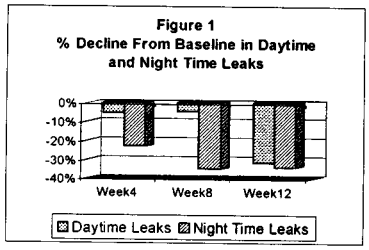
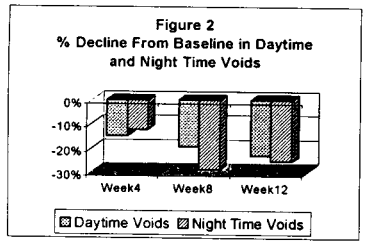
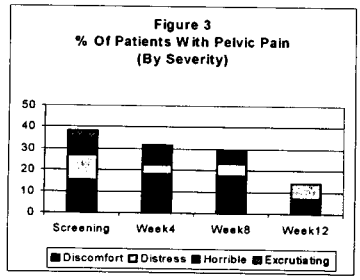
Methods: Thus far 45 patients with urgency/frequency have undergone 12 weekly outpatient treatment sessions, each lasting 30 minutes. Responders then continue according to patient specific tapering protocols. Treatment consists of percutaneous insertion of a 34-gauge solid stainless steel needle at a point (SP6) 5 cm cephalad from the medial malleolus, and just posterior to the margin of the tibia. It is advanced to the medial edge of the fibula. Electrical stimulation is applied to the needle with a low-voltage, adjustable current, external pulse generator, and to the medial surface of the calcaneous.

Results: To date, approximately 75% of patients have seen improvement in their symptoms of pelvic floor dysfunction (Figures 1-3). No study related adverse side effects were reported. Clinical results (urodynamic, voiding diary) from the prospective study to be updated and reported.

Conclusion: Percutaneous peripheral afferent nerve stimulation with the PercSANS treatment presents a minimally invasive and potentially therapeutic alternative to other current treatment options (open-surgery or pharmaceutical intervention, and the associated risks) for patients diagnosed with documented urgency/frequency due to pelvic floor dysfunction.







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FLEXIBLE DOSE STUDY WITH TOLTERODINE IN PATIENTS WITH OVERACTIVE BLADDER CONFIRMS EFFICACY AND SAFETY OF TOLTERODINE (DETROL®)

Aims of Study: Overactive bladder is a debilitating medical condition that affects millions of people worldwide. Although pharmacotherapy is the mainstay of treatment for overactive bladder, many of the established treatments are associated with side effects and poor compliance. Tolterodine is a potent,

competitive and specific muscarinic receptor antagonist that has been developed specifically for the treatment of overactive bladder. This study assessed the efficacy and safety of 2 dosage levels of tolterodine in patients with overactive bladder and was designed to mimic the patterns of dosing used with other medications for the treatment of overactive bladder.

Methods: This was a single-blind, flexible dose, 16-week study in patients with symptoms of urinary urgency and frequency with or without urge incontinence. The starting dosage of tolterodine was 1 mg BID. The dose could be increased to 2 mg BID, and subsequently decreased to 1 mg BID, based on efficacy and adverse events. Micturition diaries were collected for 72 hours at 0, 4, 8, and 16 weeks.

Results: To date in this ongoing trial, 1,380 patients have been enrolled and 950 have completed the 16-week visit. This report describes the results obtained from these 950 patients. The mean age was 62 years; 79.5% (755) were females and 20.5% (195) were males. Three dosing patterns emerged: Group I: patients who remained at 1 mg BID dose throughout the study (n = 152, 16.0%); Group II: patients who escalated to and remained on 2 mg BID dose (n = 739, 77.8%); Group III: patients who oscillated between these 2 doses (n = 59, 6.2%).

The efficacy results for the 2 mg BID group (II) is given in the table below. Significant change from baseline for all variables ($p < 0.0001$) was noted after 4 weeks of treatment and continued throughout the 16-week treatment period.

Week	Micturition /24 h	Incontinence episodes/24 h	Mean volume voided (mL)	Nocturia episodes	No. of pads used
0	11.6	3.0	174	2.0	1.7
4	10.6	1.9	191	1.7	1.2
8	10.0	1.4	207	1.7	1.1
16	9.8	1.4	208	1.6	1.0
Change Weeks 0 to 16	-1.8*	-1.6*	+34*	-0.4*	-0.7*

* $p < 0.0001$

Similar results were obtained at Week 16 for Groups I and III:

Week	Micturitions/ 24 h		Incontinence episodes/24 h		Mean volume voided (mL)		Nocturia episodes		No. of pads used	
	I	III	I	III	I	III	I	III	I	III
Change Weeks 0 to 16	-2.3*	-2.1*	-1.4*	-1.4*	+28*	+31*	-0.6*	-0.4*	-0.4*	-0.5†

* $p < 0.0001$
† $p < 0.007$

The frequencies (%) of expected adverse events as seen in registration trials are given for the 2 mg BID group in the following table.

Headache	9.9
Constipation	7.2
Dry mouth	27.2
Dyspepsia	2.7
Dry eyes	3.5
Vision abnormal	0.4
Urinary retention	0.9

The frequencies of these adverse events were in expected ranges and were similar in all 3 groups. No new previously unreported adverse events emerged.

Conclusions: As compared to baseline, all tolterodine dosing schedules significantly improved the efficacy endpoints. Significant improvement for all variables was noted at the first time point; ie, 4 weeks after treatment initiation. Tolterodine was also not shown to cause significant tolerability problems for patients. Only 27.2% of tolterodine 2 mg BID patients experienced dry mouth. The high percentage of patients on the 2 mg BID dose (78%) supports the use of tolterodine 2 mg BID as the starting dosage, as recommended in the Package Insert.

This paper is sponsored by Pharmacia & Upjohn.