INCOBOTULINUMTOXIN A
FOR THE CORRECTION OF GLABELLAR LINES
AMONG PATIENTS WITH
SKIN TYPES IV TO VI

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INTRODUCTION

Despite common use of botulinumtoxin A (BoNTA) in non-Caucasian patients, controlled studies reporting safety and efficacy are not well documented in patients with darker skin pigmentation. Several studies have investigated the use of the first two BoNTA products – onabotulinumtoxin A and abobotulinumtoxin – in non-Caucasian populations.\(^1\,\^2\) However, the latest BoNTA product, incobotulinumtoxin A, has not been widely reported in these populations to date.

The primary objective of this study was to investigate the efficacy and safety of incobotulinumtoxin A (INCO) for the correction of glabellar lines among non-Caucasian patients with Fitzpatrick skin types IV to VI.
METHODS

Study Design
• Open-label, single-center study

Key Inclusion/Exclusion Criteria
• Males and females 18 years or older with moderate to severe glabellar frown lines at maximum frown based on glabellar rhytid score of 2 or more at maximum frown on the Merz 5-point scale of glabellar severity (Figure 1).

• Subjects were excluded if they had participated in another study within 30 days, received neurotoxin within 6 months, had marked facial asymmetry or ptosis of eyelid or eyebrow, an inability to lessen glabellar frown lines by physically spreading them apart, or concomitant treatment with any cosmetic product or procedure expected to lift or tighten the forehead or eyelid skin.
Treatment

• After assessment of glabellar severity, patients were injected with INCO at 5 intramuscular injection sites with equal aliquots of 0.1 mL.

Evaluation

• At Days 30 and 90, assessments were repeated by the investigator. At Days 30 and 90, subjects rated themselves using mirrors. Both investigator and subjects used the Merz 5-point scale of glabellar severity
Primary Analysis

• The primary endpoint was response to treatment defined as a ≥1 point improvement in subject and investigator assessment of Mean Glabellar Severity Scores.

Figure 1. Validated scale used for determination of severity of glabella lines.³

• At Baseline (Day 0) evaluations included standardized photographs and investigator- and subject-assessment of glabellar frown line severity score.

• Investigator- and subject- assessments and photographs were repeated at Day 30 and Day 90.
RESULTS

• A total of 29 subjects with Fitzpatrick Skin Type IV-VI (4 males and 25 females) were enrolled
  — African American, African American-Caucasian, Hispanic, and West Indian

Efficacy
• At Day 30, 100% responded to treatment (n = 29; 95 C.I. 0.87, 1.00; P < 0.001).
• At Day 90, 69% (n=20) still responded to treatment (95% C.I. 0.52, 0.83; P = 0.42).
Table 1. Mean Glabellar Severity Scores by Patients and Investigator at 30 Days and 90 Days

<table>
<thead>
<tr>
<th>Assessment Day</th>
<th>Patient score (at max frown)</th>
<th>Investigator score (at max frown)</th>
<th>Patient mean change from baseline</th>
<th>Investigator mean change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (Baseline)</td>
<td>3.06</td>
<td>2.93</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>30</td>
<td>0.75</td>
<td>0.72</td>
<td>-1.43</td>
<td>-1.45</td>
</tr>
<tr>
<td>90</td>
<td>1.83</td>
<td>1.44</td>
<td>-1.00</td>
<td>-1.48</td>
</tr>
</tbody>
</table>

Safety

- Safety profile similar to previously reported trials with BoNTA, ie, injection site erythema.⁴,⁵
Representative Photographs

Baseline and post-treatment photographs at rest and at maximal contraction on Day 30 and Day 90 demonstrate response to treatment in (A), a 48-year-old female subject with a Fitzpatrick Skin Type of V and in (B), a 47-year-old male subject with Fitzpatrick Skin Type of 5.

A.
DISCUSSION

• Similar results to studies in fairer skin types at Day 30

• Slightly lower scores in Fitzpatrick Skin Types IV-VI than in fairer skin types at Day 90

• Satisfaction of investigator slightly greater with Rx than subjects’ satisfaction at Day 90

• Male subjects appeared to have expectations of greater difference at Day 90 than measured—reasons unclear

• Difference in muscle mass between sexes could account for differences in males compared to females—constrained by protocol to 0.1 mL aliquots, regardless of gender
CONCLUSIONS

Incobotulinumtoxin A achieved a 100% response to treatment at Day 30 and a sustained duration of treatment effect (69% at 90 days) for correction of glabellar lines.

Incobotulinumtoxin A also demonstrated a similar safety and efficacy profile in subjects with Fitzpatrick skin types IV to VI when compared to results previously found among Caucasians for correction of glabellar lines.
REFERENCES


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