Adherence to botulinumtoxin treatment: a 2-year retrospective claims database analysis

David M. Simpson[a], Jonathan Bouchard[b], Simon Page[c], Dean P. Spurden[c], Seth Goldfarb[b], Atul T. Patel[d]

[a]Department of Neurology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [b]Ipsen, Cambridge, MA, USA; [c]Ipsen, Slough, UK; [d]Kansas City Bone & Joint Clinic, Overland Park, KS, USA

EPH1

For further information, please send your question(s) to Jonathan Bouchard (**jonathan.bouchard@ipsen.com**).

Background

- Understanding the use of botulinumtoxin (BoNT) in clinical practice is essential for improving clinical care.
- Adherence to prescribed treatment is critical to successfully meet patients' needs and goals.[1]
- Real-world evidence describing long-term persistency with BoNT therapy is limited.

Objective

To describe treatment dynamics of, and persistency with, BoNT over 2 years in a retrospective longitudinal study.

Methods

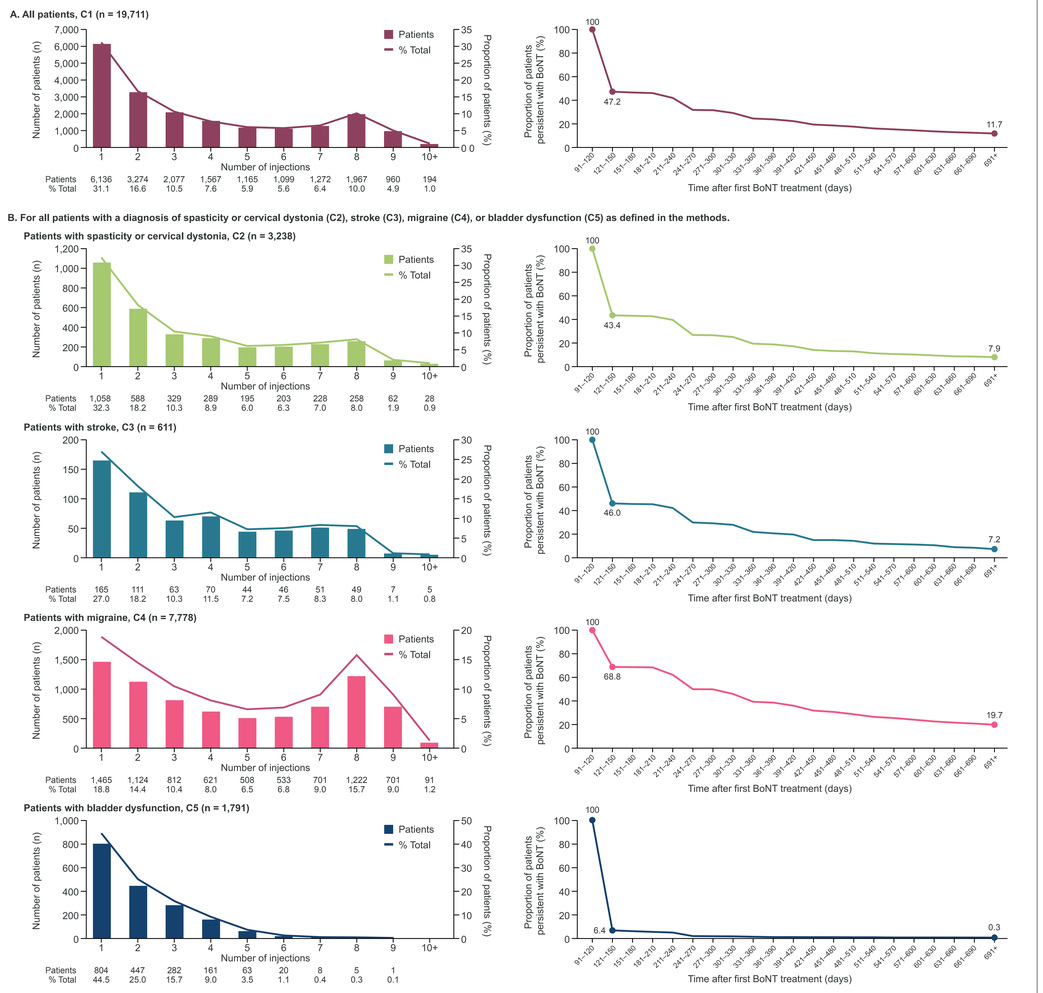
- This study assessed US medical claims data from the IBM MarketScan database among patients with a first medical claim for BoNT between 1 October 2016 and 31 October 2019.
  - All commercially available preparations of BoNT in the USA (not product-specific) were included.
- The index date was the date of the first BoNT administration, and a 1-year washout period before this date was used to identify incident BoNT use.
- There were five cohorts included in the analysis presented here.
  - Cohort 1 (C1), all patients with a first medical claim for BoNT within the index period.
  - Cohort 2 (C2), all patients with a diagnosis of spasticity or cervical dystonia and without an off-label diagnosis on the index date.
  - Cohort 3 (C3), all patients with a diagnosis of stroke before the index date and without an off-label diagnosis on the index date.
  - Cohort 4 (C4), all patients with a diagnosis of migraine on the index date and without an off-label diagnosis on or after the index date.
  - Cohort 5 (C5), all patients with a diagnosis of bladder dysfunction on the index date and without an off-label diagnosis at any time during the study period.
- On-label indications were defined as those approved for abobotulinumtoxinA.[2]
- The number of treatments in the 2-year follow-up period and persistency (120-day look forward from treatment date; 80th percentile value of days to next treatment) were evaluated for each cohort.

Table 1. Baseline patient demographics

	Cohort 1 (n = 19,711)	Cohort 2 (n = 3,238)	Cohort 3 (n = 611)	Cohort 4 (n = 7,778)	Cohort 5 (n = 1,791)
Age, years, median (IQR)	48.0 (21.0)	49.0 (36.0)	55.0 (29.0)	46.0 (17.0)	60.0 (20.0)
Sex, n (%)					
Female	15,129 (76.8)	1,939 (59.9)	337 (55.2)	6,680 (85.9)	1,462 (81.6)
Male	4,582 (23.2)	1,299 (40.1)	274 (44.8)	1,098 (14.1)	329 (18.4)
Region					
North Central	5,070 (25.7)	890 (27.5)	168 (27.5)	1,830 (23.5)	532 (29.7)
Northeast	3,945 (20.0)	690 (21.3)	156 (25.5)	1,375 (17.7)	425 (23.7)
South	7,718 (39.2)	1,228 (37.9)	224 (36.7)	3,190 (41.0)	639 (35.7)
West	2,886 (14.6)	410 (12.7)	59 (9.7)	1,343 (17.3)	191 (10.7)
Unknown	92 (0.5)	20 (0.6)	4 (0.7)	40 (0.5)	4 (0.2)
Payer type					
Commercial	17,596 (89.3)	2,811 (86.8)	473 (77.4)	7,531 (96.8)	1,129 (63.0)
Medicare	2,115 (10.7)	427 (13.2)	138 (22.6)	247 (3.2)	662 (37.0)
CCI at baseline, mean (SD)	1.0 (1.5)	1.6 (1.8)	3.7 (1.9)	0.6 (1.1)	1.5 (1.8)

Cohort 1, all patients; cohort 2, patients with spasticity or cervical dystonia; cohort 3, patients with stroke; cohort 4, patients with migraine; cohort 5, patients with bladder dysfunction.
CCI, Charlson Comorbidity Index; IQR, interquartile range; SD, standard deviation.

Figure 1. Proportion of patients receiving one to 10 or more BoNT-A injections in the 2-year follow-up period (left panels) and the BoNT-A treatment persistency curves using the 120-day look forward from treatment date (right panels)



BoNT, botulinumtoxin; C1–5, cohort 1–5

TAKE-HOME MESSAGE

A large proportion of patients receiving BoNT stop treatment after only one or two injections. Further research is warranted to determine the underlying reasons for the cessation of treatment.

Results

- Baseline demographics are shown in **Table 1**.
- There was a notable drop-off in the percentage of patients who were persistent with treatment across the five cohorts (**Figure 1, A and B**).
- In the 2-year follow-up period, 31.1% of all patients (C1), 32.3% of patients with a diagnosis of spasticity or cervical dystonia (C2), 27.0% of patients with a diagnosis of stroke (C3), 18.8% of patients with a diagnosis of migraine (C4), and 44.5% of patients with a diagnosis of bladder dysfunction (C5) received only one injection of BoNT.
- In C1, there was a peak in the number of patients receiving 8–9 injections over 2 years (14.8%) in accordance with the expected treatment regimens and representing those patients who were defined as persistent with treatment (**Figure 1A**, left panel).
  - Notable differences in 24-month persistency were observed in patients with migraine (C4) (24.7% of patients received 8–9 injections over 2 years) versus those with stroke (C3) (9.2%) or bladder dysfunction (C5) (0.34%) (**Figure 1B**, left panels).
- For all patients (C1), the mean number of treatments over the 2-year follow-up was 3.7, and the time between treatments (80th percentile) was 126 days.
  - This was similar for patients with stroke (C3); the mean number of treatments was 3.6, and the time between treatments (80th percentile) was 140 days.
  - For patients with migraine (C4), the mean number of treatments was 4.7, and the time between treatments (80th percentile) was 105 days.
  - For patients with bladder dysfunction (C5), the mean number of treatments was 2.1, and the time between treatments (80th percentile) was 319 days.

CONCLUSIONS

- This 2-year retrospective analysis showed that there was a substantial decrease in the proportion of patients receiving BoNT treatment after the first injection across the five cohorts.
- In the cohort of patients with a diagnosis of stroke (C3), fewer than 10% of patients were defined as persistent in accordance with the expected treatment regimen (8–9 treatments over 24 months).
- An understanding of the variables that affect treatment persistency is needed to inform clinical strategies that can improve outcomes for patients receiving BoNT and address knowledge gaps.

Abbreviations

BoNT, botulinumtoxin; C1–5, cohort 1–5; CCI, Charlson Comorbidity Index; IQR, interquartile range; SD, standard deviation

References

1. Esquenazi A et al. Arch Phys Med Rehab 2021;102:2172–84.
2. Ipsen. Dysport® prescribing information. 2023. Available from: https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/sites/9/2023/02/01152152/Dysport-US-PRESCRIBING-INFORMATION-Jan-2023.pdf (Accessed 3 March 2023).

Author contributions Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: all authors; drafting of the publication or revising it critically for important intellectual content: all authors; final approval of the publication: all authors.

Disclosures DMS: consultant for Ipsen. JB, SP, DPS, SG: all employees of Ipsen. ATP: consultant/advisory boards for Ipsen, AbbVie, Revance; speaker for Ipsen, AbbVie; research grants with Ipsen, AbbVie.

Medical writing support The authors thank Vicky Sanders PhD of Oxford PharmaGenesis, Oxford, UK, for providing medical writing support, which was industry sponsored in accordance with Good Publication Practice guidelines.

Presented at ISPOR 2023 | Boston, MA, USA | 7–10 May 2023

This study was sponsored by Ipsen