

Gobel H, Heinze A, et al. Efficacy and safety of a single botulinum type A toxin complex treatment (Dysport®) for the relief of upper back myofascial pain syndrome: Results from a randomized double-blind placebo-controlled study. Pain 2006;125:82-88.

Design: Randomized clinical trial

Population/sample size/setting:

- 145 patients (80% women, mean age 45) treated for myofascial pain of the upper back at 15 hospitals and clinics in Germany and Austria
- Eligible patients were 18-70 years old, had myofascial pain affecting cervical and/or shoulder muscles with at least 10 trigger points for 6-24 months, with weekly pain average of at least 3 points on a scale from 1 (no pain) to 4 (severe pain)
- Exclusion criteria were previous treatment with botulinum toxin, participation in another clinical study, concurrent muscle disease, any conditions associated with bleeding, any history of drug or alcohol abuse, body mass index greater than 30, pregnancy, or specific back pain disorders

Main outcome measures:

- All participants were disallowed the use of concomitant medications: for the 4 weeks prior to study treatment, no opioids, no corticosteroids, invasive therapy methods, or neuromuscular blocks; for the week prior to treatment, no NSAIDs, topical steroids, muscle relaxants, or antirheumatics; on the day prior to treatment, no acetaminophen, heat, massage, or bath therapy
- All participants received 2.5 ml injections into the 10 most painful trigger points and were randomized to one of two injection groups: Dysport 40 Ipsen U per site (n=74), or normal saline as placebo (n=70)
 - o Trigger points were identified by palpation
 - o All physicians were trained for standardized trigger point identification and data collection
- Participants received pain diaries which were to be completed daily for 12 weeks, and were scheduled for return evaluations every 4 weeks
- Main outcome measure was the proportion of patients with minimal or no pain at week 5 (defined as responders)
 - o At week 5, 51% of patients in Dysport group reported mild or no pain, compared with 26% in the placebo group
 - o Some related secondary measures (average change in pain intensity over time) also favored the Dysport group
 - o After week 6, the proportion of Dysport responders appears to decline (in weeks 9 and 10, Figure 3 appears to show 40% responders in Dysport group and 30% responders in placebo group)
- Adverse effects were mild or moderate in intensity; muscle soreness was reported for 59% of Dysport group and 37% of placebo group

Authors' conclusions:

- Myofascial pain in the upper back responds to injection of Dysport better than injection of placebo
- Injection of 10 trigger points with 40 Ipsen U of Dysport per site produces significant pain relief 4-6 weeks after treatment

Comments:

- Overall, methods are well reported and threats to internal validity are adequately controlled (method of randomization, allocation concealment, blinding) and risk of bias is low
- However, primary outcome (proportion of patients with mild or no pain at 5 weeks) is not as clear as it needs to be
 - o Each participant receives injection at 10 trigger points
 - o It is not clear whether a “response” was recorded if all 10 trigger points were painless, or if only some trigger points (or just one) experienced pain relief
- The injections were done in muscles which can refer pain to the upper back, but there is no description of which muscles were injected
- Since some muscles can be conveniently tested for motor strength (rhomboids, trapezius), this information would be relevant; studies of botulinum toxin in lateral epicondylitis did report on extensor strength, and there is no reason to omit formal strength testing when botulinum toxin is administered
 - o Relying on patient-reported adverse effects may not detect decreases in strength which could be detected on examination
- The duration of effectiveness of Dysport may not be greater than 5 or 6 weeks
 - o Some lateral epicondylitis studies reported continued pain relief at 16 weeks

Assessment: Inadequate for evidence that botulinum toxin injection of multiple upper back trigger points is more effective than placebo for short-term pain relief (the nature of the primary outcome is not adequate; it is vaguely described, is only brief in duration, and an important side effect, muscle weakness, is not measured)