INTRODUCTION & OBJECTIVES

Intradetrusor onabotulinumtoxinA (BoNT-A) injection benefits overactive bladder (OAB) patients, but increased postvoid residual (PVR) urine volume and urinary tract infection (UTI) remain risks. Intravesical instillation of liposomal BoNT-ONA instead of injection could prevent such adverse events. This study was aimed to evaluate the clinical outcomes of instillation of liquid liposomal BoNT-A (Lipotoxin) for OAB patients.

MATERIALS AND METHODS

This pilot study was designed as a double-blind, randomized, paralleled, controlled trial in 24 OAB patients at a single tertiary center. Patients were randomly assigned to intravesical instillation of Lipotoxin containing 80 mg liposomes and 200U BoNT-A (n=12) or normal saline intravesical instillation (n=12). Patients were retreated with Lipotoxin 1 month later if they failed the first treatment. Voiding diaries, OAB symptom scores, urodynamic studies, and adverse events were monitored. The primary end point was change of total urinary frequency per 3 days at 1 mo after treatment.

RESULTS

The median change of frequency per 3 d from baseline to 1 mo was significantly decreased in the Lipotoxin group (-6.50; IQR: -18.3 to -0.25; p=0.008) but not in the N/S group (0.00; IQR: -7.75 to 8.0; p=0.792) (Table 1, Fig. 1). Post hoc power calculation revealed the power was 0.875 based on the changes of frequency episodes between groups. The urgency episodes also significantly decreased in the Lipotoxin group (-12.0; IQR: -20.3 to -2.75; p=0.012) but not in the N/S group (-1.0; IQR: -11.0 to 2.5; p=0.196). However, the UUI episodes did not change after Lipotoxin treatment. USS decreased in 6 and 5 patients, and GRA increased in 9 and 8 patients of Lipotoxin and N/S group, respectively (p=0.682 and 1.000). There were no significant differences in the change of uroflow parameters from baseline to 1 mo in either the Lipotoxin or N/S group. No adverse events such as large PVR, urinary retention, or UTI were reported by the patients during the follow-up period.

CONCLUSION

We demonstrated that intravesical Lipotoxin instillation reduced frequency and urgency episodes at 1 month after treatment in OAB patients. This procedure is safe without an increase in PVR or the risk of UTI.