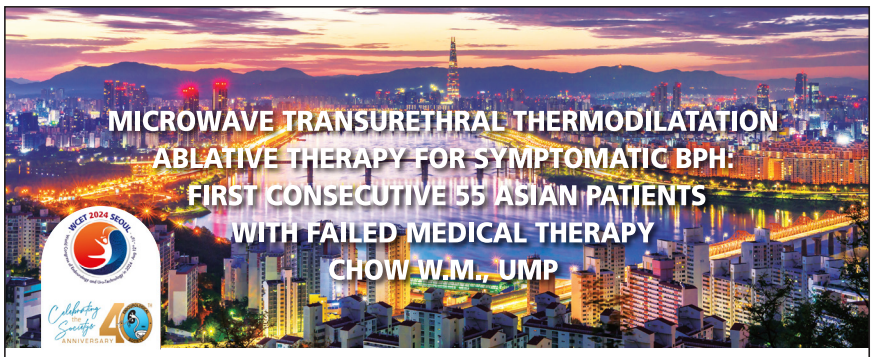

MICROWAVE TRANSURETHRAL THERMODILATATION ABLATIVE THERAPY FOR SYMPTOMATIC BPH: FIRST CONSECUTIVE 55 ASIAN PATIENTS WITH FAILED MEDICAL THERAPY

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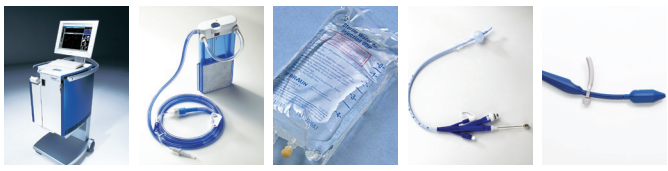
BACKGROUND:

Microwave transurethral ThermoDilatation (TUTD) offers a unique 45-minute, ambulatory outpatient procedure that is well tolerated under local anaesthesia for symptomatic benign prostatic hyperplasia (BPH) by using simultaneous focused microwave heating and pressurized balloon dilatation therapy. About 95% of patient do not require a post-treatment Foley catheter and experience significant immediate relief of their lower urinary tract symptoms (LUTS). We present our first 50 Asian patients who failed initial medical therapy clinical data pertaining to the clinical safety and efficacy of TUTD.

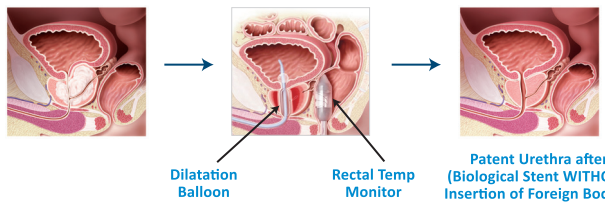
The TUTD device and accessories are presented as follows:



METHODS/MATERIALS:

From August 2018-December 2023, 55 patients (Age 52-79, mean 64) with LUTS but deteriorating symptoms on either monotherpy with alpha adrenergic blocker or combination 5-Alpha Reductase inhbitor were treated with the TUTD device, PROLIEVE. (Medifocus inc.) Their IPSS (17- 35, median 22), QOL (4-6, median 5), PSA (0.57-7.7, mean 3.5), prostatic volumes (35- 84cc, mean 65cc), Qmax (1.7-10.5 ml/s, mean 7.5ml/s) and PMRV (150-230ml, mean 190ml) were recorded pre-treatment. The parameters were reassessed at 6 weeks, 3-, and 6-months post-treatment.

The procedure is presented as follows:



RESULTS:

IPSS: 2-23 (median 12) at 6 weeks; 2-15 (median 9) at 3 months; 2-11 (median 7) at 6 month

QOL: 2-3(median 3) at 6 weeks; 2-3 (median 2) at 3 and 6 months.

Qmax: 3.6-14.9ml/s (median 10ml/s) at 6 weeks; 6.8-17.5ml/s (median 13.2ml/s) at 3 months, 7-17ml/s (median 14ml/s) at 6 months.

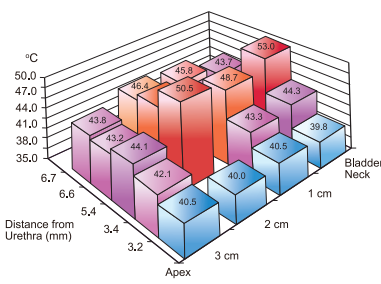
PMRV: 0-133ml (median 78ml) at 6 weeks, 0-120 ml (median 70ml) at 3 months; and 0-85ml (median 50ml) at 6 months.

Urological complications e.g., clot retention and sepsis were not observed. One patient required temporary post-treatment Foley catheterization for 72 hours. Treatment related retrograde ejaculation or erectile dysfunction has not been reported. The procedure was well tolerated under local anaesthesia. Both voiding and storage symptoms improved.

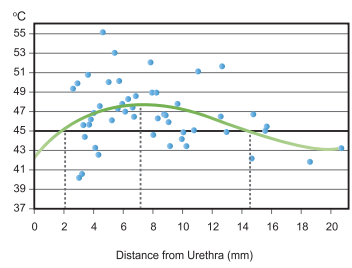
CONCLUSIONS:

Our experience with TUTD in 55 Asian patients after unsuccessful trial medication treatments compares favourably to the clinical outcomes and efficacy of the Caucasian cohort in the USFDA 5-year follow-up post-approval study. We observed initial immediate symptomatic relief with lasting post-treatment improvements into our 3 years in IPSS, QOL, Qmax and PMRV. We conclude that TUTD is safe and efficacious in the Asian population and should be offered as an option. Longterm prospective data collection in a larger patient population remains in progress. A study on the treatment of acut/chronic urinary retention is also in progress.

Prolieve® Intraprostatic Thermal Mapping Study



Tissue Ablation achieved where sustained temperatures > 45°C
Higher Temperatures near Bladder Neck & Mid-Gland than Apex



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