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100 UNITS OF INTRA-DETRUSOR BOTOX ® FOR CHILEAN IDIOPATIC DETRUSOR OVERACTIVITY PATIENTS REFRACTORY TO ANTIMUSCARINIC THERAPY

Hypothesis / aims of study

Botox ® (BTX) has been proposed as treatment for neurological and idiopathic detrusor overactivity (IDO) when medical therapy fails because its action of temporarily block of the presynaptic release of acetylcholine from the parasympatethic innervation of the detrusor muscle. The injection technique and optimal dose of BTX for IDO remains inconclusive. The majority of studies use 50 to 300 units of BTX intradetrusor in one procedure. Detrusor injection technique has not been standardised, because each center realizes its own technique. There are very few scales that measures objectively the effectiveness of this treatment. However, the lack of standardized evaluation is not relevant because the clinical effect of BTX reducing IDO symptoms and improve quality of life in this setting of patients is the paramount aim of any treatment (1). In this study we evaluated the subjective efficacy (clinical improvement) and effect duration of 100 units of intradetrusor injections of BTX in chilean patients with IDO resistant to antimuscarinic therapy.

Study design, materials and methods

This is a prospective study. We identified IDO patients who failed to antimuscarinic therapy from our outpatient clinic. All patients enrolled had multichannel urodynamic study to confirm detrusor overactivity. Botox solution was prepared with 100 units of BTX diluted into 30 ml 0,9% saline solution (3,3 BTX unit for ml.). Patients were injected in a single dose of 100 units of BTX into the detrusor under general anaesthesia. We used rigid Storz cystoscope with nontrigonal injection technic with 30 intradetrusor injection sites. Patients were followed for evidence and duration of efficacy and complications. The follow-up was made trough clinical assessment of continence related by the patient in the post-operative controls, making a comparison of clinical symptoms before and after BTX injection, like voiding frequency, nocturia and urgency.

Results

Between December 2007 and December 2009, 31 consecutive patients who met the study criteria were enrolled. All patients completed the study. There were 20 (64.5%) women and 11(35.5%) men with a mean age of 66.5 ± 13.4 years (range 44 to 88 years). We completed 33 procedures because 2 patients with complete response with the first dose, had a repeat course of BTX after 8 and 18 months of treatment. All patients reduced symptoms within the first week after treatment. In 23 (69,7%) procedures, patients shown clinically 100% response. A partial improvement regard to subjective symptoms was seen in 6 (18,2%) procedures. Two patients with partial response to BTX, improve to complete response after we prescribed Trospium 15 mg bid. In 4 procedures (12%), patients refered no improvement in their symptoms after treatment. There were no severe complication after the treatment. There were 3 adverse events in equal number of patients (9.7%). All of them presented urinary tract infection, one of them with recurrent urinary tract infection related to significant post-void residual volume. The BTX improvement effect last a mean time of 6,6 months (range 4-14 months).

Interpretation of results

BTX intravesical injection provided clinical improvement in IDO patients refractory to medical management. Improvement in symptomatology for responders patients was spectacular. Patients showed satisfaction for the treatment outcomes, the rapid onset of action during the first week after the injection, the characteristics of the procedure itself with minimal discomfort and the safety of the procedure. We don`t have cases of urine retention or other procedure related complications in our patients and less than 10% of patients had transitory adverse effects.

Concluding message

To our knowledge this is the first study of BTX in South American patients in the treatment of IDO. Our investigation has an adequate follow up although the number of participants in this study is small. Our data validates intradetrusor 100 units BTX injection to be effective, safe and durable treatment for IDO and provides a well-tolerated and rapid clinical improvement on symptoms. BTX ameloriates symptoms within the first week after treatment and its effects last for several months in the majority of the patients submitted to this treatment.

References

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**This is standard treatment in patients no responding to antimuscarinic teraphy**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**