Macrolastique and Botox are superior to Macrolastique 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 Macrolastique is effective in the treatment of secondary VUR due to neurogenic bladder¹. There is also evidence that botulinum toxin alone is effective in improving VUR².
- In this study we assess the efficacy of Macrolastique 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 Macrolastique 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 videourodynamic (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 Macrolastique procedure. We studied 34 (45.9%) intervention-naive patients who fulfilled the inclusion criteria.
- 19 patients had only Macrolastique injection (Group 1) and 15 had Macrolastique 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 Macrolastique and botulinum toxin injections is superior to Macrolastique 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 Macrolastique and botulinum toxin injection versus Macrolastique alone.
- Results need to be confirmed in larger prospective trials

References: