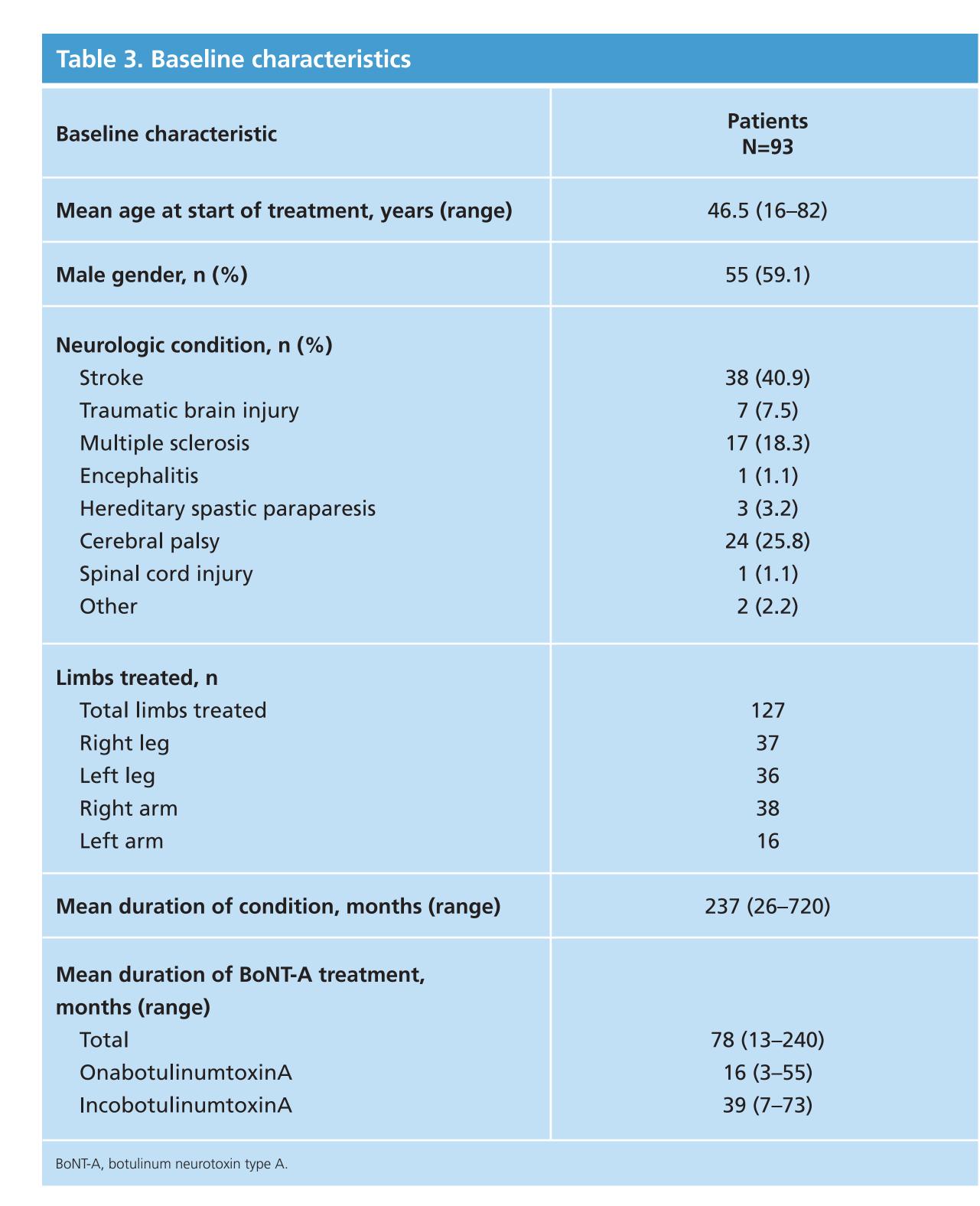
Dosing interval and dose requirements

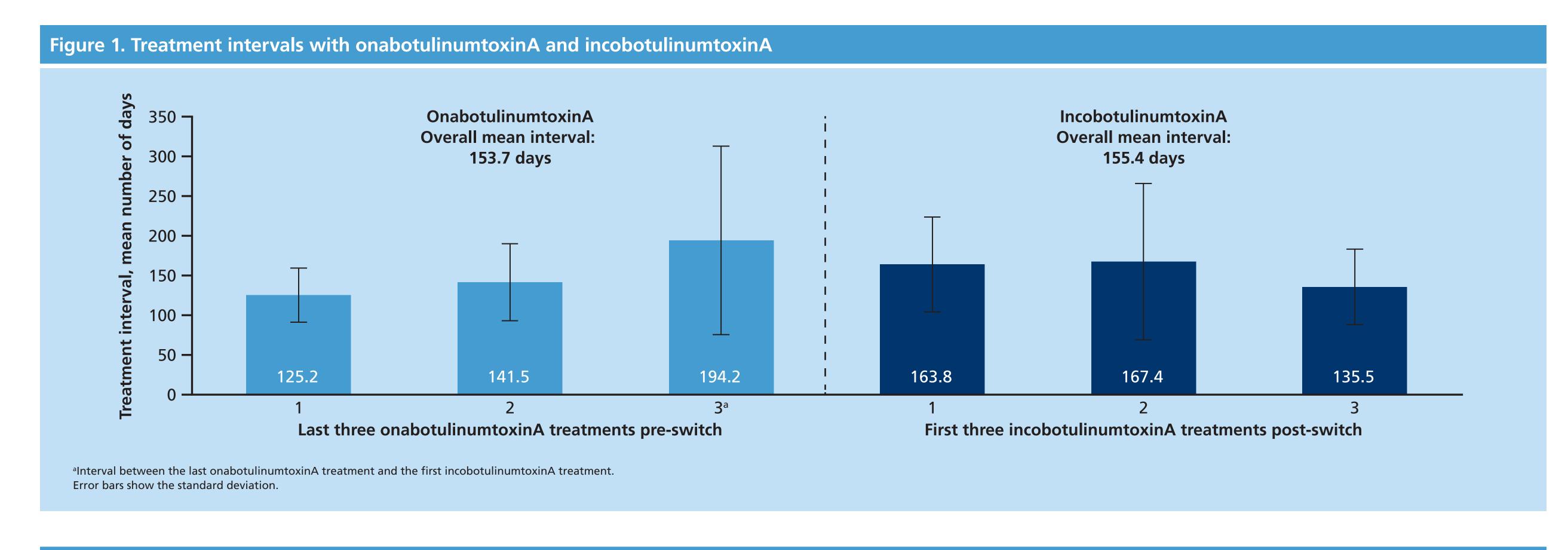
- The mean treatment intervals for onabotulinumtoxinA and incobotulinumtoxinA were similar (153.7 days and 155.4 days, respectively; **Figure 1**).
- The mean dose per limb per visit for onabotulinumtoxinA and incobotulinumtoxinA were also similar (144.8 U and 145.0 U, respectively; **Figure 2**).

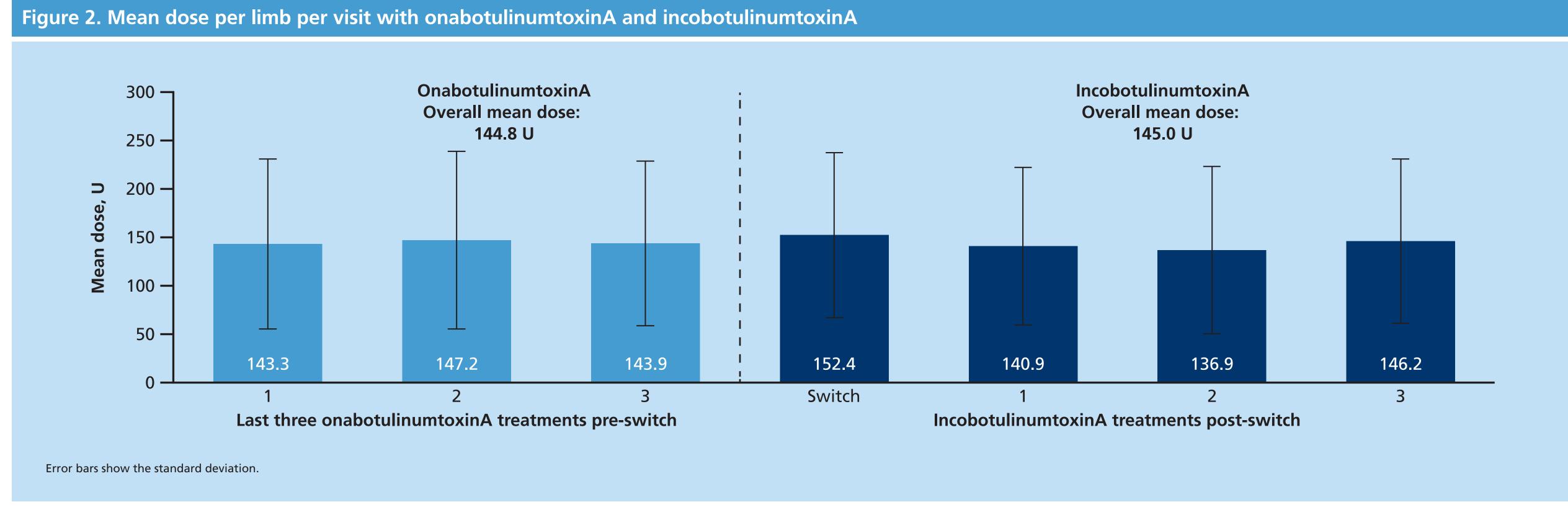
Safety

No adverse reactions occurred with either BoNT-A formulation.

Table 2. Reasons for exclusion		
Reason for exclusion	Number of patients ^a	
Treatment commenced after switch	90	
Non-switch patients	52	
Dystonia	4	
Hypersalivation	2	
No historic record available	2	
Non-neurology	1	
Double counted	9	
Incorrect patient	1	
Total exclusions	161	
^a Patients could have been excluded for more than one reason.		







Conclusions

- Switching of onabotulinumtoxinA to incobotulinumtoxinA in a 1:1 ratio did not lead to any changes in the mean treatment interval or dose per visit. As these measures have previously been used as a proxy measure of the efficacy of BoNT-A treatment,8 these results suggest that both onabotulinumtoxinA and incobotulinumtoxinA have a similar efficacy profile.
- No adverse reactions were observed with either onabotulinumtoxinA or incobotulinumtoxinA, indicating that both had similar safety and tolerability profiles.
- Overall, results indicate that onabotulinumtoxinA and incobotulinumtoxinA can be switched at a 1:1 unit dose ratio in clinical practice.

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