[average of consultant and registrar rate], outside physio A$55/hr), investigations, administration, patient travel costs, and use of urinary pads. Costs were calculated over 5 years, with QALY's being discounted (2) at 6% per annum (which resulted in 5 years being discounted to 4.2124 years). At 5 years successful treatment rates were assumed for conservative treatment at 50%.

The equation for calculating cost was: [trips to the unit x trip cost] – [cost saved on pads/month x 13 x 4.2124] + [clinician costs] + [drug costs/month x 13 x 4.2124] + [administrative costs/hr x hours of visit] + [investigation costs] + [lost time from work x trips to the unit].

Results: There were no significant differences between the two groups at baseline. A number of patients did not complete the study (N= 55), with a significantly greater number not completing the UG treatment. The objective outcomes and QOL improved significantly from baseline, with no significant differences between the two groups at three months. The NCA's spent significantly longer with their patients, as would be expected from the trial design, however did not cost significantly more owing to their reduced hourly wage (A$22 vs A$80). The final cost/QALY revealed that the NCA treatment was significantly more cost effective than the UG.

	NCA (N= 76)	UG (N= 74)	P Value
Withdrawls from the study	21	34	0.03
Age (years)	57.7	59.3	NS
Parity	2.59	2.72	NS
Weight (kgs)	70.8	74.4	NS
Reduction in leaks/week	8.5	13.0	NS
Reduction in Pad Test (g/hr)	3.3	2.4	NS
QOL gain (%)	1.51	1.21	NS
Reduction of Pad Cost (A$) 2.90	3.52	NS	
Clinician Time (minutes)	186	62	0.0001
Clinician Cost (A$)	68.21	97.70	0.001
Total Cost (A$)	910	901	NS
Cost/QALY	**28,009**	**35,312**	**0.03**

Conclusions: The NCA treatment was more cost effective than the UG both in terms of the cost/QALY and also in terms of compliance to the treatment program.

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Title (type in CAPITAL LETTERS, leave one blank line before the text):

HEALTH RELATED QUALITY OF LIFE OF PATIENTS WITH OVERACTIVE BLADDER RECEIVING TOLTERODINE ONCE-DAILY

Aims of Study: This study compared the health-related quality of life (HRQOL) as measured by the Kings Health Questionnaire (KHQ) in overactive bladder (OAB) patients receiving treatment with tolterodine 4mg once-daily (tolterodine) or placebo in the largest intervention trial in OAB to date.

Methods: A randomized, parallel groups, double-blind, multinational study compared the efficacy and safety of tolterodine with placebo. OAB patients (n = 1015) with a minimum of eight micturitions/24hrs and > 5 urge incontinence episodes/wk received tolterodine 4 mg once-daily or placebo. The KHQ, self-administered at baseline and end of treatment (12 weeks), is a 33-item, disease-specific HRQoL measure designed to evaluate the impact of urinary

incontinence on HRQoL, including areas of physical and emotional function shown to be important to patients [1,2]. It is a valid, reliable measure with 20 validated language translations making it ideal for multicentre multinational clinical trials [1,2,3]. The KHQ is scored 0-100 where 0 indicates the best possible HRQoL.

Treatment comparisons were based on two primary dimensions (Role Limitations and Incontinence Impact) selected *a priori* and tested using an intent-to-treat population for whom KHQ translations were available. The Hochberg procedure was used to control for multiple comparisons [4].

Results: The tolterodine group experienced statistically significant improvement in both Incontinence Impact and Role Limitations scores compared with the placebo group. Role Limitations includes the ability to perform household tasks, perform work, and carry out other normal daily activities. Patients in the tolterodine group also experienced statistically significant improvement in the Severity (coping) Measures, Physical Limitations, Sleep and Energy, and Symptom Severity scores versus the placebo group.

End of Treatment Differences (Adjusted for Age, Gender, and Baseline Score)

KHQ Domains	Tolterodine vs Placebo	p-value
Incontinence Impact	-6.75*	0.0002
Role Limitations	-7.36*	0.0001
Physical Limitations	-6.43*	0.0003
Social Limitations	-2.50	0.0622
Personal Relationships	-1.38	0.4460
Emotions	-2.40	0.1062
Sleep and Energy	-3.85*	0.0060
Severity (coping) Measures	-5.58*	0.0001
General Health Perception	-0.13	0.8995
Symptom Severity	-1.46*	0.0001

* Statistically significant using Hochberg procedure with an initial $p \leq 0.05$ and rejection of H_0 if $p_k \leq \alpha/k$

Conclusions: Compared to placebo, tolterodine 4mg once-daily significantly improves the quality of life of patients with overactive bladder, as evidenced by the statistically significant changes in the key dimensions of Role Limitations and Incontinence Impact. Tolterodine patients also experienced statistically significant changes in the Severity (coping) Measures, Physical Limitations, Sleep and Energy, and Symptom Severity domains compared with the placebo group. These results also reconfirm that the KHQ is a sensitive condition-specific HRQoL questionnaire which can be utilized successfully in multinational multicentre studies of OAB.

References

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3. Quality-of-life aspects of the overactive bladder and the effect of treatment with tolterodine. *BJU Int* 1999;83:583-590.

4. Some comments on frequently used multiple endpoint adjustment methods in clinical trials. *Stat Med* 1997;16:2529-2542.

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Title (type in CAPITAL LETTERS, leave one blank line before the text):
PSYCHOMETRIC ASSESSMENT AND RESPONSIVENESS OF THREE DIFFERENT HRQoL INSTRUMENTS IN FEMALE URINARY INCONTINENCE

Aims of Study
Subjective measurements of urinary incontinence (UI) severity, and symptom impact on health-related quality of life (HRQoL) as well as assessment of treatment efficacy from the patients' point of view is now recognized as an important aspect, both in clinical practice and research (1).
The purpose of this study was psychometric assessment and functional correlation of three different types of HRQoL measurements: 1. A generic 15D-QoL questionnaire, *2.* A disease-specific Urinary Incontinence Severity Score (UISS)- questionnaire and 3. The visual analogue scale (VAS). The latter is also an accepted tool in research concerning measurement of the impact of disease and effects of medical interventions on HRQoL. However, the studies of the reliability and responsiveness of the VAS designed to measure subjective evaluation of female urinary incontinence are lacking.

Study Methods
This prospective study involved 82 incontinent females suffering of urinary incontinence (mean age 52,range 25-80) referred to a gynaecological department and 29 control women who had urinary incontinence but were not bothered by it and didn't want any medical intervention. All women underwent a standardised 48h pad-testing and frequency/volume chart and 82 patients had complete urodynamic evaluation. 57 (68%) patients had stress,14 (17%) had urge, 11 (13%) mixed incontinence.
All subjects completed the above mentioned quality of life measures. The 15D –generic standardised measure of HRQoL contains fifteen-dimensions :moving, seeing, hearing, breathing, sleeping, eating, communicating, eliminating, working, social participation, mental functioning, pain/ache, depression, distress and perceived health. The score is on a 0-1 scale (0=death, 1=best HRQOL)(2). The UISS questionnaire consists of 10 questions designed to quantify the amount of leakage and the degree to which UI affects aspects of women's daily lives scored 0-2 and yielding a total score between 0 and 20. The women were asked to describe the subjective burden of incontinence on a 100 mm VAS scale which ranged from 0," not bothered" to 10 "severely bothered".
For the UISS and VAS reproducibility assessment women were asked to complete questionnaires again 1 week later. After accurate diagnosis was established, all patients were given conservative or operative treatment according to severity and type of urinary incontinence.
66 patients were re-evaluated 13 months (range 6-21) after the initial examination and initiation of the treatment plan. The patients were classified on the basis of pad test as improved (decreased leakage), stable (no change) or deteriorated (increased leakage). Responsiveness was measured by Guyatt's statistic that is the ratio of the mean change score for each group divided by the standard deviation for the stable group. A statistic of 1.00 or greater (or-1 or less when improvement is denoted by a negative change score) is considered indicative of a measure highly responsive to change.

Results
Internal consistency of UISS measured by Cronbach's alpha was high 0.85. Test-retest correlation for UISS was 0.88 (Spearman rank correlation coefficient $p<0.001$) and for VAS 0.85 ($p<0.001$). There were no differences between UISS, VAS and 15D scores for patients with different diagnoses of UI. The control women's UISS, 15D and VAS scores were significantly lower than patient's scores ($p<0.001$, Mann-Whitney *U* test) which proves good discriminant validity of these measures. The correlation between the scores of the UISS and VAS was strong: at baseline $r=0.73$; after treatment $r=0.85$. UISS and VAS correlations with the total score of the 15D was moderate: $r = -0.45$($p<0.001$) and $r = -0.23$ ($p=0.016$) in the baseline and $r = -0.50$ ($p<0.001$) and $r = -40$ ($p=0.001$) in the follow-up.
The correlation between pad test and UISS, VAS and 15D at baseline was: 0.59(Spearman rank correlation coefficient $p<0.001$), 0.67 ($p<0.001$) and 0.29 ($p=0.004$) respectively. 49 patients were improved after treatment, 12 patients had no change and in 5 patients had deteriorated. The UISS, VAS and 15D in the improved group had responsiveness (Guyatt's) statistics: 1.48, 1.74 and –0.80 respectively. The changes in pad test correlated moderately well with those in the VAS ($r=0.50$ $p<0.001$Spearman) and with those in the UISS ($r=0.30$ $p=0.040$). For the changes in the eliminating dimension of the 15D the correlation was –0.29 ($p=0.035$) but there was no correlation for changes in the total 15D score.