

RETROSPECTIVE PILOT STUDY COMPARING TREATMENT OUTCOMES OF PATIENTS WITH AND WITHOUT UNINHIBITED BLADDER CONTRACTION FOLLOWING TRIGONAL NERVE ABLATION VIA RADIOFREQUENCY ENERGY

Hypothesis / aims of study

Overactive bladder (OAB) is a prevalent disease that affects 15-21% of the population. Initial management consists of bladder training, weight loss and fluid management. If these fail, second line therapy consists of medication, like antimuscarinics or beta-3 agonists. Reports have shown that many patients taking drugs for OAB are nonadherent and nearly 75% of them discontinue treatment within one year, mainly due to the drug-related side effects, inadequate drug efficacy and poor patient education [1].

One new treatment option being investigated is fulguration of the trigonal nerves via radiofrequency ablation (RFA). RFA uses heat generated from alternating current. Three-dimensional mapping of human bladder innervation demonstrate that sensory neurons and parasympathetic fibers traverse the adventitia and penetrate the detrusor near the bladder neck at the 3 and 9 o'clock positions, around the ureteral orifices and interureteric ridge [2]. Therefore, RFA could be used specifically to treat these areas without affecting surrounding tissue.

The objectives of this institutional study were to compare clinical outcomes following RFA in female patients suffering from OAB with or without uninhibited bladder contraction (UBC) as determined by baseline urodynamic study (UDS) using a sub-set of patients from a larger multicenter study.

Study design, materials and methods

From a prospectively maintained database, we retrospectively reviewed cases of trigonal RFA at our institution. The device used for treatment is only available as part of a clinical trial. Under direct visualization of the trigone during the procedure, RF cannulae were inserted through the device followed by stabilization of the trigonal mucosa with a suction paddle. This allowed targeting of the nerves below the trigone while preserving the mucosa. RF was administered across the trigone sparing ureteral orifices. Between 3 to 6 ablations were done depending on the size of the trigone.

Patients (exclusively female) were categorized into two groups: i) presence of UBC on pre-treatment UDS (UBC+) and ii) absence of UBC (UBC-). Clinical data were available for all patients and three main post-procedural outcomes were compared between the groups at three months, namely: subjective improvement rates (SIR), 24h Pad-weight test (PWT) and number of urgency urinary incontinence/72h (UUI/72h). Baseline characteristics, voiding diaries and UDS findings between both groups were compared using Wilcoxon rank-sum tests for continuous variables and using either chi-square or Fisher exact tests for categorical variables.

Results

A total of 22 patients were enrolled. Of these, 10 were found to be UBC-. When the baseline characteristics, voiding diaries and UDS findings of patients with or without UBC were compared, no statistical differences were observed between both groups. Patients in the UBC- group reported a significantly greater 3-months SIR (70% vs 40%; $p=0.03$) than their counterparts. At 3 months, although not statistically significant, we observe a trend towards better results in the UBC- group versus UBC+ for UUI/72h (2 vs 3, $p=0.4$) and #urgency/72h (5 vs 16, $p=0.1$). PVR was not statistically different between groups after treatment (26ml vs 18ml, $p=0.3$). When stratifying groups by age, the SIR reported at 3 months was similar, but not statistically significant, for patients under 70 years old and over 70 years old (40% vs 50% respectively, $p=0.4$).

Table 1: Post operative outcomes at 3 months

Variables	UBC + (n=12)	UBC - (n=10)	P value
PWT (g)	2 (0-90)	5 (4-6)	0.5
PVR- Kt(ml)	18 (2-40)	26 (18-32)	0.3
Voids/24h (nb)	12 (10-14)	11 (9-12)	0.4
UUI /72h (nb)	3 (0-12)	2 (0-5)	0.4
#urgency/72h (nb)	16 (6-25)	5 (3-11)	0.1
SIR (%)	40 (23-65)	70 (50-80)	0.03

Interpretation of results

Our results have demonstrated that female patients who are UBC- on pre-treatment UDS have a significantly better SIR at 3 months than UBC+ patients. Voiding diary characteristics at 3-months show a trend towards better results in the UBC- group though none were statistically significant. This novel technique did not seem to put patients at risk for increased PVR at 3 months. Our data raised thoughts on patient suitability for RFA based on the presence or absence of UBC. Though both groups benefited from the treatment, one interpretation of our findings suggest UBC- patients would be better candidates for RFA of the trigonal nerves. This could relate to the underlying pathophysiology behind OAB. Patients that are UBC+ might correspond to the "myogenic theory", whereas UBC- patients may fall in the "increase sensory afferent theory"[3]. Knowing that the sensory nerves innervating the bladder are mainly derived from the bladder neck area, RFA of trigonal nerves can benefit UBC- patients since

their symptoms might be generated by sensory impulses originating from trigonal nerves. However, the mixed results and small sample size limits the interpretation of our results. Further studies with larger samples might better identify elements that would support patient selection.

Concluding message

While subjects in both groups appeared to benefit from treatment with RFA, OAB patients with UBC- on pre-treatment UDS had statistically significant improvement via SIR at 3 months following RFA treatment. This observation suggests trigonal nerve ablation may provide a greater benefit for this subset of patients with OAB refractory to medical therapy. However, as the other clinical outcomes were not significant, this is not definitive. The sample size limited the interpretation of some of the analysis. Further studies are required to validate these results.

References

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