

Macroplastique and Botox are superior to Macroplastique alone in the management of neurogenic vesicoureteric reflux in spinal cord injury population in presumed healthy bladders.

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Hypothesis / Aims of Study

- Vesico-ureteric reflux (VUR) is a known complication of neurogenic lower urinary tract dysfunction. If left untreated VUR may cause renal function deterioration and eventually renal failure.
- Surgical correction, the golden standard for VUR management, has become less popular with the introduction of bulking injections. There is data to confirm that Macroplastique is effective in the treatment of secondary VUR due neurogenic bladder¹. There is also evidence that botulinum toxin alone is effective in improving VUR².
- In this study we assess the efficacy of Macroplastique alone or in combination with Botox, in managing VUR in spinal cord injury (SCI) population with presumed healthy bladders and correlate the pre-and post-injection urodynamic findings with the outcome.

Study Design, Materials and Methods

- We defined a 'healthy bladder' as having low filling detrusor pressure (<30cmH₂O), low amplitude overactivity, good capacity (>200mls) and compliance (>10ml/cmH₂O).
- We conducted a retrospective case control study of SCI patients with unilateral or bilateral VUR who were managed with Macroplastique alone or in combination with Botox injection.
- The inclusion criteria were: age>18 years, no previous interventions for neurogenic overactivity, upper motor neuron lesion, baseline and follow-up videourodynamics (VUDS) assessment, proven VUR, adequate follow up (≥12 months) and at least 2 post-intervention annual ultrasonographic assessments of urinary tract.
- The primary end point was the overall treatment rate of VUR at 3 months and the secondary outcomes were the success rate (treated+improved) and the comparison of urodynamic parameters (pre-and post-injection).
- Data was retrieved from patient records, operation notes, clinical follow-ups and VUDS traces.
- The paired t-test was used for the intra-group and the Mann-Whitney for intergroup variability.

Results

- 74 SCI patients were identified who had either undergone unilateral or bilateral Macroplastique procedure. We studied 34 (45.9%) intervention-naïve patients who fulfilled the inclusion criteria.
- 19 patients had only Macroplastique injection (Group 1) and 15 had Macroplastique and botulinum toxin injections (Group 2).
- In total, there were 44 refluxing ureteric units (26 (59.1%) in Group 1 and 18 (40.9%) in Group 2).
- Before intervention 8/19 from Group 1 and 6/15 patients from Group 2 were on regular anticholinergics. The demographic characteristics and the baseline VUDS of both groups did not show any statistical significant differences.
- The overall treatment rate was 65.4% for group 1 and 88.9% for group 2 since 17/26 and 16/18 ureteric units showed complete resolution of VUR (p=0.029).
- The overall success rate (treated + improved) was 80.8% and 94.4% respectively (p=0.123). The results were similar at 12 months follow up. Group 1, had 4 (15.4%) ureteric units downgraded and 5 (19.2%) that failed; Group 2, had 1 ureteric unit (5.5%) downgraded and 1 failure.
- The comparison of follow up VUDS parameters showed a statistically significant rise in the detrusor pressure of group 1 (34.04 cmH₂O vs. 19.2 cmH₂O, p=0.008) and a drop in compliance (19.8 mls/cmH₂O vs 26.3 mls/cmH₂O, p=0.018) as compared to baseline.
- There were no statistical significant changes in VUDS parameters of Group 2.
- There were no immediate postoperative complications

Conclusions

- The combination of Macroplastique and botulinum toxin injections is superior to Macroplastique alone for the treatment of secondary VUR in SCI population with presumed healthy bladders.
- To our knowledge, this is the first study comparative study of Macroplastique and botulinum toxin injection versus Macroplastique alone.
- Results need to be confirmed in larger prospective trials

References:

1. Bartoli E, Niglio F, Gentile O, Penza R, Aceto G, Leggio S. Endoscopic treatment with polydimethylsiloxane in children with dilating vesicoureteric reflux. *BJU Int* 2006;96:805-808.
2. Baron M, Grise P, Cornu JN. How botulinum toxin in neurogenic detrusor overactivity can reduce upper urinary tract damage? *World J Nephrol* 2016;6:195-203.