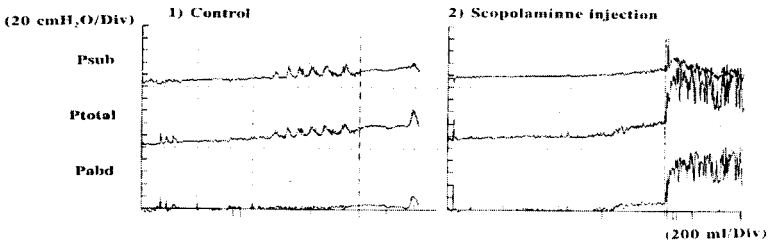
Fig.1 The effect of scopolamine on phasic contractions of an ileal neobladder



Ptotal, total reservoir pressure; Psub, subtracted reservoir pressure; Pabd, abdominal pressure

Conclusions The incidence of the phasic reservoir contraction tended to be higher in nocturnal incontinent patients than in the continent patients. Phasic contractions may therefore be one of the important factors for nocturnal incontinence. Such phasic contraction may be completely inhibited by the administration of scopolamine butylbromide in nocturnal incontinent patients. These findings show that the administration of anticholinergic agents thus appears to be an effective treatment for patients with nocturnal incontinence.

Reference

1.The Kock ileal neobladder: updated experience in 295 male patients. J Urol, 1996. **156**(3): p. 920-5.

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Title (type in CAPITAL LETTERS, leave one blank line before the text): URGE INCONTINENCE OUTCOMES IN RCTS DEPEND ON ASSUMED AND NOT ACTUAL DRUG ASSIGNMENT

Aims of Study: Efficacy of drug treatment for urinary incontinence (UI) is based on randomized controlled trials (RCTs) whose analysis depends on the assumption that subjects are blinded to their randomization. We hypothesized that blinded subjects could correctly identify their randomization to an anticholinergic agent or placebo, and that subjects' assumptions regarding randomization would effect their UI outcomes.

Methods: Data were obtained from an 8-week double-blind RCT of titrated-dose oxybutynin (OXY) vs placebo (PLC) in 88 older (mean age 71) community-dwelling persons with urodynamically-verified urge UI. Placebos were physically identical to active drug, and subjects were aware of the 3:2 oxybutynin:placebo randomization. UI outcomes were based on 72 hr voiding records obtained at baseline and the end of the trial, and subjective satisfaction using a 5-point Likert scale. At trial completion subjects were asked whether they assumed they had taken OXY or PLC. Fishers' exact test and Wilcoxon 2-sample tests were used for analyses.

Results: 81.8% of subjects correctly identified their randomization assignment (Table). Subjects taking OXY were more likely than those taking PLC to correctly identify their randomization (96% vs 61%, p<.001). Subjects who assumed they were on active drug did not differ from those who thought they were on placebo in regards to age, sex, baseline UI rate, baseline most bothersome symptom, or final drug dose during the trial. However, subjects who assumed they were on active drug had significantly better final UI rate (p<.0001) and percentage improvement in UI (p=.01) compared with subjects who thought they were on PLC, regardless of their actual randomization (p≤.01). Among subjects on OXY, those who assumed they were on PLC had virtually no change in their UI, while those who assumed they were on active drug had marked improvement (p=.01). Subjects who thought they were on active drug experienced more dry mouth (p<.001) and constipation (p=.017) and yet had better subjective improvement (83% vs 8% cured/much better, p=.001) as well as objective decrease in their UI than those who assumed they took placebo.

Table: Mean % Change in UI Episodes

	Randomized OXY	Randomized PLC
Assumed on active drug	80% decrease (n = 50)	82.6% decrease (n = 14)
Assumed on placebo	7.2% decrease (n = 2)	1.1% decrease (n = 22)

Conclusions: 1) Efficacy of anticholinergic agents for urge UI demonstrated in previous RCTs must be reinterpreted because the majority of subjects likely were not blinded; 2) Observed efficacy of drug therapy for urge UI includes an impressive placebo effect possibly driven by patients' beliefs about drug efficacy; 3) Although RCT subjects who assume they are taking active drug experience more anticholinergic side effects, their subjective and objective UI outcomes remain significantly superior to subjects who assume they are taking placebo; and 4) These results may explain the discrepancy between the observed efficacy of anticholinergic agents for urge UI and the lack of basic science and ultrastructural evidence supporting cholinergic mediation of detrusor instability.