

Articles in Literature Using the I-QOL from January 1, 1996 to February 27, 2013

Almeida, F. G., H. Bruschini, et al. (2004). "Urodynamic and clinical evaluation of 91 female patients with urinary incontinence treated with perineal magnetic stimulation: 1-year followup." *J Urol* **171**(4): 1571-1574; discussion 1574-1575.

PURPOSE: We evaluate the perineal magnetic stimulation (PMS) effect on continence and quality of life in women with urinary incontinence. **MATERIALS AND METHODS:** We prospective studied 91 women with demonstrable urinary incontinence treated with 16 sessions of PMS. Pretreatment and posttreatment evaluation was done by clinical history, physical examination, voiding diary, validated quality of life survey (I-QOL) and urodynamic study (UDS). Patients with no leakage after treatment were evaluated at 3, 6 and 12 months. **RESULTS:** Mean patient age +/- SD was 60.5 +/- 10.1 years. Immediately after treatment the I-QOL score increased 35% ($p < 0.001$), the number of pads daily decreased 40% ($p < 0.001$), the number of leaks daily decreased 54% ($p < 0.001$) and 34 patients (37%) became dry. Of the 91 patients 41 were evaluated before and after treatment by UDS. The average increase in vesical leak point pressure (VLPP) was 24.3% ($p = 0.001$) and initial VLPP in patients who became dry was greater than 80 cm H₂O. After treatment 77% of patients with initial low pressure detrusor overactivity on UDS became free of this condition. One year after discontinuing PMS 94% of patients who became dry immediately after treatment had recurrence. **CONCLUSIONS:** Immediately after 16 sessions of PMS women with urinary incontinence have significant improvement in the I-QOL score with decreased daily pad use and leakage episodes but 63% had failure. Therapy is more effective in patients with a VLPP of greater than 80 cm H₂O. The beneficial effect is temporary with high and early recurrence after discontinuing treatment.

Anifantaki, S., T. M. Filiz, et al. (2009). "Does urinary incontinence affect quality of life of Greek women less severely? A cross-sectional study in two Mediterranean settings." *Qual Life Res* **18**(10): 1311-1319.

OBJECTIVE: Numerous studies have identified a reduced health-related quality of life (QoL) in patients with urinary incontinence (UI). The aim of this study was to assess and compare QoL in women with UI in the island of Crete, Greece, and in Turkey. **METHODS:** Incontinent women from two community-based primary health care (PHC) groups (Greece and Turkey) and one outpatient clinic-based group were studied. **RESULTS:** A total of 231 (24.7%) women out of 932 women from the PHC group in Greece and Turkey reported UI whereas another 38 incontinent women visited the secondary care outpatient clinic. Mean Incontinence Quality of Life questionnaire (I-QoL) total score of women visiting PHC centers was 73.8 (SD = 23.5). There was significant difference among the three groups regarding I-QoL total and subscale scores, with women from the Greek community-based group having the highest score (mean = 81.8, SD = 20.7, $P < 0.001$). Impaired QoL was significantly associated with severity ($P < 0.001$), incontinence type ($P = 0.026$), seeking secondary care, and Turkey as

sample setting ($P < 0.001$). CONCLUSION: Urinary incontinence is a frequent problem for women visiting PHC centers, affecting negatively their quality of life. Besides incontinence severity, Turkey as place of residence emerged as another essential predictor of impaired quality of life, suggesting that other social and cultural factors may also play an important role.

Appell, R. A., S. Juma, et al. (2006). "Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence." Neurourol Urodyn **25**(4): 331-336.

AIMS: This prospective, randomized, controlled clinical trial was performed to demonstrate the 12 months safety and efficacy of transurethral radiofrequency energy (RF) collagen micro-remodeling in women with stress urinary incontinence (SUI). MATERIALS AND METHODS: Women with SUI, bladder outlet hypermobility, and leak point pressure (LPP) $>$ or $=60$ cmH₂O were randomized to RF micro-remodeling or "sham treatment." Adverse events (AEs) were recorded. Incidence of $>$ or $=10$ point incontinence quality of life (I-QOL) score improvement, a magnitude of improvement with a demonstrated responsiveness to patient satisfaction with treatment and to $>$ or $=25\%$ reduction in both incontinence episode frequency and stress pad weight, served as a subjective outcome measurement. Change in mean LPP served as an objective outcome measurement. RESULTS: 110 women underwent RF micro-remodeling and 63 underwent virtually identical "sham treatment" (with the exception of RF delivery). The 12 months RF micro-remodeling safety profile was statistically no different than that of sham treatment (a brief bladder catheterization). Seventy-four percent of women with moderate to severe baseline SUI experienced $>$ or $=10$ point I-QOL score improvement at 12 months ($P = 0.04$). Women who underwent RF micro-remodeling demonstrated LPP elevation at 12 months, while sham treated women demonstrated LPP reduction ($P = 0.02$). CONCLUSIONS: Non-surgical, transurethral RF micro-remodeling is a safe treatment for women with SUI. In women with moderate to severe SUI, this novel therapy resulted in statistically significant improvement in quality of life of a magnitude associated with patient satisfaction with the treatment. Women who underwent RF micro-remodeling demonstrated a statistically significant elevation in mean LPP at 12 months.

Appell, R. A., G. Singh, et al. (2007). "Nonsurgical, radiofrequency collagen denaturation for stress urinary incontinence: retrospective 3-year evaluation." Expert Rev Med Devices **4**(4): 455-461.

Transurethral radiofrequency collagen denaturation, a nonsurgical treatment for stress urinary incontinence, reduces regional dynamic tissue compliance without causing tissue necrosis or gross tissue shrinkage, unlike transvaginal radiofrequency tissue ablation. This retrospective study evaluated long-term safety and efficacy in 21 patients from a 12-month, randomized controlled trial utilizing 3-day diaries and the Incontinence Quality of Life (I-QOL) survey. Significant increases in overall I-QOL scores 3 years or more post treatment was the primary end point. Secondary end points were reductions in frequency and

severity of incontinence episodes. After 3 years, mean overall I-QOL score improvement was 12.7 (+/-26); 56% of patients achieved 50% or more reduction in frequency. No new adverse events occurred. These results indicate that radiofrequency collagen denaturation is safe and provides durable efficacy.

Bakar, Y., O. Cinar Ozdemir, et al. (2011). "The use of extracorporeal magnetic innervation for the treatment of stress urinary incontinence in older women: a pilot study." Arch Gynecol Obstet **284**(5): 1163-1168.

PURPOSE: Stress urinary incontinence (SUI) is a major health problem that has substantial and important effects on health-related quality of life. In recent years, extracorporeal magnetic innervation (ExMI) has become a preferred method of treatment in urinary incontinence. This study presents the effects of ExMI treatment on pelvic floor muscle strength, urinary symptoms, incontinence conditions and quality of life of older women with SUI. **METHODS:** A total of 13 patients between the ages of 61 and 69 (mean 65.23 +/- 2.8 years) were treated for SUI with ExMI. The following parameters were investigated: urinary symptoms, pelvic floor electromyographic (EMG) activity, 1-h pad test, incontinence conditions utilizing visual analog scale (VAS) and quality of life using Turkish version of the Urogenital Distress Inventory (UDI-6) and the Incontinence Quality of Life Instrument (I-QoL). All assessments were conducted at baseline and at the end of the study. Treatment lasted for 20 min, twice a week and for a total of 6 weeks. **RESULTS:** The urinary symptoms and incontinence conditions decreased after the ExMI treatment sessions. The pad test results indicated a reduction in urine loss ($p = 0.016$). EMG values were improved ($p = 0.005$). Scores of I-QoL, UDI-6 and VAS were reduced after the treatment, respectively ($p = 0.002$), ($p = 0.002$) and ($p = 0.006$). **CONCLUSION:** Extracorporeal magnetic innervation can be considered as it is an alternative, non-invasive and painless treatment method with good compliance for treatment of SUI in older patients.

Basak, T., S. Uzun, et al. (2012). "Incontinence features, risk factors, and quality of life in Turkish women presenting at the hospital for urinary incontinence." J Wound Ostomy Continence Nurs **39**(1): 84-89.

PURPOSE: The aim of this study was to determine the characteristics, risk factors, and quality of life among women presenting at a urology outpatient department for evaluation and management of urinary incontinence (UI). **METHODS:** The target population comprised women with a complaint of UI during a 1-year period presenting at the urology outpatient department of a training hospital in Ankara, Turkey. A data collection form was developed by the authors based on literature review. Validated instruments, including the International Consultation on Incontinence Questionnaire Short Form and the Incontinence Quality of Life Scale (I-QOL), were included in the questionnaire. **RESULTS:** Women aged 45 to 54 years made up 36.4% of the sample. Women reported stress UI symptoms (21.8%), urge UI symptoms (23.6%), and mixed UI symptoms (45.5%). Sixty percent stated that they experienced UI episodes several times daily, 38.2% experienced UI in large amounts, and 21.8% had

experienced UI for 11 years or longer. Women suffering from UI had a total I-QOL median score of 46.36 (interquartile range = 28.18). It was found that UI moderately affects the quality of life in the Turkish women. **CONCLUSIONS:** Urinary incontinence exerts a major influence on health-related quality of life in affected women. Mixed UI was associated with the greatest level of social embarrassment assessed by the I-QOL.

Bauer, R. M., M. E. Mayer, et al. (2009). "Prospective evaluation of the functional sling suspension for male postprostatectomy stress urinary incontinence: results after 1 year." *Eur Urol* **56**(6): 928-933.

BACKGROUND: Although surgical techniques for radical prostatectomy (RP) have been refined significantly, a significant number of patients still suffer from persisting postprostatectomy stress urinary incontinence (SUI). In recent years, various minimally invasive sling systems have been investigated as treatment options for such incontinence. **OBJECTIVE:** The aim of the study was the prospective evaluation of the efficacy of the retrourethral transobturator sling for the functional treatment of male SUI after RP. **DESIGN, SETTING, AND PARTICIPANTS:** The study documents a single-centre prospective evaluation of the outcome of 124 patients with mild to severe SUI following RP in whom an AdVance sling was implanted between February 2006 and September 2008. **MEASUREMENTS:** All patients were comprehensively evaluated preoperatively and after 6 mo and 1 yr regarding daily pad use, 1-h and 24-h pad tests, residual urine, uroflowmetry, Incontinence Quality of Life Scale (I-QOL) score, and Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) score. Data were collected prospectively. **RESULTS AND LIMITATIONS:** After 6 mo, a cure rate (no pads or one dry security pad) of 55.8%, an improved rate (one to two pads or pad reduction $\geq 50\%$) of 27.4%, and a failure rate of 16.8% were observed. After 1 yr, the cure rate was 51.4%, the improved rate was 25.7%, and the failure rate was 22.9%. Daily pad use and pad weight decreased significantly postoperatively. No significant changes were seen in residual urine and flow rate. Quality-of-life scores improved significantly. Postoperative acute urinary retention was seen in 12.9% of patients. One patient had a local wound infection that was cured with antibiotics. One patient had the sling removed due to misplacement. **CONCLUSIONS:** The retrourethral transobturator sling is an effective and attractive treatment option for male SUI resulting from RP after 1 yr of implantation.

Bauer, R. M., I. Soljanik, et al. (2011). "Results of the AdVance transobturator male sling after radical prostatectomy and adjuvant radiotherapy." *Urology* **77**(2): 474-479.

OBJECTIVES: To prospectively evaluate the efficacy of the functional AdVance transobturator sling for the treatment of male stress urinary incontinence (SUI) in patients after radical prostatectomy and additional adjuvant radiotherapy. **METHODS:** Between February 2007 and November 2008, 24 patients with postprostatectomy SUI (ICS grade 2-4) and additional adjuvant radiotherapy were treated consecutively with the AdVance sling. Preoperatively, intensive workup, including urodynamic assessment and flexible urethroscopy, was

performed. Physical examinations (pad test, uroflowmetry, ultrasound) and questionnaires (I-QOL score, ICIQ-UI-SF score) were performed during baseline and during follow-up. Cure rate was defined as no pad use or one dry pad, and improved rate as 1-2 pads or reduction of pads by $\geq 50\%$. RESULTS: After a median follow-up of 18.0 months (range 12-33 months, mean 18.8 months), the success rate was 50%. Daily pad use and pad weight in the 1-hour pad test decreased significantly. Patients with ICS grade 2 SUI exhibited a trend for a better success rate in comparison with patients with grade 3 and 4 SUI. Results were durable over time. Postoperatively, 16.7% of the patients exhibited transient acute urinary retention which resolved without further treatment after a maximum of 6 weeks. 1 sling had to be removed because of initial misplacement. CONCLUSIONS: In selected patients after adjuvant radiotherapy, the AdVance sling achieved a success rate of 50% and results were stable in a median follow-up of 18 months. Complication rates were low and comparable to complication rates for patients without additional radiotherapy.

Bent, A. E., A. E. Gousse, et al. (2008). "Duloxetine compared with placebo for the treatment of women with mixed urinary incontinence." *Neurourol Urodyn* **27**(3): 212-221. AIMS: Evaluate duloxetine in the treatment of women with mixed urinary incontinence (MUI). MATERIALS AND METHODS: 588 women, 19-85 years old with ≥ 4 incontinence episodes/week were randomly assigned to duloxetine 80 mg/day (N = 300) or placebo (N = 288). Patients were classified into three symptom subgroups: stress or urge predominant MUI (SPMUI or UPMUI) or balanced MUI (BMUI) based on their responses to the validated Stress/Urge Incontinence Questionnaire. Half the population was randomly assigned to have urodynamics; SPMUI, UPMUI, and BMUI condition diagnoses were based on signs, symptoms, and urodynamic observations. The primary outcome measure was the change in incontinence episode frequency (IEF). Secondary outcome measures included the Incontinence Quality of Life (I-QOL) scores, the ICIQ Quality of Life (ICIQ-SF) score, and the Patient Global Impression of Improvement (PGI-I) rating. RESULTS: At baseline, women with SPMUI averaged 15.9 IEF/week (61% stress), those with UPMUI averaged 13.2 (70% urge), and those with BMUI averaged 16.5 (52% urge). Overall IEF decreases were significantly greater with duloxetine than placebo (median percent reduction 60% vs. 47%, $P < 0.001$); both UUI and SUI episodes were significantly decreased with duloxetine (median SUI IEF reduction 59% vs. 43%, $P = 0.001$; UUI IEF reduction 58% vs. 40%, $P < 0.001$). Duloxetine IEF decreases were significantly greater for patients with SPMUI conditions and symptoms and for those with UPMUI conditions but not symptoms. Significant benefits were also demonstrated with duloxetine for improvements in I-QOL total score (11.5 points vs. 8.1 points, $P = 0.002$), all three I-QOL subscale scores, and for the ICIQ-SF score (-2.6 vs. -1.7, $P = 0.002$) as well as for PGI-I ratings (much/very much better 44.2% vs. 27.3%, $P = 0.001$). CONCLUSION: Duloxetine demonstrated significant efficacy in this population of women with MUI.

Bump, R. C., P. A. Norton, et al. (2003). "Mixed urinary incontinence symptoms: urodynamic findings, incontinence severity, and treatment response." Obstet Gynecol **102**(1): 76-83.

OBJECTIVE: To investigate the relationship between the symptom of mixed urinary incontinence and incontinence severity, urodynamic findings, and treatment response. **METHODS:** This is a secondary analysis of data from 553 women randomized into a double-blind, placebo-controlled study evaluating duloxetine (serotonin-norepinephrine reuptake inhibitor) for the treatment of predominant stress urinary incontinence. Assessment variables included incontinent episode frequency, the Incontinence Quality of Life Questionnaire (I-QOL), and the Patient Global Impression of Severity Scale (PGI-S). Urge symptoms were identified with three urge I-QOL questions not included in corrected I-QOL calculations. **RESULTS:** At baseline, 171 women (31%) had mixed urinary incontinence. They had more severe baseline urinary incontinence than did those with stress urinary incontinence (mean incontinent episode frequency 14.3 versus 10.5; PGI-S normal or mild 26.5% versus 70.4%; mean corrected I-QOL 59.1 versus 79.9; all P s <.001). Baseline urodynamics were performed on a subset of 86 women. Subjects with both urodynamic stress incontinence and detrusor overactivity had less severe incontinence compared with subjects with only urodynamic stress incontinence. Both mixed urinary incontinence and stress urinary incontinence groups had significant decreases in median incontinent episode frequency at a 40 mg per day (62% and 58%, respectively) and 80 mg per day (63% and 65%) duloxetine dose compared with placebo (33% and 44%; all P s <.05). Response was not dependent on the type of symptoms (interaction P =.47). **CONCLUSION:** For women presenting with predominant stress urinary incontinence symptoms, the major determinant of concurrent urge symptoms was incontinence severity and not the pathophysiologic condition(s) causing the incontinence; duloxetine demonstrated equal efficacy for women with mixed urinary incontinence and pure stress urinary incontinence.

Bushnell, D. M., M. L. Martin, et al. (2005). "Quality of life of women with urinary incontinence: cross-cultural performance of 15 language versions of the I-QOL." Qual Life Res **14**(8): 1901-1913.

Urinary incontinence (UI) has substantial and important impacts on health-related quality of life. The purpose of this research is to report the psychometric performance of 15 different language versions of the Incontinence-specific Quality of Life (I-QOL) measure, a patient-reported outcome measure specific to stress, urge and mixed urinary incontinence. The multi-national dataset consisted of data from four clinical trials for stress incontinent females and from two additional population studies, enrolling women with stress, urge and mixed UI. All enrolled patients completed the I-QOL and comparative measures at baseline. The clinical trial populations had multiple administrations up to 12 weeks, and the two population studies included a shorter retest. Country-specific psychometric testing for validity, reliability, and responsiveness followed standardized procedures. Confirmatory factor analyses were performed to assess the I-QOL

subscales. The I-QOL measurement model was confirmed as three subscales. Summary and subscale scores for the 15 versions were internally consistent (alpha values = 0.91-0.96) and reproducible (ICC = 0.72-0.97). Using changes in the independent measures of incontinence episode frequency standardized response means were predominantly strong (ranged 0.71-1.05) across 13 versions (out of 15) in association with these measures and effect sizes. These additional language versions of the I-QOL instrument demonstrate psychometric properties similar to the original version. The I-QOL has shown good results in both community studies and clinical trials with varying types and severity of urinary incontinence. It is a reliable and valid measure of HRQOL, suitable for use in a variety of international settings.

Campeau, L., L. M. Tu, et al. (2007). "A multicenter, prospective, randomized clinical trial comparing tension-free vaginal tape surgery and no treatment for the management of stress urinary incontinence in elderly women." *Neurourol Urodyn* **26**(7): 990-994.

AIMS: The aim of our study was to test the hypothesis that elderly women undergoing tension-free vaginal tape surgery (TVT) will have a better quality of life (QOL) and satisfaction compared to non-treated women despite age- and technique-related potential morbidity. METHODS: This multicenter, prospective, randomized, controlled trial enrolled a total of 69 women aged over 70 years who initially consented to be randomized to either undergo immediate TVT surgery or to wait for 6 months before submitting to the same surgery (control group). The main outcomes measured at every visit (pre-randomization, 8-12 weeks and 6 months) consisted of the Incontinence-Quality of Life (I-QOL) Questionnaire, the Patient Satisfaction Questionnaire and the Urinary Problems Self-assessment Questionnaire, among others. RESULTS: The analysis included 31 patients in the immediate surgery group and 27 subjects in the control group. Peri-operative complications in the immediate surgery group were bladder perforation (22.6%), urinary retention (12.9%), urinary tract infection (3.2%) and de novo urgency (3.2%). At 6 months, the mean I-QOL scores for the TVT and control groups were respectively 96.5 +/- 15.5 and 61.6 +/- 19.8 ($P < 0.0001$); mean Patient Satisfaction scores were respectively 8.0 +/- 2.7 and 2.0 +/- 2.4 ($P < 0.0001$); and mean Urinary Problems scores were respectively 4.5 +/- 4.3 and 11.6 +/- 3.5 ($P < 0.0001$). CONCLUSION: At 6 months post-randomization, the group of elderly women who underwent immediate TVT surgery showed a significant improvement in QOL, patient satisfaction and less urinary problems compared to the group of women waiting for the same surgery.

Cardozo, L., H. P. Drutz, et al. (2004). "Pharmacological treatment of women awaiting surgery for stress urinary incontinence." *Obstet Gynecol* **104**(3): 511-519.

OBJECTIVE: Duloxetine, a serotonin/norepinephrine reuptake inhibitor, has been effective in the treatment of mild and moderate stress urinary incontinence. The aim of this trial was to assess its efficacy for women with severe stress urinary incontinence. METHODS: One hundred nine women, aged 33-75 years, enrolled into this double-blind, randomized, placebo-controlled study. Subjects had to have a predominant symptom of stress urinary incontinence with an incontinence

episode frequency 14 per week or more, pure urodynamic stress urinary incontinence, and continence surgery already scheduled. Women were randomized to placebo (n = 54) or duloxetine 80 mg/d (n = 55) for 4 weeks, escalated to 120 mg/d for 4 weeks. Assessment variables included incontinence episode frequency, continence pad use, the Incontinence Quality of Life (I-QOL) questionnaire, and the Willingness to Consider Surgery rating. A responder was defined as a subject with an incontinence episode frequency reduction of 50% or more. RESULTS: There were significant improvements with duloxetine compared with placebo in incontinence episode frequency (-60% versus -27%, $P < .001$), I-QOL score (+10.6 versus +2.4, $P = .003$), and pad use (-34.5% versus -4.8%, $P = .008$). At the conclusion of the 8-week study, 10/49 (20%) duloxetine-treated women were no longer interested in surgery, compared with 0/45 placebo-treated women ($P = .001$). Duloxetine-treated subjects were significantly more likely to be classified as responders (relative risk 4.68, 95% confidence interval 2.27-9.66). The number of subjects-needed-to-treat to gain an additional incontinence episode frequency responder with duloxetine was 2.02. All duloxetine responses were observed within 2 weeks. Side effects and discontinuations because of side effects were significantly more common with duloxetine. CONCLUSION: The data support duloxetine's efficacy in women with severe stress urinary incontinence and suggest that some women responding to duloxetine may reconsider their willingness to undergo surgery.

Castro, R. A., R. M. Arruda, et al. (2008). "Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence." Clinics (Sao Paulo) **63**(4): 465-472.

PURPOSE: To compare the effectiveness of pelvic floor exercises, electrical stimulation, vaginal cones, and no active treatment in women with urodynamic stress urinary incontinence. PATIENTS AND METHODS: One hundred eighteen subjects were randomly selected to receive pelvic floor exercises (n=31), ES (n=30), vaginal cones (n=27), or no treatment (untreated control) (n=30). Women were evaluated before and after completion of six months of treatment by the pad test, quality of life questionnaire (I-QOL), urodynamic test, voiding diary, and subjective response. RESULTS: In the objective evaluation, we observed a statistically significant reduction in the pad test ($p=0.003$), in the number of stress urinary episodes ($p<0.001$), and a significant improvement in the quality of life ($p<0.001$) in subjects who used pelvic floor exercises, electrical stimulation, and vaginal cones compared to the control group. No significant difference was found between groups in the urodynamic parameters. In the subjective evaluation, 58%, 55%, and 54% of women who had used pelvic floor exercises, electrical stimulation, and vaginal cones, respectively, reported being satisfied after treatment. In the control group, only 21% patients were satisfied with the treatment. CONCLUSION: Based on this study, pelvic floor exercises, electrical stimulation, and vaginal cones are equally effective treatments and are far superior to no treatment in women with urodynamic stress urinary incontinence.

Chaisaeng, S., A. Santingamkun, et al. (2006). "IQOL: translation & reliability for use with urinary incontinence patients in Thailand." J Med Assoc Thai **89** **Suppl 3**: S33-39.

BACKGROUND AND OBJECTIVE: Urinary incontinence is consistently associated with an adverse effect on the quality of life (QoL) for patients. The I-QOL is a self-report quality-of-life measure specific to urinary problems that can be used to assess the impact of urinary incontinence and urinary problems (such as overactive bladder without incontinence) and their treatment. The objectives of the present study were to develop and test the reliability of a Thai version of the Incontinence Quality of Life Questionnaires (IQOL). **MATERIAL AND METHOD:** The I-QOL was formally translated from the original version to the Thai language with Permission. The translation process included forward translation by 2 translators. Cultural and linguistic modifications of both forward versions were done by a group of urologists who had extensive experience in the management of urinary incontinence. Another two Thai-English translators performed the back translation into English. Enrolled subjects included urinary incontinence patient and normal subjects were asked to complete the translated versions of I-QOL and repeated the same two weeks apart for test-retest analysis. Reliability was determined from Cronbach's alpha (reliability coefficient). Pearson's correlation was used to assess test-retest reliability. **RESULTS:** A 22 items questionnaire was developed. Sixty patients with urinary incontinence and fifty normal subjects were enrolled into the present study. Mean ages (SD) of patients with incontinence and controlled groups were 52.42(13.54) and 48.22(10.27) years. Of the 60 patients with urinary problems, 15(13.6%) had stress urinary incontinence (SUI), 17(15.5%) had overactive bladder (OAB), 13(11.8%) had mixed urinary incontinence, 15(13.6%) had urge urinary incontinence from BPH. The mean scores(SD) of I-QOL in the normal group was 89.63(12.64) and 57.65(20.04) in the urinary incontinence group. Cronbach's alpha of the overall IQOL scores was 0.96. Test-retest reliability done at 2 weeks apart was 0.905. **CONCLUSION:** The translated I-QOL is valid and applicable in Thais with urinary incontinence problems. I-QOL score reveals that QOL in these patients is lower than that in the normal population.

Chartier-Kastler, E., P. Costa, et al. (2007). "[French multicentre prospective study of the use of ACT balloons (Uromedica, Inc., Plymouth, Min, U.S.A.; Medtronic, Minneapolis, U.S.A.) for the treatment of female stress urinary incontinence]." Prog Urol **17**(7): 1372-1377.

OBJECTIVE: French multicentre prospective study to evaluate the efficacy and feasibility of ACT (Adjustable Continence Therapy) balloons for the management of female stress urinary incontinence (SUI). **MATERIALS AND METHODS:** The ACT system comprises two adjustable balloons implanted on either side of the bladder neck in order to restore continence. The feasibility of this technique was evaluated perioperatively. Adverse events were recorded to evaluate the acceptability of the technique. Evaluation of efficacy was based on individual interviews to determine the severity of incontinence (use of pads and quality of life questionnaire (I-QoL)) and by Direct Visual Stress Testing (DVST). **RESULTS:** 68 patients with SUI were included. The mean operating time was

31.8 +/- 11.7 minutes. The ACT was implanted with no particular difficulties in 91% of cases. Evaluation of patients (mean follow-up: 2 years) after implantation revealed a marked improvement of incontinence (87%), DVST (85%) and I-QoI (score: 75/100). The ACT was removed in 18 patients for various reasons and was reimplanted in 6 cases. The ACTI was removed in 8 patients at their request due to complete absence of efficacy. CONCLUSION: ACT balloon implantation is a new, reversible and promising minimally invasive technique for the management of female stress urinary incontinence. The possibility of percutaneous adjustment of the size of the balloons according to clinical efficacy appears to be an essential advantage of this technique.

Chen, G. and L. Liao (2011). "Injections of Botulinum Toxin A into the detrusor to treat neurogenic detrusor overactivity secondary to spinal cord injury." Int Urol Nephrol **43**(3): 655-662.

BACKGROUND: To present a comprehensive experience of botulinum toxin A (BTX-A) injected into the detrusor muscle in patients with spinal cord injuries (SCI) causing neurogenic detrusor overactivity. METHODS: Three hundred units of BTX-A were injected cystoscopically into the detrusor muscle of 108 patients with neurogenic detrusor overactivity secondary to SCI at 30 different locations. Evaluations were performed before the injections and 6 weeks after, and they included determination of bladder urinary continence status, frequency/volume chart of CIC, concomitant anticholinergic medication use, Incontinence Quality of Life questionnaire (I-QOL) and patient satisfaction. Key urodynamic parameters (reflex volume, maximum detrusor pressure during voiding, detrusor compliance and maximum cystometric capacity) were analyzed at the outset and during the follow-up (6, 12 and 36 weeks) examinations. RESULTS: By the time of the urodynamic follow-up examinations (6, 12 and 36 weeks), the mean cystometric capacity ($P < 0.05$) and the mean reflex volume ($P < 0.05$) increased significantly, while the mean voiding pressure ($P < 0.05$) decreased significantly. No complications or side effects were reported. Most patients considerably reduced or even stopped taking anticholinergic drugs and were satisfied with the treatment. CONCLUSIONS: This retrospective study indicates that BTX-A injections into the detrusor muscle to treat neurogenic detrusor overactivity secondary to SCI are safe and valuable. Significant improvement of bladder function corresponded with continence and subjective satisfaction indicated by the treated patients.

Chen, T. Y., Y. Ponsot, et al. (2005). "Multi-centre study of intraurethral valve-pump catheter in women with a hypocontractile or acontractile bladder." Eur Urol **48**(4): 628-633.

OBJECTIVES: To compare the safety, effectiveness and patient satisfaction of an intraurethral valve-pump catheter (In-Flow) versus the current standard of care, clean intermittent catheterization (CIC), for females with hypocontractile or acontractile bladder. MATERIALS AND METHODS: The study was a multi-centre, prospective, single-arm crossover study. Eligible patients underwent a 1-week In-Flow tolerability trial. Successful patients then continued through an 8-

week baseline phase using CIC, followed by a 16-week In-Flow treatment phase, and a final 4-week treatment withdrawal phase. Outcome measures included post-void residual (PVR), Wagner incontinence-specific quality of life (I-QOL), rate of urinary tract infection and adverse events. At study completion, open enrollment was offered. RESULTS: A total of 273 women with a mean age of 48.9 years using CIC entered the study in 18 centres under either the original (n=88) or revised protocols (n=185). The revised protocol included the addition of a 1-week tolerability trial. The reasons for the large early withdrawal of subjects (169/273) were mainly related to initial discomfort and leakage. A total of 77 patients completed the In-Flow treatment phase. PVR was comparable during baseline CIC phase and In-Flow treatment phase (20.3 ml vs. 16.1 ml), with significantly improved quality of life (QOL; mean improvement of I-QOL score +25.9; $p < 0.001$). CONCLUSION: The In-Flow catheter appears to be a viable alternative to CIC. A subgroup of patients, mainly those unsatisfied with the currently available treatments, was more likely to tolerate In-Flow catheters, and they may achieve enhanced independence and QOL.

Cornu, J. N., B. Merlet, et al. (2011). "Duloxetine for mild to moderate postprostatectomy incontinence: preliminary results of a randomised, placebo-controlled trial." *Eur Urol* **59**(1): 148-154.

BACKGROUND: Duloxetine is effective in the management of stress urinary incontinence (SUI) in women but has been poorly evaluated in the treatment of SUI following radical prostatectomy (RP). **OBJECTIVE:** To establish the superiority of duloxetine over placebo in SUI after RP. **DESIGN, SETTING, AND PARTICIPANTS:** We conducted a prospective, randomised, placebo-controlled, double-blind, monocentric superiority trial. After a placebo run-in period of 2 wk, patients with SUI after RP were randomised to receive either 80mg of duloxetine daily or matching placebo for 3 mo. **MEASUREMENTS:** The primary outcome measure was the relative variation in incontinence episodes frequency (IEF) at the end of study compared to baseline. Secondary outcomes included quality of life (QoL) measures (Incontinence Impact Questionnaire Short Form [IIQ-SF], Urogenital Distress Inventory Short Form [UDI-SF], Incontinence Quality of Life [I-QoL]), symptom scores (Urinary Symptom Profile [USP] questionnaire, International Consultation on Incontinence/World Health Organisation Short Form questionnaire [ICIQ-SF], the Beck Depression Inventory [BDI-II] questionnaire), 1-h pad test, and assessment of adverse events. **RESULTS AND LIMITATIONS:** Thirty-one patients were randomised to either the treatment (n=16) or control group (n=15). Reduction in IEF was significant with duloxetine compared to placebo (mean \pm standard deviation [SD] variation: -52.2% \pm -38.6 [range: -100 to +46] vs +19.0% \pm -43.5 [range: -53 to +104]; mean difference: 71.2%; 95% confidence interval [CI] for the difference: 41.0-101.4; $p < 0.0001$). IIQ-SF total score, UDI-SF total score, SUI subscore of the USP questionnaire, and question 3 of the ICIQ-SF questionnaire showed improvement in the duloxetine group ($p = 0.006$, $p = 0.02$, $p = 0.0004$, and $p = 0.003$, respectively). Both treatments were well tolerated throughout the study period. **CONCLUSIONS:** Duloxetine is

effective in the treatment of incontinence symptoms and improves QoL in patients with SUI after RP.

Cruz, F., S. Herschorn, et al. (2011). "Efficacy and safety of onabotulinumtoxinA in patients with urinary incontinence due to neurogenic detrusor overactivity: a randomised, double-blind, placebo-controlled trial." *Eur Urol* **60**(4): 742-750.

BACKGROUND: Neurogenic detrusor overactivity (NDO) frequently results in urinary incontinence (UI) which impairs quality of life (QOL) and puts the upper urinary tract at risk. **OBJECTIVE:** To assess the effects of onabotulinumtoxinA (BOTOX((R)), Allergan, Inc.) on UI, urodynamic variables, and QOL in incontinent patients with NDO. **DESIGN, SETTING, AND PARTICIPANTS:** This multicentre, randomised, double-blind, placebo-controlled study enrolled patients with multiple sclerosis (MS; n=154) or spinal cord injury (SCI; n=121) with UI due to NDO (≥ 14 UI episodes per week). **INTERVENTION:** Patients received 30 intradetrusor injections of onabotulinumtoxinA 200 U (n=92), 300 U (n=91), or placebo (n=92), avoiding the trigone. **MEASUREMENTS:** Primary end point was change from baseline in UI episodes per week (week 6). Secondary end points included urodynamics (maximum cystometric capacity [MCC], maximum detrusor pressure during first involuntary detrusor contraction [P(detmaxIDC)]), and Incontinence Quality of Life (I-QOL) total score. Adverse events (AEs) were assessed. **RESULTS AND LIMITATIONS:** At baseline, mean UI episodes per week (33.5) were similar across groups. At week 6, onabotulinumtoxinA 200 U and 300 U significantly reduced UI episodes per week (-21.8 and -19.4, respectively) compared with placebo (-13.2; $p < 0.01$); onabotulinumtoxinA benefit was observed by the first posttreatment study visit at week 2. Improvements in MCC, P(detmaxIDC), and I-QOL at week 6 were significantly greater with both onabotulinumtoxinA doses than with placebo ($p < 0.001$). Benefits were observed in both the MS and SCI populations. The median time to patient request for retreatment was the same for both onabotulinumtoxinA doses (42.1 wk) and greater than placebo (13.1 wk; $p < 0.001$). Most frequent AEs were localised urologic events (urinary tract infections and urinary retention, which were dose related in patients not using clean intermittent catheterisation [CIC] at baseline). Significant increases in postvoid residual were observed in patients not using CIC prior to treatment, and 12%, 30%, and 42% of patients in the placebo, 200-U, and 300-U groups, respectively, initiated CIC posttreatment. **CONCLUSIONS:** OnabotulinumtoxinA significantly reduced UI and improved urodynamics and QOL in MS and SCI patients with NDO. Both doses were well tolerated with no clinically relevant differences in efficacy or duration of effect between the two doses (<http://www.clinicaltrials.gov>; NCT00461292).

Drahoradova, P., A. Martan, et al. (2003). "[Quality of life in women after urogynecologic surgery]." *Ceska Gynekol* **68**(4): 243-249.

OBJECTIVE: The aim of this study is to verify the change in the quality of life, by a subjective assessment of women, following their surgery for stress incontinence. We also evaluate any connection with postoperative complications. **DESIGN:** A pilot prospective study. **SETTING:** Department of Obstetrics and

Gynecology General Faculty Hospital, 1st Medical Faculty, Charles University, Prague. METHODS: Quality of life is measured in accordance with the results of a questionnaire. We chose to use a standardized questionnaire by Donald L. Patrick "Incontinence of Life Instrument" (I-QoL). I-QoL consists of 22 subjects of measure, each with a five point scale, addressing various aspects of urine incontinence. We assessed the percentage results of I-QoL before and between 3-6 months after surgery for a connection to postoperative complications. RESULTS: Our patient set was 64 women, all of whom had undergone an operation for stress incontinence. The most common was Kolpopexis secundum Burch at 74%. The average age of the subjects was 54. 59.4% of those tested displayed BMI in excess of 25, whilst 49% of the women had previously undergone laparotomy surgery. The average value of I-QoL before the operation was 46.21%. In the second reading, post operation, this had risen to 80.86%. The difference of 34.65% strongly suggests a significant rise in the quality of life following the operation. 68.74% (44x) of the women were significantly improved, meaning their quality of life had increased by at least 13%. 12.5% (8x) showed slight improvement, 14.07% (9x) maintained their quality of life, and just 4.68% (3x) showed signs of deterioration. We found the biggest improvements in those suffering with stress incontinence. The patients felt generally more healthy, helping to reduce the depression and anxiety associated with incontinence. In contrast, our treatment caused a case of postoperative urgency and nycturia. CONCLUSION: Early complications had no impact on the quality of life, but those which came later--urgency and nycturia did. The result of I-QoL generally depends on the intensity of difficulties before the operation. The question to ask is, whether the subjective assessment can ever be used as a comparison to the objective research.

Drahoradova, P., J. Masata, et al. (2009). "Can the preoperative value of VLPP and MUCP predict the postoperative quality of life?" Prague Med Rep **110**(1): 42-50.

OBJECTIVE: The aim of this study was to determine whether low values of VLPP (Valsava Leak Point Pressure) and low values of MUCP (Maximal Urethral Closure Pressure) before operation can predict quality of life (QOL) after anti-incontinence surgery. METHODS: 72 stress incontinent women were included in this study. All women underwent anti-incontinent surgery. We compared the quality of life using I-QOL (Incontinence Quality of Life) assessment with parameters of urodynamic measurement VLPP and MUCP. The women filled in an I-QOL questionnaire before surgery and three months afterwards. RESULTS: As in other studies, low preoperative value of the VLPP ≤ 60 cmH₂O was not related to a statistically lower quality of life (average I-QOL for VLPP ≤ 60 cmH₂O was 38.4 and 48.9 for VLPP > 60 cmH₂O). We did not find statistically significant lower quality of life in women with MUCP ≤ 20 cmH₂O (average I-QOL 38.2, and for MUCP > 20 39.7). The quality of life was significantly changed after successful anti-incontinent operation, but independently of the preoperative value of VLPP or MUCP, average I-QOL for VLPP ≤ 60 cmH₂O was 81.5 and 82.8 for VLPP > 60 cmH₂O, for MUCP ≤ 20 cmH₂O 79.5, and 86.4 for MUCP > 20 . CONCLUSIONS: Low preoperative values of MUCP and VLPP did

not correlate with QOL. Preoperative VLPP and MUCP do not predict the QOL after anti-incontinent surgery.

Drutz, H. (2006). "Duloxetine in women awaiting surgery." BJOG **113 Suppl 1**: 17-21. Stress urinary incontinence (SUI) is a common condition affecting millions of women worldwide. It has a significant impact on the quality of life (psychosocial, social and economic well-being) of sufferers and their families. Until recently, treatment options for SUI were limited to conservative treatments such as pelvic floor muscle training, which usually has a poor compliance over time, or surgical procedures that carry the risk of complications and are mainly an option for more severely affected women. Duloxetine, a potent and relatively balanced serotonin and noradrenaline reuptake inhibitor, has been evaluated in phase II and phase III clinical trials and was found to be efficacious and safe in the treatment of women with moderate to severe SUI symptoms. Even in a subgroup of women with severe SUI awaiting surgery, with or without the presence of intrinsic sphincter deficiency, duloxetine was found to be effective. In addition, a good correlation was found between efficacy outcome measures and ratings of global impression scores. Women begin to perceive themselves as being better with treatment when their incontinence episodes frequency (IEF) decreases by 46% or their Incontinence Quality of Life (I-QOL) score improves by 6.3 points. The improvements in IEF and I-QOL obtained with duloxetine were well above these threshold levels, whereas these with placebo were not. All duloxetine responses were observed within 2 weeks. Overall, duloxetine is an effective treatment for a wide variety of women presenting with SUI symptoms. It has been approved in Europe for the treatment of women with moderate to severe SUI symptoms and is now available in many European countries.

Dupuy, H. J., D. L. Patrick, et al. (1999). "Psychological General Well-Being Index." Quality of life of women with urinary incontinence: Further development of the Incontinence Quality of Life Instrument (I-QOL) **53**: 71-76.

Elser, D. M., G. K. Mitchell, et al. (2009). "Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 12-month results from a prospective long-term study." J Minim Invasive Gynecol **16**(1): 56-62.

STUDY OBJECTIVE: To assess efficacy of nonsurgical transurethral collagen denaturation (Renessa) in women with stress urinary incontinence (SUI) caused by bladder outlet hypermobility. **DESIGN:** Continuing, prospective, 36-month, open-label, single-arm clinical trial. Twelve-month results from intent-to-treat (ITT) analysis are reported. Canadian Task Force classification II-2. **SETTING:** Thirteen physician offices or ambulatory treatment centers. **PATIENTS:** Women with SUI secondary to bladder outlet hypermobility for 12 months or longer who failed earlier conservative treatment and had not received earlier surgical or bulking agent therapy. **INTERVENTIONS:** Women were treated as outpatients and received an oral antibiotic and local periurethral anesthesia before undergoing treatment with transurethral radiofrequency collagen denaturation. **MEASUREMENTS AND MAIN RESULTS:** Voiding diaries and in-office stress

pad weight tests yield objective assessments. Subjective measures include the Incontinence Quality of Life (I-QOL), Urogenital Distress Inventory (UDI-6), and Patient Global Impression of Improvement (PGI-I) instruments. In total, 136 women received treatment (ITT population). Patients experienced significant reductions versus baseline in median number of leaks caused by activity/day and activity/week ($p < .0026$ for both), with 50% of patients reporting 50% or more reduction. Pad weight tests revealed that 69% of women had 50% or more reduction in leakage (median reduction 15.2 g; $p < .0001$); 45% were dry (29% no leaks; 16% < 1-g leakage). Significant improvements occurred in median scores on the I-QOL (+9.5 [range -66.0 to 91.0]; $p < .0001$) and mean scores on the UDI-6 (-14.1 +/- 24.7; $p < .0001$). Furthermore, 71.2% showed I-QOL score improvement, including 50.3% with 10-point or greater improvement, and 49.6% reported on the PGI-I that they were "a little," "much," or "very much" better. CONCLUSION: At 12 months, treatment of SUI with nonsurgical transurethral collagen denaturation resulted in significant improvements in activity-related leaks and quality of life.

Elser, D. M., G. K. Mitchell, et al. (2010). "Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 18-month results from a prospective long-term study." Neurourol Urodyn **29**(8): 1424-1428.

AIMS: To evaluate 18-month safety and durability of efficacy of nonsurgical transurethral collagen denaturation as treatment for stress urinary incontinence (SUI) in women. METHODS: Study comprised women with SUI due to bladder outlet hypermobility for at least 12 months who failed conservative treatment and had not undergone surgery or bulking agent treatment. This one-time procedure was performed in a physician's office or ambulatory treatment center. Patients kept voiding diaries and completed the Incontinence Quality of Life (I-QOL), Urogenital Distress Inventory (UDI-6), and Patient Global Impression of Improvement measures at baseline and at 3, 6, 12, and 18 months posttreatment. RESULTS: At 18 months, intent-to-treat analysis revealed that patients experienced significant reductions in the median number of stress leaks daily (0.43; $P < 0.006$) and weekly (3.0; $P < 0.006$) versus baseline, with 46.7% reporting a 50% or greater reduction in leakage. Mean I-QOL score improved 10.9 points (median 8.5; $P < 0.0001$), with 47.8% having a 10-point or greater improvement and 50.4% reporting improved symptoms versus baseline. Mean UDI-6 improvement was 13.0 points, with a stress incontinence subscore improvement of 17.0 points. Overall, 47.0% of patients were "somewhat" or "very" satisfied, and 52.9% would recommend the procedure to a friend. The procedure was shown to be safe and effective, with no new treatment-related adverse events reported at 18 months. CONCLUSIONS: Transurethral collagen denaturation resulted in significant improvements in stress leaks and quality of life for at least 18 months. This procedure offers a safe, effective, nonsurgical treatment option for women with SUI.

Elser, D. M., G. K. Mitchell, et al. (2011). "Nonsurgical transurethral radiofrequency collagen denaturation: results at three years after treatment." Adv Urol **2011**: 872057.

Objective. To assess treatment efficacy and quality of life in women with stress urinary incontinence 3 years after treatment with nonsurgical transurethral radiofrequency collagen denaturation. **Methods.** This prospective study included 139 women with stress urinary incontinence due to bladder outlet hypermobility. Radiofrequency collagen denaturation was performed using local anesthesia in an office setting. Assessments included incontinence quality of life (I-QOL) and urogenital distress inventory (UDI-6) instruments. **Results.** In total, 139 women were enrolled and 136 women were treated (mean age, 47 years). At 36 months, intent-to-treat analysis (n = 139) revealed significant improvements in quality of life. Mean I-QOL score improved 17 points from baseline (P = .0004), while mean UDI-6 score improved (decreased) 19 points (P = .0005). **Conclusions.** Transurethral collagen denaturation is a low-risk, office-based procedure that results in durable quality-of-life improvements in a significant proportion of women for as long as 3 years.

Erdinc, A., B. Gurates, et al. (2009). "The efficacy of venlafaxine in the treatment of women with stress urinary incontinence." *Arch Gynecol Obstet* **279**(3): 343-348.

OBJECTIVE: To examine the efficacy of venlafaxine, which is used as an antidepressant, in the treatment of stress urinary incontinence. **MATERIALS AND METHODS:** The study was designed as a placebo-controlled, double-blind and randomized clinical study. Patients in Group 1 (n=20) were administered 75 mg venlafaxine, those in Group 2 (n=20) were administered placebo for 12 weeks. All the cases were evaluated in terms of weekly incontinence episode frequency (IEF), change in void interval (VI), the Incontinence Quality of Life (I-QOL) in weeks 0, 4, 8 and 12. Additionally, PGI-S was assessed at baseline and was followed by PGI-I evaluations in weeks 4, 8 and 12. **RESULTS:** Evaluations in weeks 0, 4, 8 and 12 did not show any significant difference in IEF, VI, IQOL and PGI-I values of placebo group (p>0.05). However, in the patients who were administered venlafaxine declines in IEF and PGI-I values as well as the elevations in VI and IQOL scores showed significant changes parallel to the increasing follow-up period (p<0.05). Nausea was observed in 40% of cases in venlafaxine group, and 15% of those in placebo group (p<0.05). **CONCLUSION:** It was seen in our study that efficacy of venlafaxine started early and the clinical efficacy associated with the use of the drug continued in the following months. Venlafaxine should be considered a clinically efficient alternative drug in the treatment of SUI.

Eyigor, S., H. Karapolat, et al. (2010). "Quality of life in patients with multiple sclerosis and urinary disorders: reliability and validity of Turkish-language version of Incontinence Quality of Life Scale." *J Rehabil Res Dev* **47**(1): 67-71.

Incontinence is one of the most frequently encountered problems in multiple sclerosis (MS), and it has a negative effect on the daily lives of patients. Therefore, it is important to investigate this complaint and start appropriate treatment early. The aim of our study was to demonstrate the validity and reliability of the Turkish-language Incontinence Quality of Life Scale (I-QOL) in patients with MS. We included 37 patients with MS in this study. For analysis of

test-retest reliability, we administered the Turkish-language version of I-QOL developed by a "translation-back translation" method to patients on the day of admission and 1 week after admission. To assess validity, we also evaluated patients with the Multiple Sclerosis Quality of Life Scale (MQOL-54) and Expanded Disability Status Scale (EDSS). We calculated the intraclass correlation coefficient of the I-QOL (total and all subscores) as 0.88 to 0.91 and the Cronbach alpha score as 0.88 to 0.91 ($p < 0.05$). We found a significant correlation among all subscores of I-QOL and physical and mental subscores of MQOL-54 and EDSS ($p < 0.05$). Our study has demonstrated the internal consistency and reliability of the I-QOL in the Turkish language in patients with MS.

Fialkow, M. F., J. L. Melville, et al. (2003). "The functional and psychosocial impact of fecal incontinence on women with urinary incontinence." *Am J Obstet Gynecol* **189**(1): 127-129.

OBJECTIVES: The study was undertaken to determine the impact of fecal incontinence (FI) on functional status and quality of life in women with urinary incontinence (UI). **STUDY DESIGN:** In 24 months 732 women completed a standardized assessment and questionnaire, including the Short Form (SF)-12 and Incontinence Quality of Life (I-QOL) scores. Analysis of variance was used to compare SF-12 scores between groups defined as having UI, FI, or both UI and FI. I-QOL scores in patients with UI or UI and FI were compared by using the Student t test. **RESULTS:** Of the 732 patients enrolled, 425 patients had either UI ($n = 342$, 80%), FI ($n = 18$, 4%), or both ($n = 65$, 15%). Greater impairment in physical functioning was seen in the group with UI and FI (38.6; $P = .027$) compared with the group with UI (42.4). Significant decreases in I-QOL scores were seen for the group with UI and FI compared with those with UI ($P < .005$). **CONCLUSION:** Fecal incontinence further reduces the functional status and quality of life of women with urinary incontinence.

Filocamo, M. T., V. Li Marzi, et al. (2007). "Pharmacologic treatment in postprostatectomy stress urinary incontinence." *Eur Urol* **51**(6): 1559-1564.

OBJECTIVES: The aim of this study was to assess efficacy and safety of association of duloxetine and rehabilitation compared with rehabilitation alone in men with SUI after radical retropubic prostatectomy (RRP), and to compare continence rate even after planned duloxetine suspension. **METHODS:** After catheter removal, 112 patients were randomized to receive rehabilitation and duloxetine (group A) or rehabilitation alone (group B), for 16 wk. Inclusion criteria: postprostatectomy SUI with daily incontinent episodes frequency (IEF) of four or greater. After 16 wk both groups suspended duloxetine/placebo and continued rehabilitation. All patients completed incontinence quality of life (I-QoL) questionnaire and bladder diary. Wilcoxon test was used to analyse changes in IEF and in I-QoL score; Fisher exact test was used to compare continent patients between the groups. **RESULTS:** Adverse events for duloxetine was 15.2%. 102 men completed the study. There was a significant decrease in pad use in group A. After 16 wk, 39 patients versus 27 were dry ($p=0.007$). At 20 wk, 4 wk after

planned interruption of duloxetine, we observed a U-turn, 23 patients were completely dry in group A versus 38 in group B ($p=0.008$). Whereas, after 24 wk, 31 in group A versus 41 in group B were dry ($p=0.08$). The decrease in IEF and improvements in I-QoL scores were significantly greater in group A for the first 16 wk. CONCLUSIONS: The data suggest that combination therapy might provide another treatment option for SUI in men that might increase the percentage of early postsurgery continence.

Finazzi Agro, E., A. Campagna, et al. (2005). "Posterior tibial nerve stimulation: is the once-a-week protocol the best option?" Minerva Urol Nefrol **57**(2): 119-123.

AIM: Aim of our study was to compare the results of posterior tibial nerve stimulation (PTNS) performed weekly with those of PTNS performed 3 times per week in patients with overactive bladder syndrome. METHODS: Thirty-five patients (28 females, 7 males) with overactive bladder syndrome not responding to antimuscarinic therapy were enrolled in a prospective study. A total of 17 out of 35 patients were randomly assigned to group A and treated with a PTNS protocol based on weekly stimulation sessions; 18 out of 35 patients were randomly assigned to group B and treated with a PTNS protocol based on stimulation sessions performed 3 times per week. All subjects were evaluated by means of 24 h bladder diaries, quality of life questionnaires (I-QoL, SF36) and urodynamic evaluation before and after treatment. Patients were asked after each stimulation session to give their opinion on the efficacy of the treatment. We have considered "success" those patients who presented a reduction $>50\%$ of the micturition episodes/24 h (ME/24) or (if incontinent) of the incontinence episodes/24 h (IE/24). Results before and after treatments in both groups were collected and statistically compared. RESULTS: As a whole, 11/17 patients (63%) in group A and 12/18 patients (67%) in group B were considered "success"; 4/11 (36%) incontinent patients in group A and 5/11 (45%) incontinent patients in group B were completely cured after treatment. In both groups, patients reported subjective improvement after 6-8 stimulation sessions. CONCLUSIONS: Our findings seem to show that the periodicity of stimulation does not effect the results of PTNS treatment. The advantage of more frequent stimulation sessions is to achieve earlier a clinical improvement.

Finkelstein, M. M., J. Skelly, et al. (2002). "Incontinence Quality of Life Instrument in a survey of primary care physicians." J Fam Pract **51**(11): 952.

OBJECTIVE: To assess the performance of the Incontinence Quality of Life (I-QOL) Instrument in measuring the impact of urinary incontinence on the quality of life of family medicine patients. STUDY DESIGN: Postal survey. Multiple imputations of missing answers. Linear regression analysis of I-QOL predictors. Comparison by receiver operating characteristic of the I-QOL and the Short Form 12 (SF-12). POPULATION: Women 45 years or older attending either of 2 family medicine clinics. Response rate was 605 (61%) of 992. OUTCOMES MEASURED: Prevalence of stress, urge, and mixed incontinence. Scores on the I-QOL and SF-12 instruments. RESULTS: Of the 605 respondents, 310 (51%) reported urinary incontinence in the month before the survey. One or more items

were missing on 19% of the I-QOL scales and scores were imputed. The relation between I-QOL and the number of leakage episodes was nonlinear. I-QOL scores decreased with the number of episodes, the amount of leakage, and poorer general health. There was no association between the I-QOL and age, education, or type of incontinence. The I-QOL was more sensitive than the SF-12 to the statement, "urinary incontinence is a problem." CONCLUSIONS: The I-QOL is a useful instrument for the investigation of incontinence-related quality of life in the community setting.

Foglia, G., E. Mistrangelo, et al. (2007). "Transfascial vaginal tape (TFT): a simple, safe and cost-effective procedure for stress urinary incontinence. A preliminary study." Arch Gynecol Obstet **276**(1): 59-63.

OBJECTIVE: To analyse prospectively the effectiveness of a new simple, minimally invasive, and cost-effective technique for the treatment of female urinary stress incontinence: the transfascial vaginal tape (TFT). **MATERIALS AND METHODS:** In a prospective study, we enrolled 45 women undergoing TFT with or without hysterectomy and/or another pelvic reconstructive procedure between 1st December 2003 and 31st December. TFT consists of a tension-free urethrosuspension using a sling located at the mid-urethral level and placed laterally in the endopelvic fascia previously perforated. Follow-up evaluations were established at 3 and 6 months and at 1 year after the operation. During each follow-up, women underwent cough stress test and they answered to the "Incontinence quality of life questionnaire" (I-QOL), to the Patient Global Impression of Severity (PGI-S) and of Improvement (PGI-I) questions. **RESULTS:** Thirty-nine patients (88.9%) had a follow-up examination 1 year after surgery. Of these, 30 (76.9%) were defined cured, 6 (15.4%) improved and 3 (7.7%) failed. **CONCLUSIONS:** TFT procedure can be considered a simple, safe and cost-effective procedure for the treatment of stress urinary incontinence and can be an alternative to tension-free vaginal tape or transobturator route for sub-urethral tape procedures.

Fowler, C. J., S. Auerbach, et al. (2012). "OnabotulinumtoxinA improves health-related quality of life in patients with urinary incontinence due to idiopathic overactive bladder: a 36-week, double-blind, placebo-controlled, randomized, dose-ranging trial." Eur Urol **62**(1): 148-157.

BACKGROUND: Patients with urgency urinary incontinence (UUI) due to overactive bladder (OAB) refractory to oral antimuscarinics have limited therapeutic options. OnabotulinumtoxinA appears to be an effective new treatment. **OBJECTIVE:** Assess disease-specific quality-of-life outcomes and general health-related quality-of-life (HRQOL) outcomes following treatment with onabotulinumtoxinA in patients with idiopathic OAB and UUI inadequately managed with antimuscarinics. **DESIGN, SETTING, AND PARTICIPANTS:** A phase 2, randomized, double-blind, placebo-controlled, dose-ranging study conducted at 40 sites from July 2005 to June 2008 with 313 patients (288 females) with idiopathic OAB experiencing eight or more UUI episodes per week and eight or more micturitions per day at baseline, with follow-up of 36 wk.

INTERVENTION: Intradetrusor onabotulinumtoxinA (50 U, 100 U, 150 U, 200 U, or 300 U) or placebo. **OUTCOME MEASUREMENTS AND STATISTICAL ANALYSIS:** HRQOL was assessed using the urinary Incontinence-Specific Quality-of-Life Instrument (I-QOL), the King's Health Questionnaire (KHQ) symptom component, and the Medical Outcomes Study 36-Item Short-Form Health Survey. Descriptive statistics were used for absolute scores/changes from baseline. Within-group changes from baseline were assessed using paired t tests. Change from baseline for each onabotulinumtoxinA group compared with placebo was analyzed using an analysis of covariance model. **RESULTS AND LIMITATIONS:** OnabotulinumtoxinA treatment at doses ≥ 100 U produced significantly greater improvements than placebo in the I-QOL total and subscale scores at all follow-up visits from week 2 through week 24 ($p < 0.05$). OnabotulinumtoxinA doses ≥ 100 U produced significantly greater improvements than placebo in the KHQ symptom score at a majority of follow-up visits. HRQOL instruments demonstrated low to moderate correlations (Spearman correlation range: 0.01-0.51) with the symptoms of UUI recorded using daily diary data, with I-QOL demonstrating the highest correlations. A study limitation was that certain quality-of-life measures were exploratory and not validated. **CONCLUSIONS:** A single onabotulinumtoxinA treatment with doses ≥ 100 U resulted in statistically significant and clinically meaningful improvement in HRQOL by week 2 compared with placebo, and this improvement was sustained for ≤ 36 wk in patients with idiopathic OAB and UUI who were inadequately managed by oral antimuscarinics. **TRIAL REGISTRATION:** ClinicalTrials.gov identifier: NCT00168454.

Gaj, F., J. Andreuccetti, et al. (2011). "[Chronic pelvic pain treatment with posterior tibial nerve stimulation]." Clin Ter **162**(4): e111-114.

INTRODUCTION: Chronic pelvic pain is a common problem that has a high impact on quality of life of patients who are affected. The technique of percutaneous neuromodulation by electrical stimulation of the tibial nerve (Percutaneous Tibial Nerve Stimulation PTNS) is described by Stoller for the treatment of overactive bladder syndrome in the 90s is currently being tested in the treatment of chronic pelvic pain. **MATERIALS AND METHODS:** The study included 35 patients with chronic pelvic pain: 17 were treated with a protocol based on 12 PTNS stimulation sessions performed weekly (Group A), 18 were treated with a protocol based on 12 sessions PTNS stimulation performed 3 times a week (group B). All patients were evaluated before and after treatment, by means of diary quality of life score (I-QoL, SF36) and proctologic examination. **RESULTS:** At the end of treatment 11/17 patients (63%) in group A and 12/18 patients (67%) in group B were considered a successes. Overall 4/11 (36%) patients in group A and 5/11 (45%) patients in group B recovered completely after treatment. In both groups, patients reported a subjective improvement after 6-8 stimulation sessions. At follow-up 36/8 months there were more complications. **CONCLUSIONS:** In conclusion, the use of PTNS in the treatment of chronic pelvic pain shows encouraging results in patients not responding to standard analgesic therapy.

Garley, A. and J. Unwin (2006). "A case series to pilot cognitive behaviour therapy for women with urinary incontinence." Br J Health Psychol **11**(Pt 3): 373-386.

OBJECTIVE: Psychological factors have been identified with respect to female urinary incontinence. However, there is limited research regarding psychological interventions. The effectiveness of cognitive behaviour therapy (CBT) as a treatment for women with urinary incontinence was investigated. **DESIGN:** The study adopted an AB case series design with a follow-up phase. **METHODS:** Ten women with urinary incontinence each attended individual sessions. The Hospital anxiety and depression scale (HADS) and Incontinence Quality of Life (I-QOL) were administered pre-treatment, post-treatment, and 3-months post-treatment. Participants kept weekly records of bladder functioning. An unstandardized client satisfaction questionnaire was administered at 3-months post-treatment. **RESULTS:** Anxiety and depression, as measured by the HADS did not show any significant changes. Improvements in incontinence-related quality of life reached statistical significance at the post-treatment administration and were maintained at the 3-months post-treatment follow-up. Significant changes in bladder functioning were not apparent until the 3-month post-treatment follow-up. The satisfaction questionnaires suggest that the participants found the intervention of value. **CONCLUSIONS:** The findings of this study tentatively suggest that incontinence-related quality of life might be improved by involvement in a CBT intervention. Some modest improvements occurred in bladder functioning. Further research is required to confirm these findings.

Gilling, P. J., D. F. Bell, et al. (2008). "An adjustable continence therapy device for treating incontinence after prostatectomy: a minimum 2-year follow-up." BJU Int **102**(10): 1426-1430; discussion 1430-1421.

OBJECTIVE: To evaluate the efficacy and safety of the ProACT (Uromedica, Inc., MN, USA) balloon device, an alternative for the surgical management of incontinence after prostatectomy. **PATIENTS AND METHODS:** The initial patients who received this device at our institution were evaluated, using urodynamics at baseline and at 6 months. Perioperative variables were recorded and pad usage, volume adjustments, an estimate of Incontinence Quality of Life (I-QoL) and adverse events were recorded at baseline, and 1, 3, 6, 12 and 24 months after surgery. **RESULTS:** In all, 37 patients were treated on this protocol between November 2001 and March 2005. Of these, 30 had had radical prostatectomy and seven holmium laser enucleation of the prostate. The mean (range) pad usage decreased from 2.81 (1-12) at baseline to 0.7 (0-4) pads at 24 months, and the I-QoL increased from 49.7 (4.5-77) to 81.3 (13.6-100) over the same period. At 24 months, 62% of 34 men were pad-free and 81% required one pad or less. Bilateral explantation was required in three patients (11%) for infection (one) and balloon migration (two). All other adverse events were mild and transient. **CONCLUSIONS:** The ProACT balloon device is an acceptable therapy for the surgical management of incontinence after prostatectomy.

Gilling, P. J., L. C. Wilson, et al. (2009). "A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs sham therapy in the treatment of women with stress urinary incontinence." BJU Int **103**(10): 1386-1390.

OBJECTIVE: To compare the efficacy of extracorporeal electromagnetic stimulation (ES) of the pelvic floor for treating stress urinary incontinence (SUI) vs sham ES. **PATIENTS AND METHODS:** In all, 70 women with urodynamically confirmed SUI were randomized to receive active (35) or sham (35) ES. The NeoControl chair (NeoTonus, Marietta, GA, USA) was used, and treatment consisted of three sessions per week for 6 weeks. data were collected before and after treatment on all women, including a 20-min provocative pad-test with a predetermined bladder volume (primary outcome measure), a 3-day bladder diary and 24 h pad-test. Circumvaginal muscle (CVM) rating score, perineometry using two separate instruments and video-urodynamics were also used, and the Urinary Incontinence Quality of Life Scale (I-QOL) and King's Health Questionnaires. Patients were fully re-evaluated 8 weeks after treatment, and the bladder diary, pad-test and questionnaires were repeated at 6 months. The urotherapist and physician were unaware to which treatment group the patient was assigned. **RESULTS:** In the overall group of 70 patients there were significant improvements in each of the primary and secondary outcome measures at 8 weeks. There were also significant improvements in primary and secondary outcome measures in the active treatment group when compared with baseline measures. At 8 weeks, there were improvements in the mean (sd) values for the 20-min pad-test, of 39.5 (5.1) vs 19.4 (4.6) g ($P < 0.001$); the 24-h pad-test, of 24.0 (4.7) vs 10.1 (3.1) g ($P < 0.01$); the number of pads/day, of 0.9 (0.1) vs 0.6 (0.1) ($P < 0.01$), the I-QOL score, of 63.7 (2.8) vs 71.2 (3.3) ($P < 0.001$); and King's Health Questionnaire score, of 9.6 (0.8) vs 6.9 (0.7) ($P < 0.001$). However, these improvements were not statistically significant when compared with the sham-treatment group. In those patients on active treatment who had a poor pelvic floor contraction at the initial assessment (defined by the CVM score and perineometry), there was a significant reduction ($P < 0.05$) in the 20-min pad-test leakage when compared with the sham-treatment group. **CONCLUSIONS:** ES was no more effective overall than sham treatment in this patient group. However, in those women who were unable to generate adequate pelvic floor muscle contractions, there was an objective improvement in provocative pad testing when compared to sham treatment.

Gumus, II, I. Kaygusuz, et al. (2011). "Effect of the Macroplastique Implantation System for stress urinary incontinence in women with or without a history of an anti-incontinence operation." Int Urogynecol J **22**(6): 743-749.

INTRODUCTION AND HYPOTHESIS: We evaluated the outcomes and the effect of the Macroplastique Implantation System on the quality of life in women with stress incontinence with or without a history of an anti-incontinence operation during 12 to 62 months follow-up. **METHODS:** Thirty-five women with urodynamically proven stress incontinence with intrinsic sphincter deficiency were included in this study. Macroplastique injection was performed in all patients. Quality of life was evaluated prior to therapy, in early postoperative time

(at the sixth weeks) and in late postoperative time (12 to 62 months follow-up) with the use of three different questionnaires: Incontinence Quality-of-Life Questionnaire (I-QOL), Incontinence Impact Questionnaire-7 (IIQ-7), and Urogenital Distress Inventory-6 (UDI-6). Questionnaires were also compared with those previous to the anti-incontinence operation and to the primary procedure groups. RESULTS: The median age of the women was 50.00 (interquartile range = 17.00) years. There were 24 primary procedures and 11 had undergone previous anti-incontinence surgery. Maximum follow-up time was 62 months, minimum follow-up time was 12 months, and the median follow-up time of the study was 58 (interquartile range = 44-60) months. When preoperative and postoperative median of the I-QOL, IIQ-7, and UDI-6 scores were compared, the differences between scores were found to be statistically significant. I-QOL, IIQ-7, and UDI-6 scores were related to the previous surgery. The overall I-QOL, IIQ-7, and UDI-6 summary scores showed high internal consistency. CONCLUSIONS: The Macroplastique injection system is an effective, safe, and acceptable option for stress urinary incontinence in women with or without a history of an anti-incontinence operation. Moreover, it can be performed under local anesthesia without cystoscopic guidance; moreover, side effects are rare.

Hatem, M., W. Fraser, et al. (2005). "Postpartum urinary and anal incontinence: a population-based study of quality of life of primiparous women in Quebec." J Obstet Gynaecol Can **27**(7): 682-688.

OBJECTIVE: To describe the quality of life of primiparous women with urinary or anal incontinence. METHODS: A questionnaire was mailed at six months postpartum to 2492 primiparous women living in Quebec. The prevalence of urinary incontinence was assessed at six months postpartum through the FPSUND severity score index; the prevalence of anal incontinence was assessed by the grading system of Vaizey et al.; the quality of life of women who developed incontinence was assessed using the Shumaker's I-QOL for urinary incontinence and Lowry's quality of life instrument for anal incontinence. Descriptive analysis, t-test, analysis of variance, and linear regression were used. RESULTS: The prevalence of urinary incontinence was 29.6% and of anal incontinence was 20.6%. Quality of life was affected significantly by the presence of urinary incontinence or both forms of incontinence (P 0.001) and by the type of urinary incontinence (P < 0.001). Women with all types of anal incontinence had significantly lower quality of life scores for access to toilet (P < 0.001), lifestyle (P < 0.01), self-esteem (P = 0.037), and total score (P < 0.001). Quality of life correlated with the severity of both urinary incontinence and anal incontinence: the more severe the urinary or anal incontinence, the lower the quality of life score. CONCLUSION: Women who have urinary or anal incontinence, or both, have significant reductions in indicators of quality of life. Research is needed to evaluate strategies for preventing and treating these problems.

Hayashi, T., K. Kawaguchi, et al. (1997). "[Indication for percutaneous transluminal coronary angioplasty based on quality of life of patients with angina pectoris]." J Cardiol **29**(1): 13-22.

The changes in quality of life (QOL) before and after percutaneous transluminal coronary angioplasty (PTCA) were investigated to establish criteria for determining whether patients with angina pectoris should undergo PTCA. The QOL was surveyed twice by self-completed questionnaire for QOL by Lida and Kohashi (QUIK) before and about 4 months after PTCA in 84 patients (mean age 62.8 +/- 10.1 years) with angina pectoris. High QUIK score reflects a poor QOL, of which the internal consistency was 0.86, demonstrating high reliability. The subjects were classified into three groups according to the changes of total QUIK score before and after PTCA (I: QOL improved 31.0%, II: QOL unchanged 48.8%, III: QOL worsened 20.2%). Age, gender, total QUIK score prior to PTCA, presence of anginal pain, complications extent and degree of coronary artery stenosis, and left ventricular ejection fraction were compared between the three groups. The total QUIK score prior to PTCA in the improved QOL group was higher than that in the worsened QOL group (11.6 vs 5.1, $p < 0.01$). Most patients showing a poor QOL prior to PTCA demonstrated an improvement in their QOL after PTCA. The number of patients with anginal pain prior to PTCA was high in the improved QOL group (35.8%, $p < 0.05$). Percutaneous transluminal coronary angioplasty might not aggravate QOL (12.1%, $p = 0.1$) in patients with single-vessel disease. In patients with multivessel disease, PTCA might not improve (35.3%) but also might aggravate QOL (25.5%). Multivariate analysis showed that PTCA improved QOL in male or sixty-ager patients and in patients with a total QUIK score of 10 or more prior to PTCA ($p < 0.01$). The total QUIK score, presence of anginal pain and extent of coronary artery stenosis prior to PTCA, gender and age are factors predicting QOL after PTCA. The adaptation of PTCA for those patients should be prudently and inclusively taken into consideration to extend their QOL.

Haywood, K. L., A. M. Garratt, et al. (2008). "EuroQol EQ-5D and condition-specific measures of health outcome in women with urinary incontinence: reliability, validity and responsiveness." *Qual Life Res* 17(3): 475-483.

OBJECTIVES: To evaluate the measurement properties of the EuroQoL EQ-5D and two condition-specific patient-reported outcome measures--the Symptom Severity Index (SSI) and the Urinary Incontinence-Specific Quality of Life instrument (I-QoL)--in women with urinary incontinence. **METHODS:** A questionnaire comprising all instruments was completed by women taking part in a clinical trial of physiotherapy for urinary incontinence. Follow-up questionnaires were at 6 weeks and 5 months. Data quality, internal consistency reliability, validity and responsiveness were assessed. **RESULTS:** One hundred and seventy-four patients taking part in the clinical trial completed the questionnaire. Instruments had low levels of missing data. The EQ-5D had a large ceiling effect and poor responsiveness. The SSI had poor validity and responsiveness. The I-QoL had levels of reliability that supported application in group assessment, and in some cases, individual assessment, and good evidence of validity. The I-QoL was the most responsive instrument at both 6 weeks and 5 months. **CONCLUSION:** The I-QoL was the best performing instrument and is recommended as a continence-specific measure of quality of life in a clinical trial

setting. The SSI and EQ-5D are not recommended. Alternative generic instruments, which support economic evaluation, require further evaluation in trials of female urinary incontinence.

Higashi, T., R. D. Hays, et al. (2005). "Do proxies reflect patients' health concerns about urinary incontinence and gait problems?" Health Qual Life Outcomes **3**: 75.

BACKGROUND: While falls and urinary incontinence are prevalent among older patients, who sometimes rely on proxies to provide their health information, the validity of proxy reports of concern about falls and urinary incontinence remains unknown. **METHODS:** Telephone interviews with 43 consecutive patients with falls or fear of falling and/or bothersome urinary incontinence and their proxies chosen by patients as most knowledgeable about their health. The questionnaire included items derived from the Medical Outcomes Study Short Form 12 (SF-12), a scale assessing concerns about urinary incontinence (UI), and a measure of fear of falling, the Falls Efficacy Scale (FES). Scores were estimated using items asking the proxy perspective (6 items from the SF-12, 10 items from a UI scale, and all 10 FES items). Proxy and patient scores were compared using intraclass correlation coefficients (ICC, one-way model). Variables associated with absolute agreement between patients and proxies were explored. **RESULTS:** Patients had a mean age of 81 years (range 75-93) and 67% were female while proxies had a mean age of 70 (range 42-87) and 49% were female. ICCs were 0.63 for the SF-12, 0.52 for the UI scale, and 0.29 for the FES. Proxies tended to understate patients' general health and incontinence concern, but overstate patients' concern about falling. Proxies who lived with patients and those who more often see patients more closely reflected patient FES scores compared to those who lived apart or those who saw patients less often. Internal consistency reliability of proxy responses was 0.62 for the SF-12, 0.86 for the I-QOL, and 0.93 for the FES. In addition, construct validity of the proxy FES scale was supported by greater proxy-perceived fear of falling for patients who received medical care after a fall during the past 12 months ($p < .05$). **CONCLUSION:** Caution should be exercised when using proxies as a source of information about older patients' health perceptions. Questions asking about proxies' views yield suboptimal agreement with patient responses. However, proxy scales of UI and fall concern are internally consistent and may provide valid independent information.

Hollingworth, W., J. D. Campbell, et al. (2010). "Exploring the impact of changes in neurogenic urinary incontinence frequency and condition-specific quality of life on preference-based outcomes." Qual Life Res **19**(3): 323-331.

PURPOSE: Many trials do not measure quality-adjusted life years (QALYs). Therefore, decision analysts often map condition-specific outcomes to preference scores. We estimated the relationship between changes in preference scores and commonly reported condition-specific outcomes in patients with urinary incontinence (UI) due to neurogenic detrusor overactivity. **METHODS:** In 59 patients recruited to a neurogenic UI trial, clinical outcomes (UI episodes), condition-specific quality of life (Incontinence Quality of Life Instrument (I-QOL)), and SF-6D preference scores were measured at enrollment and 24 weeks. We

used multiple linear regression to estimate the impact on SF-6D scores of 50; 50-99 and 100% reductions in UI episodes and a 10-point improvement in I-QOL. RESULTS: By 24 weeks, mean (95% CI) daily UI episodes fell by 0.85 (0.04, 1.3) and mean I-QOL scores improved by 18 (12, 24). SF-6D scores increased by 0.03 (0.003, 0.058), due to improvements in role limitations. A > or = 50% reduction in UI episodes was achieved by 49% of patients and corresponded to a 0.09 (0.02, 0.16) SF-6D increase. A > or = 10-point increase in I-QOL was attained by 65% of patients and was associated with a 0.05 (-0.02, 0.12) SF-6D increase. CONCLUSIONS: These estimates provide preliminary data for decision analysts wishing to map neurogenic UI outcomes to preference scores.

Horstmann, M., I. Fischer, et al. (2012). "Pre- and postoperative urodynamic findings in patients after a bulbourethral composite suspension with intraoperative urodynamically controlled sling tension adjustment for postprostatectomy incontinence." Urology **79**(3): 702-707.

OBJECTIVES: To compare pre- and postoperative urodynamic findings in patients with a bulbourethral composite suspension and intraoperative urodynamically controlled sling tension adjustment. METHODS AND PATIENTS: All data were prospectively collected from 10 patients (mean age 66 years) who successfully underwent bulbourethral composite suspension for moderate to severe postprostatectomy incontinence. Patients were evaluated preoperatively and 3-6 months postoperatively by urodynamic measurements, including urethra pressure profiles (UPPs) and pressure flow studies (PFSs). Clinical outcome was evaluated by patient-reported pad use and questionnaires (ICIQ-UI SF and I-QOL). Intraoperatively sling tension was adjusted under repeated urodynamic measurements of abdominal leak point pressure. Data were evaluated using the Kruskal-Wallis Wilcoxon test. RESULTS: Sling implantation was successful in all patients. Pre- to postoperative pad use decreased significantly ($P < .005$). Five patients were pad-free, 3 used 1 pad, and 2 used 2 pads per day. Continence and quality of life improved significantly (ICIQ-UI SF: pre-op 17 vs post-op 4.9; I-QOL: pre-op 66 vs post-op 91; $P < .05$ for both). Urodynamic parameters during the filling phase remained unchanged. UPPs revealed a significant increase of the maximal urethral closure pressure (pre-op 40 cm H₂O vs post-op 58 cm H₂O) and functional length (pre-op 31 mm vs post-op 40 mm; $P < .05$ for both). Postoperatively, urodynamic maximal flow rates were slightly reduced from 16 mL/s to 12 mL/s ($P = .4$). PFSs revealed an unobstructed voiding in all patients. CONCLUSIONS: According to the present evaluation, a bulbourethral composite suspension with intraoperative urodynamically controlled sling tension adjustment improves continence without causing prolonged clinically or urodynamically significant voiding obstruction.

Hubner, W. A., H. Gallistl, et al. (2011). "Adjustable bulbourethral male sling: experience after 101 cases of moderate-to-severe male stress urinary incontinence." BJU Int **107**(5): 777-782.

OBJECTIVES: * To report our experience using an adjustable bulbourethral sling since April 2005 for male stress urinary incontinence (SUI) after prostatic

surgery. * To evaluate the safety, efficacy and health-related quality of life in recipients of the Argus(R) (Promedon SA; Cordoba, Argentina) adjustable bulbourethral sling. PATIENTS AND METHODS: * Between April 2005 and April 2009, 101 men with moderate-to-severe SUI after prostatic surgery were implanted with the Argus sling. * The radio-opaque Argus system comprises a thick silicone-foam pad for soft bulbar urethral support. The pad is attached to silicone columns that, after being passed with needles from the perineum to the abdominal wall, are adjusted with silicone washers to maintain the desired position. * Between prostatic surgery and Argus sling placement, most patients (74.3%) had undergone various procedures for SUI or bladder neck pathologies: 22 had undergone secondary irradiation therapy after surgery (19 after retropubic radical prostatectomy [RP], one after perineal RP and two after transurethral resection of the prostate). * All patients were evaluated before and after sling placement with 20-min pad tests, the Urinary Incontinence Quality of Life Scale (I-QoL), cystoscopy and uroflowmetry. The study was designed in a retrospective longitudinal fashion. RESULTS: * The mean (range) follow-up was 2.1 (0.1-4.5) years. The mean (range) sling surgery duration was 49 (28-105) min. * Adjustment was necessary in 39 cases (38.6%), either loosening (10/101; 9.9%) or tightening (29/101; 28.7%) at a mean of 104.3 (14-910) days after the initial implantation. * The sling had to be removed in 16/101 patients (15.8%) at a mean of 371.1 (20-1260) days after implantation due to urethral erosion or infection. However, six of the 16 patients were within the first 22 placements and probably represent the 'learning curve'. In all, 13 of these patients received later successful treatment (seven with an artificial urinary sphincter, five with re-implantation of the sling). Four of these patients were lost for follow-up. * After a median (mean) follow-up of 2.2 (2.1) years, 80/101 (79.2%) patients were considered as dry, with a pad test of 0-1 g (70 patients, 0 g; 10 patients, 1 g). The I-QoL score improved from a mean of 28.8 (14.5-61.8) to 63.2 (16.4-115) points after sling placement. * Both the 20-min pad-weight tests and I-QoL responses improved significantly compared with baseline ($P < 0.001$). CONCLUSION: * We think that the Argus male bulbourethral sling system is an excellent first- or second-line treatment for moderate-to-severe male SUI, even after external beam radiation treatment.

Hubner, W. A. and O. M. Schlarp (2005). "Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy." BJU Int **96**(4): 587-594.

OBJECTIVE: To evaluate the safety and efficacy of a new minimally invasive urological implant for incontinence after prostatectomy. PATIENTS AND METHODS: The adjustable continence therapy device (ProACT, Uromedica, Plymouth, MN, USA) consists of two balloons placed via a perineal approach bilaterally at the bladder neck in patients after prostatectomy. Titanium ports, attached via discrete tubing to each balloon, are placed in the scrotum, allowing for separate volume adjustments of the balloons at any time during and after surgery. Changes in a quality-of-life questionnaire (I-QoL), pad usage and a subjective continence grading score were assessed in 117 consecutive men after

implanting the Pro-ACT, at baseline and at 1, 3, 6, 12 and 24 months. RESULTS: After a mean (range) follow-up of 13 (3-54) months and with a mean of 3 (0-15) adjustments, 67% of men were dry, using at most one 'security' pad daily; 92% were significantly improved, and 8% showed no improvement. The I-QoL score improved from a median of 34.7 to 66.3 after 2 years (42 men; $P < 0.001$), the daily pad count decreased from a mean of 6 (1-24)/day to 1 (0-6)/day at 2 years ($P < 0.001$). Continence achieved at $< \text{or} = 6$ months after implantation through incremental adjustment remained durable at $> \text{or} = 2$ years in most patients. There were complications during and after surgery in 54 patients, mostly minor and decreasing with increasing expertise, primarily reflecting the development and refinement of the new surgical technique and its instrumentation. Re-implantation for complications was required in 32 patients, with a 75% success rate. CONCLUSIONS: The ProACT peri-urethral prosthesis produces durable outcomes equivalent or better than other minimally invasive treatments for incontinence after prostatectomy. Its unique design allows for easy adjustment after surgery to achieve the desired urethral resistance, with no further surgical intervention, thus allowing for an optimum balance between voiding pressures and continence. The promising results reported here suggest that this may be an appropriate, effective and durable first-line treatment to offer men with stress urinary incontinence after prostatectomy.

Hubner, W. A. and O. M. Schlarp (2007). "Adjustable continence therapy (ProACT): evolution of the surgical technique and comparison of the original 50 patients with the most recent 50 patients at a single centre." *Eur Urol* **52**(3): 680-686.

OBJECTIVES: The desire for an adjustable surgery for male stress urinary incontinence that avoids further surgery has produced a percutaneous adjustable device. The adjustable continence therapy (ProACT) consists of two balloons, placed bilaterally at the bladder neck after prostatectomy. Titanium ports, attached via tubing to each balloon are placed in the scrotum allowing for volume adjustments of the balloons at any time perioperatively and postoperatively. This paper examines the evolution of the technique and the impact of this progression on patient outcomes. METHODS: Two groups, one representing the first 50 patients, the second consisting of the last 50 patients are compared for changes in pad use and incontinence quality of life (I-QOL) with a mean follow-up of 23 mo (range: 1-46 mo) in group 1 and 20 mo (range: 18-24) in group 2. A comparison of complications and retreatment is summarised. RESULTS: Pad usage was reduced significantly in both groups ($p < 0.001$). Overall, group 2 patients obtained more consistent outcomes compared to group 1 (80% vs. 60% dry or $> 50\%$ improved). I-QOL improved in both groups although more significantly in group 2 ($p = 0.005$). Operative time was reduced in group 2. The rate and range of complications experienced in group 1 as the technique evolved decreased dramatically in group 2. CONCLUSIONS: The evolution of technique and expertise has facilitated an efficient surgical implantation procedure with reproducible and effective objective and subjective outcomes. The implantation of this device is now conducted in > 100 centres across Europe.

Innerkofler, P. C., V. Guenther, et al. (2008). "Improvement of quality of life, anxiety and depression after surgery in patients with stress urinary incontinence: results of a longitudinal short-term follow-up." Health Qual Life Outcomes **6**: 72.

OBJECTIVE: The objective of this study was to compare the effect of incontinence surgery and pelvic floor training on quality of life (QOL), anxiety and depression in patients with stress urinary incontinence (SUI). **METHODS:** In a prospective longitudinal study, females with proven SUI were asked to complete a set of standardized questionnaires (sociodemographic data sheet, FACT-G, I-QOL, HADS) before and eight weeks after treatment. The comparison groups consisted of a surgical treatment group and a conservative group that underwent supervised pelvic floor training for eight weeks. **RESULTS:** From the 67 female patients included in the study a number of 53 patients completed both assessment time points (mean age 57.4, mean years of SUI 7.6). The surgical treatment group consisted of 32 patients of which 21 patients received a modified Burch colposuspension and 11 patients a tension-free mid-urethral tape suspension. The 21 patients in the conservative group attended eight once-weekly supervised pelvic floor training sessions. After treatment the surgical intervention group showed a significantly higher improvement of QOL (FACT-G and I-QOL) and anxiety (HADS) than the pelvic floor training group. **CONCLUSION:** For female patients with SUI surgery yielded a better outcome than pelvic floor training with regard to quality of life and anxiety.

Jo, D. G., S. A. Yang, et al. (2010). "Effects of transobturator adjustable tape sling procedure on the therapeutic outcome in patients with stress urinary incontinence and detrusor underactivity." Int Neurourol J **14**(1): 20-25.

PURPOSE: To evaluate the outcome and efficacy of transobturator adjustable (TOA) tape sling operations on women with intrinsic sphincter deficiency (ISD) and/or detrusor underactivity (DU) combined with stress urinary incontinence (SUI). **MATERIALS AND METHODS:** This retrospective analysis comprised 60 TOA patients. 30 patients had DU ($Q_{max} < 15\text{ml/s}$) and/or ISD (Valsalva leak point pressure; VLPP $< 60\text{cmH}_2\text{O}$) on the preoperative UDS and the rest only had SUI. I-QoL, visual analog scale (VAS), Patient's Perception of Urgency Severity (PPUS), and Self-Assessment/Sandvik Questions were performed before and 1 year after surgery. The mesh tension was controlled at 1 day after surgery. The objective cure rate was defined as no leakage using the cough test with a full bladder. **RESULTS:** PATIENTS WERE DIVIDED INTO TWO GROUPS: Group A: SUI with ISD and/or DU, $n=30$; Group B: only SUI without ISD and DU, $n=30$. The two groups showed a difference in Q_{max} and VLPP preoperatively. Objective success rates were 18 (60.0%) completely cured, 10 (33.3%) improved in Group A, and 23 (76.7%) completely cured, 7 (23.3%) improved in Group B. Three cases needed tape-tension adjustment due to urinary leakage one-day after surgery (2 in Group A, 1 in Group B). There was no postoperative urinary retention. **CONCLUSIONS:** After TOA for SUI with ISD and/or DU, 3 cases were needed tension adjustment after surgery. TOA procedures seem to be effective and safe, more clinical studies with long-term follow up are required for a definite conclusion.

Kafri, R., R. Langer, et al. (2007). "Rehabilitation vs drug therapy for urge urinary incontinence: short-term outcome." Int Urogynecol J Pelvic Floor Dysfunct **18**(4): 407-411.

The objective of this study was to compare the short-term effectiveness of rehabilitation treatment with a standard drug treatment for urge urinary incontinence (UUI). The study design includes parallel clinical trial in an outpatient urogynecologic clinic setting. The subjects were 44 women who suffered from UUI and who were systematically assigned to a rehabilitation group (REH) (N=24) or a medication group (MED) (N=20). The intervention for REH was consisted of five visits during a 3-month period of pelvic floor muscle training and behavioral training, whereas for MED was extended release oxybutynin at 5 mg/day, for 3 months. The urinary symptoms considered were frequency of voiding per day and night (freq/day and freq/night), number of incontinent episodes per week based on a bladder diary, and data based on the Incontinence Quality of Life Instrument (I-QoL). In the within-group comparison, both groups had improved significantly over time with respect to urinary symptoms and I-QoL ($p < 0.01$). In addition, there was a significant group-time interaction effect on freq/day. While REH improved during the 3-month follow-up period, the MED group deteriorated to mean baseline value ($p < 0.01$). A significant negative association was found between the urinary symptoms and the I-QoL at the end of follow-up ($r(p) = -0.35$ to -0.62 , $p < 0.05$). Three months after the intervention, both groups maintained the achievements of the intervention period. In addition, the REH group demonstrated additional improvement in mean freq/day while the condition of MED patients deteriorated to baseline values.

Kafri, R., J. Shames, et al. (2012). "Self-report function and disability: a comparison between women with and without urgency urinary incontinence." Disabil Rehabil **34**(20): 1699-1705.

PURPOSE: To compare self-reported function and disability between women with urgency urinary incontinence (UUI) and healthy controls. **METHOD:** Self-reported function and disability were evaluated using the Late Life Function and Disability Instrument (LLFDI) in 66 women with UUI (mean age 61.9 +/- 5.6) and 66 age-matched control women without UUI in a cross-sectional study. The function component evaluates difficulty in performing physical activities in upper and lower extremities and the disability component evaluates limitations in life activities and frequency in taking part in life tasks. Body Mass Index (BMI), self-report incontinence quality of life questionnaire (I-QoL) and Visual Analog Scale (VAS) that indicate the degree to which the bladder problems limited the subject's daily life activity were also evaluated. **RESULTS:** The LLFDI scores in overall function, basic and advanced lower limb function, were significantly lower in women with UUI compared with continent women, while the upper extremity function and disability components were not. There was significant negative correlation between BMI and function scores in women with UUI. **CONCLUSION:** Our results support the assumptions that the women with UUI are likely to show

poorer lower extremity physical functioning and that disability is a multifactorial combination of behavioral, psychological and environmental factors, and not functional limitations per se.

Kafri, R., J. Shames, et al. (2008). "Rehabilitation versus drug therapy for urge urinary incontinence: long-term outcomes." Int Urogynecol J Pelvic Floor Dysfunct **19**(1): 47-52.

The objective of this study was to compare the residual effect of a 3-month rehabilitation treatment and a standard drug treatment for urge urinary incontinence (UUI) 21 months post intervention. Forty-four women (ages 27-68 years) who were diagnosed with overactive bladder (OAB) were divided into 2 treatment groups over 3 months: 24 women received rehabilitation (REH) and 20 women were treated with medication (MED) (oxybutynin ER). Outcomes measures included frequency of urination, quality of life (QoL), and number of side effects (no/SE), which were measured upon entry into the study (entry), completion of the intervention (3 months), and at follow-up 3 and 21 months after completion of treatment. In the follow-up period, there was a significant group-time interaction effect on freq/day and freq/night ($p < 0.01$). At the end of follow-up, the mean number of no/SE was significantly greater in the MED group compared to the REH group (3.3 ± 0.5 vs 2.4 ± 0.4 ; $p < 0.05$). A significant negative association was found between the urinary symptoms and the I-QoL at the 21-month follow-up ($r(p) = -0.45$ to -0.57 , $p < 0.05$). In the long-term, the REH patients maintained and even improved the achievements of the intervention period while the MED patients deteriorated to baseline values in urinary frequency. The suggestion for future work is to investigate the effect of each REH treatment component on UUI symptoms.

Kavia, R. B., D. De Ridder, et al. (2010). "Randomized controlled trial of Sativex to treat detrusor overactivity in multiple sclerosis." Mult Scler **16**(11): 1349-1359.

BACKGROUND: Bladder dysfunction is a common feature of multiple sclerosis (MS). **Objective:** In this study we aimed to assess the efficacy, tolerability and safety of Sativex((R)) (nabiximols) as an add-on therapy in alleviating bladder symptoms in patients with MS. **METHODS:** We undertook a 10-week, double-blind, randomized, placebo-controlled, parallel-group trial in 135 randomized subjects with MS and overactive bladder (OAB). **RESULTS:** The primary endpoint was the reduction in daily number of urinary incontinence episodes from baseline to end of treatment (8 weeks). Other endpoints included incidence of nocturia and urgency, overall bladder condition (OBC), daytime frequency, Incontinence Quality of Life (I-QOL), Patient's Global Impression of Change (PGIC) and volume voided. The primary endpoint showed little difference between Sativex and placebo. Four out of seven secondary endpoints were significantly in favour of Sativex: number of episodes of nocturia (adjusted mean difference -0.28 , $p = 0.010$), OBC (-1.16 , $p = 0.001$), number of voids/day (-0.85 , $p = 0.001$) and PGIC ($p = 0.005$). Of the other endpoints, number of daytime voids was statistically significantly in favour of Sativex (-0.57 , $p = 0.044$). The improvement in I-QOL was in favour of Sativex but did not reach statistical significance. **CONCLUSIONS:** Although the primary endpoint did not reach

statistical significance, we conclude that Sativex did have some impact on the symptoms of overactive bladder in patients with MS, providing evidence of some improvement in symptoms associated with bladder dysfunction in these subjects.

Kim, J. C., B. S. Chung, et al. (2007). "A safety and quality of life analysis of intravaginal slingplasty in female stress incontinence: a prospective, open label, multicenter, and observational study." *Int Urogynecol J Pelvic Floor Dysfunct* **18**(11): 1331-1335.

This prospective, open label, multicenter, and observational study was performed to determine the efficacy, safety, and the impact of this procedure on the current quality of life (QOL). One hundred three women underwent the intravaginal slingplasty (IVS) procedure. The postoperative evaluation consisted of clinical examination, Incontinence Quality of Life (I-QOL) questionnaire, 3-day consecutive frequency volume chart, free flowmetry, and measurement of post void residual. At 12 months, 83 patients have completed follow-up and are included in this analysis. Patient assessment of continence revealed 89.2% (74/83) cure rate. During follow-up period, one patient (1.2%) has presented with vaginal erosion of the sling material. The I-QOL showed significant improvement in total and three subscale scores at 12 months of follow-up period. This study demonstrated that the IVS procedure provides a safe and effective means for the treatment of female stress incontinence and improvement of QOL.

Kim, J. J., Y. S. Lee, et al. (2010). "Randomized Comparative Study of the U- and H-Type Approaches of the TVT-Secur Procedure for the Treatment of Female Stress Urinary Incontinence: One-Year Follow-Up." *Korean J Urol* **51**(4): 250-256.

PURPOSE: We compared outcomes of the U- and H-type approaches of the tension-free vaginal tape (TVT)-Secur procedure for the treatment of female stress urinary incontinence (SUI). **MATERIALS AND METHODS:** From March 2007 to July 2008, 115 women with SUI underwent TVT-Secur by a single surgeon. Patients were randomly assigned to either the U- or the H-type approach. After 12 months, postoperative changes in the Sandvik questionnaire, incontinence quality of life questionnaire (I-QoL), Bristol female lower urinary tract symptoms-scored form (BFLUTS-SF), and postoperative patient satisfaction were evaluated. Cure was regarded as no leakage on the Sandvik questionnaire. Complications were also evaluated. **RESULTS:** Of 115 women, 53 were treated with the U approach, and 62 women were treated with the H approach. At 12 months, 88.7% of those treated with the U approach and 87.1% of those treated with the H approach were cured ($p=0.796$). The I-QoL and filling, incontinence, sexual function, and QoL sum (BFLUTS-SF) scores were improved with both approaches, and there were no significant differences in the degree of improvement between approaches. Approximately 83.7% and 82.9% of the women treated with the U and H approaches, respectively, were satisfied with the outcome ($p=0.858$). There were 3 cases of intra-operative vaginal wall perforation in the H-type group. Immediate postoperative retention was observed in 2 women in the U-type group and 1 woman in the H-type group. One woman in the U-type group underwent tape releasing and cutting procedures for persistent large post-void residuals. **CONCLUSIONS:** The U- and the H-type approaches of

the TVT-Secur procedure provided comparable effectiveness for the treatment of female SUI.

Kim, S. H. and S. J. Oh (2010). "Comparison of voiding questionnaires between female interstitial cystitis and female idiopathic overactive bladder." Int Neurourol J **14**(2): 86-92.

PURPOSE: This study aimed to find out any different characteristics in various different voiding symptom questionnaires in the outpatient clinics between interstitial cystitis and overactive bladder. **MATERIALS AND METHODS:** Between October 2005 and December 2007, retrospectively were analyzed the consecutive 41 IC female patients' and 43 OAB female patients' questionnaires, who had completed three questionnaires at the outpatient department (Incontinence Quality of Life; I-QoL, King's Health Questionnaire; KHQ, International Prostate Symptom Score; IPSS). Additionally, the 41 IC patients also completed O'Leary Sant Questionnaire (OLS, or ICSI/ICPI). **RESULTS:** No statistical differences existed in age and symptom duration between two groups ($p > 0.05$). In I-QoL, only the social embarrassment score was statistically different between two groups ($p < 0.05$), but the total score, avoidance and limiting behavior, and psychosocial impact scores were not ($p > 0.05$). In KHQ, the general health perceptions, impact on life, social limitations, personal relationships, emotions, and sleep/energy scores were statistically different ($p < 0.033$), but the role limitations, physical limitations, and incontinence severity measures scores were not ($p > 0.059$). In IPSS, the straining symptom, and quality of life scores were different between two groups ($p < 0.05$). The IC patients also completed OLS questionnaire with mean interstitial cystitis symptom index score of 14.10 ± 3.92 , and interstitial cystitis problem index score of 11.79 ± 3.75 . **CONCLUSIONS:** This study showed that some differences among symptom questions in questionnaires did exist between the two groups and that the IC group had much more impaired quality of life than the OABs.

Kinchen, K. S., R. Obenchain, et al. (2005). "Impact of duloxetine on quality of life for women with symptoms of urinary incontinence." Int Urogynecol J Pelvic Floor Dysfunct **16**(5): 337-344.

The objective of this study was to evaluate the effectiveness of duloxetine in improving quality of life among women with stress and mixed urinary incontinence. The study included 451 women with self-reported stress incontinence episodes (≥ 1 /week) who were randomized to duloxetine (40 mg BID) or placebo in a double-blind, usual care design. Patients and physicians were allowed to titrate, augment, and/or discontinue treatment. Concomitant treatments were permitted. The primary outcome was the Incontinence Quality of Life Questionnaire (I-QOL) score, with assessments at 3, 6, and 9 months. Other measures included the Patient Global Impression of Improvement (PGI-I) and adverse events. The adjusted mean change in I-QOL total score was greater in the duloxetine group than in the placebo group and at a level comparable to that found in previous clinical trials, but the difference between placebo and duloxetine was not statistically significant in the intent-to-treat, last observation

carried forward (LOCF) analysis. The difference approached statistical significance in favor of duloxetine at 3 months ($p=0.07$). PGI-I ratings did not demonstrate significant superiority for duloxetine in LOCF analysis; however, study completers taking duloxetine were significantly more likely to rate themselves as "better" (70.2%) than completers taking placebo (50.8%, $p<0.05$). Women utilized a variety of treatment methods including pelvic floor muscle training, estrogen, anticholinergic medication, weight reduction, and smoking cessation. In this study, while mean I-QOL change scores were numerically higher for the duloxetine group than mean change scores for the placebo group, this difference was not statistically significant. Among women who completed the study on study drug, a significantly greater proportion of duloxetine women versus placebo women rated their condition to be better.

Kocjancic, E., S. Crivellaro, et al. (2008). "Transobturator tape in the management of female stress incontinence: clinical outcomes at medium term follow-up." Urol Int **80**(3): 275-278.

OBJECTIVE: To assess the efficacy of transobturator tape (TOT) in the management of stress urinary incontinence at a medium term follow-up. **METHODS:** TOT is a polypropylene tape positioned through the obturator foramen. 70 patients with type II urinary stress incontinence were treated with TOT between June 2003 and May 2006. Patients were prospectively studied by physical examination, quality of life questionnaire (I-QOL), visual analog scale, global impression (dry, improved, same, worse), preoperative urodynamic study, and pre- and postoperative flowmetry. Statistical analysis (t test) of the difference in I-QOL scores and flowmetry was made by StatSoft V. 5.1. **RESULTS:** The average follow-up was 32 (range 12-48) months. The I-QOL score increased statistically significantly by 40 points. The average percent improvement was 80%. 90% (63/70) of the patients were dry and 5% (4/70) were improved. The pre- and postoperative uroflowmetry studies were not statistically different. Vaginal erosion occurred in 4 patients. **CONCLUSION:** TOT is a safe procedure with a good efficacy at 32-month follow-up.

Krhut, J., M. Gartner, et al. (2009). "[Combination therapy with anticholinergics and alpha-blockers for the treatment of overactive bladder in female patients--pilot study]." Ceska Gynekol **74**(6): 416-420.

INTRODUCTION: Overactive bladder (OAB) is one of the most common medical conditions with an estimated 16 percent of adult population being affected in Europe. The administration of anticholinergics is considered as the most frequent and most effective treatment. There is a evidence that alpha-blockers affect a detrusor function. The aim of the study is to investigate if the combinant therapy consisting of anticholinergics plus alpha-blockers could be beneficial for women suffering from OAB. **Material and methods:** 28 female patients with OAB were included into the pilot study. Mean age of the patients was 54.8 (42-77) years. Patients have been randomised into two groups: one group of patients has been treated by propiverin 30 mg daily, another group of patients has been treated by combination of both propiverin 30 mg daily and tamsulosin 0.4 mg daily.

Satisfaction with the treatment has been evaluated by I-QoL questionnaire. Semi-objective parameters have been obtained by analysis of 3-days voiding diaries (number of micturitions, number of urgency episodes, voided volume). Peak flow (Qmax) has been measured as a objective parameter. RESULTS: We observed a decrease of frequency by 2.833 (-23.43%) comparing to base-line, decrease of number of urgency episodes by 1.417 (-36.22%), increase of voided volume by 33.333 ml (+19.14%), increase of quality of life index by 22.583 (+51.52%) and increase of Qmax by 0.17 ml/s (+0.58%) in the propiverin group. We observed decrease of frequency by 3.813 (-30.48%), decrease of number of urgency episodes by 1.875 (-45.52%), increase of voided volume by 51.250 ml (+26.88%), increase of quality of life index by 33.438 (+76.0%) and increase of Qmax by 2.13 ml/s (+7.87%) in the combination treatment group. No significant difference has been found between both groups except the quality of life index. CONCLUSION: Our results can not show explicitly higher efficacy of combination treatment using anticholinergics plus alpha-blockers comparing to standard therapy by anticholinergics alone. Further randomised placebo-controlled studies are needed for final evaluation of the role of alpha-blockers in the treatment of OAB.

Krhut, J., R. Holanova, et al. (2007). "[Results of conservative non-pharmacological therapy in female patients with urinary incontinence]." *Ceska Gynekol* **72**(6): 406-409.

INTRODUCTION: The urinary incontinence belongs among the most frequent health problems especially in female population. Hundreds millions people suffer from urinary incontinence worldwide. This condition is not associated with a high morbidity or mortality; it influences the quality of life of affected patients however. The article assesses both subjective and objective results of the conservative non-pharmacological therapy and its effect to the quality of life in the set of female patients with urinary incontinence of all types. MATERIAL AND METHODS: The set totaled 69 female patients suffering from urinary incontinence treated by conservative non-pharmacological therapy. Patients with all type of incontinence (stress incontinence, urgent incontinence, mixed-type incontinence) of the 1st - 2nd seriousness degree were included into the set. The average age of the set was 55 (19-80) years. All patients were treated in a complex way in accordance with principles of the so-called "Ostrava concept" of the conservative non-pharmacological therapy. Subjective results were evaluated using the visual-analog scale (VAS) while objective results were evaluated by the perineometric measurement of the pelvic floor. The quality of life was assessed using the I-QoL questionnaire. The assessment was performed before the therapy started and 6 months after. RESULTS: Before the therapy the value at VAS was 5.82, after the therapy the value at VAS was 2.73. The index of the quality of life in our set before the treatment was 55.6 (13.6-92.7), after the treatment it was 72.6 (22.7-98.7). The value of the maximum contraction force of the pelvic floor muscles before the treatment was 16.9 (5-51) cm H₂O, after the treatment it was 17.4 (5-37) cm H₂O, the mean value of the contraction force of the pelvic floor muscles before treatment was 10.8 (6-39) cm H₂O, after the treatment it was 12.8 (3-33) cm H₂O, average persistence time of the maximum

contraction of pelvic floor muscles before the therapy was 5.5 (1-16) sec while after the therapy it changed to 9.1 (1-19) sec. CONCLUSION: Based on results obtained the conservative non-pharmacological therapy can be assessed as an efficient treatment method in case of the incontinence of 1st and 2nd degree. Due to its non-invasive character and the absence of adverse effects it should be considered to be the first choice treatment in case of female patient with urinary incontinence.

Kwon, B. E., G. Y. Kim, et al. (2010). "Quality of life of women with urinary incontinence: a systematic literature review." *Int Neurourol J* **14**(3): 133-138.

PURPOSE: The purpose of this study was to review studies that have examined the quality of life of women with urinary incontinence. MATERIALS AND METHODS: A review was conducted that used the databases PubMed, Proquest, CINAHL, and Sciencedirect. Articles were included that were published in English between 2005 and 2010 the key words use were urinary incontinence, women, and quality of life. RESULTS: A total of 18 studies were identified, and the prevalence of urinary incontinence varied depending on the definition of incontinence used and the age of the population studied. The Incontinence Quality of Life (I-QoL), Incontinence Impact Questionnaire-short form (IIQ-7), and King's Health Questionnaire (KHQ) were the most commonly used instruments. Demographic, medical, physical, psychological, health, and intervention factors were reported as influencing factors on the quality of life of women with incontinence. Age, severity of urinary incontinence, type of urinary incontinence, number of urinary incontinence episodes, body weight, stress, and help-seeking behavior were statistically significant variables influencing quality of life. CONCLUSION: Future studies are needed to identify factors related to quality of life among women with incontinence and to use validated instruments according to specific subjects.

Lee, H. N., Y. S. Lee, et al. (2010). "Transurethral injection of bulking agent for treatment of failed mid-urethral sling procedures." *Int Urogynecol J* **21**(12): 1479-1483.

INTRODUCTION AND HYPOTHESIS: We evaluated the efficacy of transurethral injection (TUI) for the treatment of recurrent or persistent stress urinary incontinence after mid-urethral sling (MUS) procedures. METHODS: A retrospective study was conducted among 23 women who had undergone TUI for failed MUS using bulking agents, Macroplastique(R) and Durasphere(R). The Sandvik questionnaire, Subjective Symptom Visual Analogue Scale (VAS), Incontinence Quality of Life (I-QOL) assessment, and Benefit, Satisfaction, and Willingness to Continue questionnaire were used to evaluate the efficacy of TUI. RESULTS: The cure rate was 34.8% for a median follow-up of 10 months. Subjective symptom VAS, total, and all domains of I-QOL scores were significantly improved after TUI. Ninety-two percent of the patients reported a benefit and 77% of the patients were satisfied with the treatment. CONCLUSIONS: TUI for failed MUS demonstrated a low cure rate but high patient satisfaction, and the procedure was minimally invasive with no significant complications.

Lee, K. S., Y. S. Lee, et al. (2010). "A prospective multicenter randomized comparative study between the U- and H-type methods of the TVT SECUR procedure for the treatment of female stress urinary incontinence: 1-year follow-up." *Eur Urol* **57**(6): 973-979.

BACKGROUND: No studies have been published comparing the U- and H-type methods of the TVT SECUR (TVT-S) procedure. **OBJECTIVE:** Our aim was to compare the efficacy and safety of the two types of TVT-S for female stress urinary incontinence (SUI). **DESIGN, SETTING, AND PARTICIPANTS:** Women with urodynamic SUI were enrolled in this 12-mo multicenter randomized study. **INTERVENTION:** Subjects were randomly allocated to either the U- or H-type method of TVT-S. **MEASUREMENTS:** Pre- and postoperative evaluations included a standing stress test, the Sandvik questionnaire, the Incontinence Quality of Life (I-QOL) questionnaire, and the International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS). Patients' satisfaction and complications were evaluated. Objective and subjective cures were defined as no leakage on the stress test and responses on the Sandvik questionnaire, respectively. We compared the surgical outcomes between the two methods. **RESULTS AND LIMITATIONS:** Of 285 women, 144 had the U-type method and 141 had the H-type method. Objective cure rates were 87.5% for the U-type method and 80.1% for the H-type method ($p=0.091$). Subjective cure rates were 77.1% for the U-type method and 75.7% for the H-type method ($p=0.786$). Improvement in I-QOL and domain scores of the ICIQ-FLUTS (filling and incontinence sum, QOL score), and patients' satisfaction favored the U-type method. There were three cases of intraoperative vaginal wall perforation, one case of increased bleeding, and three cases of temporary postoperative retention. A power calculation was not performed, and some baseline characteristics were not balanced between the two methods. **CONCLUSIONS:** Both methods of TVT-S provided comparable cure rates for female SUI. However, QOL and treatment satisfaction favored the U-type method. **TRIAL REGISTRATION:** The protocol of this study was not registered.

Lenihan, J. P. (2005). "Comparison of the quality of life after nonsurgical radiofrequency energy tissue micro-remodeling in premenopausal and postmenopausal women with moderate-to-severe stress urinary incontinence." *Am J Obstet Gynecol* **192**(6): 1995-1998; discussion 1999-2001.

OBJECTIVE: This study was undertaken to determine the effect of menopause and hormone replacement therapy (HRT) on incontinence quality of life (I-QOL) score improvement in women with moderate-to-severe stress urinary incontinence (SUI) after nonsurgical, transurethral radiofrequency energy (RF) tissue micro-remodeling. **STUDY DESIGN:** Retrospective review of prospective, randomized, controlled clinical trial. Women with moderate-to-severe SUI were analyzed by menopausal status and HRT use for 10-point or greater I-QOL score improvement (an increase associated with subjective and objective SUI improvement). **RESULTS:** RF micro-remodeling resulted in 81% of subjects achieving 10-point or greater I-QOL score improvement versus 49% of sham

subjects at 12 months ($P = .04$). Outcomes did not differ statistically when premenopausal (85%), postmenopausal using HRT (70%), and postmenopausal not using HRT (71%) groups were compared. CONCLUSION: Menopausal status and HRT demonstrated no impact on the quality of life improvement experienced by women with moderate-to-severe SUI who underwent RF tissue micro-remodeling.

Li, B., L. Zhu, et al. (2012). "Long-term outcomes of the tension-free vaginal tape procedure for female stress urinary incontinence: 7-year follow-up in China." J Minim Invasive Gynecol **19**(2): 201-205.

STUDY OBJECTIVE: To estimate the long-term objective rates of cure, late complications, and satisfaction after tension-free vaginal tape (TVT) procedure. DESIGN: Retrospective study (Canadian Task Force classification II-3). SETTING: Single-center. PATIENTS: Fifty-five patients with moderate to severe stress urinary incontinence (SUI) underwent the TVT procedure from May 2002 to March 2005. INTERVENTION: TVT procedure. MEASUREMENTS AND MAIN RESULTS: Changes in 1-hour pad test results and incontinence quality-of-life (I-QOL) questionnaire scores before surgery and at 1- and 7-year follow-up were compared. Changes in objective rates of cure, late complications, and satisfaction at 1- and 7-year follow-up were also compared. The mean duration of follow-up was 6.80 years. Both the 1-hour pad test results and the I-QOL questionnaire scores improved significantly after surgery ($p < .001$). The TVT procedure satisfaction rate at 7-year follow-up decreased significantly compared with that at 1-year follow-up ($p = .001$); however, I-QOL score did not change significantly. CONCLUSIONS: The TVT procedure is an effective treatment for SUI in female patients. Despite little persistent or recurrent SUI over 7-year follow-up, satisfaction with the procedure decreases. Therefore, other age-related bladder conditions must be considered when counseling patients about the TVT procedure. Assessment of the efficacy of the TVT procedure should include both objective and subjective standards.

Liebergall-Wischnitzer, M., D. Hochner-Celnikier, et al. (2005). "Paula method of circular muscle exercises for urinary stress incontinence--a clinical trial." Int Urogynecol J Pelvic Floor Dysfunct **16**(5): 345-351.

The aim of this study was to determine the efficacy of the Paula method of circular muscle training in the management of stress incontinence (SI). The theory behind this method states that activity of distant sphincters affects other muscles. In a pilot study, 59 women, mainly hospital employees, were randomly assigned to participate in exercises according to the Paula method or pelvic floor training. Efficacy was measured by reports of incontinence, quality of life (I-QOL), pad test, and pelvic floor muscle strength (assessed by perineometer and digital examination). Both the Paula exercises and pelvic floor training produced significant changes in urinary leakage compared to baseline as measured by the pad test [mean decrease of 5.4 g ($p=0.002$) and 9.5 g ($p=0.003$), respectively]. Women randomized to the Paula method reported improvement in I-QOL scores. The Paula method was found to be efficacious for SI in a population of Israeli

women. Larger community-based studies will be required to confirm these results and enable evaluation of between-group differences.

Liebergall-Wischnitzer, M., O. Paltiel, et al. (2011). "Sexual function and quality of life for women with mild-to-moderate stress urinary incontinence." J Midwifery Womens Health **56**(5): 461-467.

INTRODUCTION: Sexual function is affected by stress urinary incontinence with or without pelvic organ prolapse. The aim of the study was to describe the sexual function of women with mild-to-moderate stress urinary incontinence, with or without pelvic organ prolapse (up to stage 2) and examine correlations with symptoms and quality of life. This investigation was part of a large, randomized, clinical trial of women with stress urinary incontinence who participated in an exercise intervention. **METHODS:** Women included in the study suffered from stress urinary incontinence as measured by a pad test and were interested in an exercise intervention. All participants underwent assessment for prolapse staging. Instruments included: the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), Incontinence Quality of Life Questionnaire (I-QOL), and a health and urinary leakage questionnaire. **RESULTS:** One hundred and eighty-seven ambulatory women, aged 20 to 65 years, had a mean sexual function score of 36.9 (standard deviation [SD] 5.9). No significant correlation was found between the sexual function scores and quantity of urinary leakage. A significant correlation existed between the sexual function and I-QOL scores ($P < .001$). An additional finding was that women with urgency symptoms were older ($P = .04$) and had significantly lower sexual function scores (mean 35.7; SD 6.4) than those who did not report urgency (mean 38.7; SD 4.6; $P < .001$). **DISCUSSION:** Women with mild-to-moderate stress urinary incontinence, without or with lower stages of pelvic organ prolapse, demonstrated good sexual function, which correlated with physical and psychosocial factors. Health professionals need to perform multifaceted intake assessments on women with urinary leakage to customize their health promotion regimen.

Lim, H. S., J. M. Kim, et al. (2010). "Impact of the midurethral sling procedure on quality of life in women with urinary incontinence." Korean J Urol **51**(2): 122-127.

PURPOSE: This study was designed to objectively assess the impediment of incontinence to quality of life (QoL) in females and its improvement by the midurethral sling (MUS) procedure. **MATERIALS AND METHODS:** From June 2006 to June 2007, 93 female patients underwent the MUS procedure at our institute because of urinary incontinence. The incontinence quality of life (I-QoL) questionnaire was administered to measure the QoL of the incontinent patients before and 1 and 12 months after the MUS procedure. Preoperative data and urodynamic factors were analyzed retrospectively by I-QoL scores to identify factors that may affect the QoL of incontinent patients. **RESULTS:** The average preoperative I-QoL score of the 93 patients was 61.1 \pm 21.0 points. At 1 year after surgery, the average I-QoL score was found to have improved to 98.4 \pm 20.7 points. There were no significant differences between stress and mixed urinary incontinence in terms of cure and satisfaction ($p > 0.05$). I-QoL scores of

the cured and improved patients increased at 1 year after surgery ($p < 0.01$). There were no statistically significant differences in the increment of I-QoL between cured and improved patients ($p > 0.05$). Although urinary urgency and large urine leak amounts significantly reduced preoperative QoL in incontinent patients, the MUS procedure effectively improved the QoL regardless of these factors. CONCLUSIONS: Preoperative I-QoL assessment revealed a significant impairment of QoL in incontinent women, but the MUS procedure effectively improved these women's QoL.

Lin, A. T., M. J. Sun, et al. (2008). "Duloxetine versus placebo for the treatment of women with stress predominant urinary incontinence in Taiwan: a double-blind, randomized, placebo-controlled trial." *BMC Urol* **8**: 2.

BACKGROUND: This manuscript compares the efficacy and safety of duloxetine with placebo in Taiwanese women with SUI. METHODS: Taiwanese women with SUI were randomly assigned to placebo ($n = 61$) or duloxetine 80 mg/day ($n = 60$) in this double-blind, 8-week, placebo-controlled study. Outcome variables included: incontinence episode frequency (IEF), Incontinence Quality of Life questionnaire (I-QOL) scores, and Patient Global Impression of Improvement rating (PGI-I). RESULTS: Decrease in IEF was significantly greater in duloxetine-treated than placebo-treated women (69.98% vs 42.56%, $P < .001$). No treatment differences in I-QOL scores were significant. There were significant differences in PGI-I rating. Treatment-emergent adverse events (TEAEs) were experienced by more duloxetine-treated than placebo-treated women (80.0% vs 44.3%; $P < .001$). Discontinuations due to adverse events were significantly greater for duloxetine-treated than placebo-treated women (26.7% vs 6.6%; $P = .003$). CONCLUSION: Data provide evidence for the safety and efficacy of duloxetine for the treatment for Taiwanese women with SUI. TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT00475358.

Masata, J., A. Martan, et al. (2009). "[Long-term efficacy of TVT procedure in the treatment of stress urinary incontinence]." *Ceska Gynekol* **74**(2): 118-123.

OBJECTIVE OF THE STUDY: The objective of the study was to ascertain the long-term efficacy of TVT procedure in the treatment of stress urinary incontinence. DESIGN: Prospective observational study. SETTINGS: Department of Gynecology and Obstetrics, First Faculty of Medicine, Charles University and the General University Hospital, Prague, EuroMISE centre of the Academy of Science, Prague. MATERIAL AND METHODS: 111 women with urodynamically proven stress incontinence who had undergone a TVT operation were included in the study; patients suffering with the mixed type of incontinence were included as well while a major prolapse of anterior vaginal wall (POP-Q II and more) was applied as the exclusion criterion. An overall pre-operation examination was carried out, including urodynamic and ultrasound examination, while the patients also completed an i-QOL quality of life questionnaire. The success of the operation was assessed using objective and subjective parameters. Occurrence of post-operation complications was correlated to the pre-operation mobility of the urethra, the surgeon who carried out the procedure,

the post-operation position and mobility of the tape. RESULTS: Of the 111 patients, 105 appeared for the 3-month post-operation check. Another 10 failed to appear for the one year check, and yet another 10 dropped out from the subsequent monitoring. A failure of the procedure was subsequently described for 9 patients (8.1%), who had to undergo another procedure: for 7 patients a re-operation was carried out to treat recurrence of the stress urinary incontinence, and for 2 patients discision of the tape was carried out for the reason of problems with urine retention and repeated infections of urinary tract. At the beginning of the post-operation monitoring 80% of patients were objectively stress continent. At the end of the monitoring, 74% of women were fully continent and 15% subjectively improved, with objectively proved SI. We have, however, observed a relatively higher increase in de novo urgency, where at the beginning of the monitoring, 10% of patients were thus affected, and at the end of the monitoring 22.5%. At the end of the monitoring the tape is 20% narrower and 2 mm closer to the urethra; otherwise its position unchanged. We have not proved that the pre-operation mobility of the urethra or choice of surgeon would affect the results of the operation. Neither have we proved any difference in the position and mobility of the tape in relation to the result of the operation. CONCLUSIONS: In our group of patients we have proved very good long-term efficacy of the TVT operation for treatment of stress urinary incontinence. We have, nevertheless, observed a rather high increase in de novo occurrence of urgency at the end of the monitoring period - 21%. The increase of de novo urgency might be explained by the change in the position of the tape, which is closer to the urethra at the end of the monitoring.

Mattarozzi, K., L. Vignatelli, et al. (2012). "Effect of the disclosure of MS diagnosis on anxiety, mood and quality of life of patients: a prospective study." *Int J Clin Pract* **66**(5): 504-514.

BACKGROUND: In the light of the new diagnostic criteria for multiple sclerosis (MS) and currently available early treatment, this study aimed to explore whether, and to what extent, disclosure of the diagnosis of MS or clinically isolated syndrome (CIS) affects patients' anxiety, mood and quality of life (QoL).

METHODS: Eligible participants were all patients referred for the first time to the Neurological Unit who had manifested symptoms suggestive of MS for no more than 6 months. All patients were evaluated for (i) QoL (SEIQoL and MS-QoL54), (ii) Anxiety (STAI) and Depression (CMDI) on study inclusion (T0), 30 days after diagnosis disclosure (T30), and after 1 (T1y) and 2 (T2y) years' follow-up.

RESULTS: Two hundred and twenty-nine patients were enrolled; 93 of these were unaware of their diagnosis. Patients who already knew their diagnosis (100 with CIS and 22 with MS) were excluded from the main analyses and used to perform control analyses. At the end of the screening, an MS diagnosis was disclosed to 18 of the 93 patients, whereas a CIS diagnosis was disclosed to 62 patients (12 patients received a diagnosis other than MS or CIS). Thirty days after diagnosis disclosure, irrespective of the diagnosis disclosed, both QoL and Anxiety and Depression were significantly rated as better compared to the start of screening, ($p(s) < 0.03$), and this improvement remained stable over the two

annual follow-ups. However, as suggested by a significant 'Time' x 'Diagnosis' interaction with regard to both QoL and Anxiety and Depression ($p(s) < 0.02$), the effect of the disclosure in the short term differed depending on CIS or MS diagnosis. Specifically, on MSQoL, which is a health-related QoL scale, we found a statically significant improvement, immediately after the diagnosis disclosure, in both the MS and CIS groups ($p(s) < 0.01$). Differently, on SEIQoL, which is a non health-related QoL measure, and on the anxiety scale, we observed a statistically significant improvement only in the group which received a MS diagnosis ($p(s) < 0.03$). CONCLUSIONS: This first prospective study provides objective data showing that early disclosure of MS diagnosis improves both the patient's QoL and psychological well-being. In addition, the results seem to suggest that CIS disclosure does not lead to the same favourable effects.

McCormack, P. L. and G. M. Keating (2004). "Duloxetine: in stress urinary incontinence." *Drugs* **64**(22): 2567-2573; discussion 2574-2565.

Duloxetine is an orally administered, balanced, dual serotonin and norepinephrine (noradrenaline) reuptake inhibitor that increases neural input to the urethral sphincter, thereby relieving the symptoms of stress urinary incontinence (SUI). Duloxetine 40 mg twice daily for 12 weeks reduced the median incontinence episode frequency (IEF) to a significantly greater extent than placebo in women with predominant symptoms of SUI. In most studies, Incontinence Quality of Life (I-QOL) questionnaire total scores were significantly improved compared with placebo. In a dose-escalation study in women with severe SUI scheduled for continence surgery, duloxetine 80-120 mg/day for 8 weeks significantly reduced IEF and increased I-QOL total scores compared with placebo, and caused 20% of recipients to reconsider their willingness to undergo surgery. Duloxetine or duloxetine plus pelvic floor muscle training (PFMT) were more effective in reducing the median IEF than PFMT alone or no treatment in women with SUI. Mean I-QOL total scores suggested that combination therapy was more effective than either therapy alone. Nausea was the most frequent adverse event and was the main cause for discontinuing duloxetine therapy.

Millard, R. J., K. Moore, et al. (2004). "Duloxetine vs placebo in the treatment of stress urinary incontinence: a four-continent randomized clinical trial." *BJU Int* **93**(3): 311-318.

OBJECTIVES: To further assess, in a phase 3 study, treatment with duloxetine for women with stress urinary incontinence (SUI) in other geographical regions, including Argentina, Australia, Brazil, Finland, Poland, South Africa and Spain, as previous trials in North America and Europe provided evidence for the safety and efficacy of duloxetine as a pharmacological treatment for SUI in women.

PATIENTS AND METHODS: The study included 458 women aged 27-79 years enrolled in a double-blind, placebo-controlled trial. The patients with predominantly SUI were identified using a validated clinical algorithm. They were randomly assigned to receive placebo (231) or duloxetine 40 mg twice daily (227) for 12 weeks. The primary outcome variables included the incontinence episode frequency (IEF) and the Incontinence Quality of Life (I-QOL) questionnaire. Van Elteren's test was used to analyse the percentage changes in IEF where the

stratification variable was weekly baseline IEF (IEF < 14 and > or = 14). Analysis of covariance was used to analyse I-QOL scores. RESULTS: The mean baseline IEF was 18.4/week; 55% of patients had a baseline IEF of > or = 14. There was a significantly greater median decrease in IEF with duloxetine with placebo (54% vs 40%, P = 0.05), with comparable significant improvements in quality of life (I-QOL score increases of 10.3 vs 6.4, P = 0.007). The improvements with duloxetine were associated with significantly greater increases in voiding intervals than with placebo (20.4 vs 8.5 min, P < 0.001). The placebo response was 10.7% and 12.5% higher than those reported in two European and North American phase 3 trials. This may have been related to more patients being naive for incontinence management in the current trial. Discontinuation rates for adverse events were 1.7% for placebo and 17.2% for duloxetine (P < 0.001), with nausea being the most common reason for discontinuation (3.1%); it was the most common adverse event with duloxetine, but was mild or moderate in most (81%), did not worsen in any patient and resolved within 7 days in 60% and within 1 month in 86% of continuing patients; 88% of women who experienced nausea while taking duloxetine completed the trial. CONCLUSIONS: These results show improvements in incontinence and quality of life with duloxetine 40 mg twice daily for 12 weeks that are in keeping with those reported in two other recently completed phase 3 trials in Europe and North America.

Mitterberger, M., R. Marksteiner, et al. (2007). "Autologous myoblasts and fibroblasts for female stress incontinence: a 1-year follow-up in 123 patients." BJU Int **100**(5): 1081-1085.

OBJECTIVE: To assess the efficacy and safety of the application of autologous myoblasts and fibroblasts for treating female stress urinary incontinence (SUI) after a follow-up of ≥ 1 year. PATIENTS AND METHODS: In all, 123 women with SUI (aged 36-84 years) were treated with transurethral ultrasonography-guided injections with autologous myoblasts and fibroblasts obtained from skeletal muscle biopsies. The fibroblasts were suspended in a small amount of collagen as carrier material and injected into the urethral submucosa, while the myoblasts were implanted into the rhabdosphincter. All patients were evaluated before and 12 months after the injection using the Incontinence and Quality of Life Instrument (I-QOL) scores, urodynamic variables, and morphology and function of the urethra and rhabdosphincter. RESULTS: At 1 year after implanting the cells, 94 of the 119 women (79%) were completely continent, 16 (13%) had a substantial improvement and nine (8%) a slight improvement. Four patients were lost to follow-up. The incontinence and I-QOL scores, and the thickness, contractility and electromyographic activity of the rhabdosphincter were significantly improved after treatment. CONCLUSIONS: These results show the efficacy and safety of transferring autologous myoblasts and fibroblasts in the treatment of female SUI, after a follow-up of 1 year.

Monz, B., E. Chartier-Kastler, et al. (2007). "Patient characteristics associated with quality of life in European women seeking treatment for urinary incontinence: results from PURE." Eur Urol **51**(4): 1073-1081; discussion 1081-1072.

OBJECTIVE: To investigate the association between patient characteristics and disease-specific and generic quality of life (QOL) as well as the degree of bother in women seeking treatment for urinary incontinence (UI). **METHODS:** The Prospective Urinary Incontinence Research (PURE) was a 6-mo observational study with 1055 physicians from 15 European countries enrolling 9487 women. QOL was assessed at the enrolment visit using the urinary Incontinence Quality of Life questionnaire (I-QOL) and the generic EQ-5D. A single-item instrument was used to measure the degree of bother. UI severity was assessed using the Sandvik Index. UI was categorised into stress (SUI), mixed (MUI), and urge (UUI) urinary incontinence by a patient-administered instrument (Stress and Urge Incontinence Questionnaire [S/UIQ]). Multivariate linear (I-QOL, EQ-5D Visual Analogue Scale) and logistic (bother, EQ-5D health state index) regressions were performed. **RESULTS:** Mean total I-QOL scores were significantly and independently associated with UI severity, nocturia, age, UI subtype, number of selected concomitant medical conditions, length of suffering from UI before contacting a doctor, smoking status, ongoing use of UI medication, and country. After adjusting for all the covariates, the total I-QOL scores for SUI, MUI, and UUI were 62.7, 53.8 and 60.1, respectively. As with I-QOL, UI severity was also the most important predictor for bother. The number of concomitant medical conditions, together with UI severity, was the variable most strongly associated with EQ-5D. **CONCLUSION:** In addition to the UI subtypes, severity of UI should be given more importance in treatment algorithms and in treatment decision-making by both the patient and the physician.

Monz, B., M. E. Pons, et al. (2005). "Patient-reported impact of urinary incontinence--results from treatment seeking women in 14 European countries." Maturitas **52 Suppl 2**: S24-34.

OBJECTIVES: To describe the patient-reported impact of urinary incontinence (UI) in treatment-seeking women in Europe. **DESIGN:** PURE was a non-interventional, observational study, which aimed to describe the direct costs of treatment for European women seeking treatment for UI. A secondary study objective was to describe the impact of UI on health-related quality of life (HRQoL) by UI subtype and severity of disease. This paper presents the results from quality of life assessments as well as bothersomeness and interference with daily activities from the first study observation. **SUBJECTS:** Nine thousand four hundred and eighty-seven European women who had UI symptoms in the last 12 months were enrolled. Their UI symptoms were frequently those defined as mixed urinary incontinence (MUI) and were moderate to severe in nature. **MEASUREMENTS:** HRQoL was assessed at the first observation using the urinary Incontinence-specific Quality of Life Questionnaire (I-QOL) and the EQ-5D, a generic quality of life questionnaire. Data collected from EQ-5D provided insight into the patients' general health perception, while the I-QOL data indicated how affected the women were about their UI symptoms. Higher EQ-5D and I-QOL scores represent better quality of life. Patients were asked to indicate how much UI symptoms limited selected activities and to indicate the degree to which they found their symptoms to be bothersome. **RESULTS:** Overall, the median

self-rated health status on the EQ-5D visual analogue scale (VAS) was 70.0 and the median EQ-5D health state index was 0.85, with small but noticeable differences observed between countries. Of the five health dimensions of the EQ-5D, patients' self-care appeared to be the least affected by UI, with fewer than 10% of the women reporting that they had some problems. Between 20 and 40% of patients had some problems with their mobility and usual activities, or had pain/discomfort or anxiety/depression. However, the impact of existing co-morbidity was not assessed and may have affected some women's scoring of the EQ-5D domains. The mean total I-QOL score overall was 57.7 and of the three subscales of the I-QOL, psychosocial impact had the highest overall scores, representing fewer problems, with lower scores observed for the avoidance and limiting behaviour subscale, and even lower scores for the social embarrassment subscale. The greatest patient-reported impact of UI symptoms on activities was on exercise, with more than 45% of patients moderately to totally limited in this activity. In most of the countries, more than 60% of the women reported that they were moderately to extremely bothered by their UI symptoms. **CONCLUSIONS:** There was considerable impact of UI on HRQoL in a treatment seeking population, as demonstrated by the disease-specific quality of life scale and by the high percentage of patients who were bothered by their symptoms.

Moore, K. (2004). "Duloxetine: a new approach for treating stress urinary incontinence." Int J Gynaecol Obstet **86 Suppl 1**: S53-62.

Duloxetine is a potent and balanced dual serotonin and norepinephrine reuptake inhibitor (SNRI) that enhances urethral rhabdosphincter activity and bladder capacity in a cat irritated bladder model. Whether this is beneficial in women suffering from stress urinary incontinence (SUI) has been investigated in one phase 2 and three phase 3 placebo-controlled clinical trials with very comparable inclusion and exclusion criteria and outcome variables. In addition, one phase 3 study was performed in women with SUI awaiting incontinence surgery. These trials involved investigational centers in 5 continents: North America, Europe, Australia, South America and Africa. Duloxetine 80 mg per day (40 mg twice daily) decreased the frequency of incontinence episode frequency (IEF) and improved incontinence-related quality of life (I-QOL) independent of baseline incontinence severity and also in patients awaiting surgery. In the trial in patients awaiting surgery, onset of action was closely monitored and all patients who responded to duloxetine did so within 1-2 weeks. The decrease in IEF and improvement in I-QOL were not due to more frequent voiding, as the mean time between voids increased. Nausea was the most common treatment emergent adverse event. This was mostly experienced early after the start of duloxetine (usually within the first few days) and was usually mild or moderate and non-progressive in severity. The majority of patients reporting nausea continued treatment with duloxetine and in most of these patients the nausea resolved within 1 to 4 weeks. It can, therefore, be concluded that duloxetine 40 mg twice daily is a new and promising pharmacological treatment approach for women with SUI.

Nerli, R. B., A. G. Kumar, et al. (2009). "Transobturator vaginal tape in comparison to tension-free vaginal tape: A prospective trial with a minimum 12 months follow-up." Indian J Urol **25**(3): 321-325.

Background: The tension-free vaginal tape (TVT) procedure is based on the integral theory that the midurethra has an important role in the continence mechanism. Transobturator vaginal tape (TOT) is the same in concept as TVT but it differs from TVT in that, rather than passing through the retropubic space, sling materials are drawn through the obturator foramina. We prospectively compared TVT with TOT with respect to operation-related morbidity and surgical outcomes at a minimum follow up of 12 months. Materials and Methods: A total of 36 women with stress urinary incontinence (SUI) were alternatively assigned to the TVT group (18) or the TOT group. Preoperative evaluation included urodynamic study and I-QOL questionnaire. One year after operation the surgical result, patient satisfaction, incontinence quality-of-life questionnaire, long-term complications, and uroflowmetry were evaluated in both groups. Results: The patient characteristics in both the TVT and TOT group were similar. Mean operating time was significantly shorter in the TOT group likened to the TVT group. Conclusions: Both the TVT and TOT procedures are minimally invasive and similar in operation-related morbidity. TOT appears to be as effective as TVT, and safer than TVT for the surgical treatment of SUI in women at 12 months follow-up.

Nojomi, M., P. Baharvand, et al. (2009). "Incontinence quality of life questionnaire (I-QOL): translation and validation study of the Iranian version." Int Urogynecol J Pelvic Floor Dysfunct **20**(5): 575-579.

INTRODUCTION AND HYPOTHESIS: Because of the importance and prevalence of incontinence among women, there is increasing interest in the development and use of well-constructed questionnaires studying quality of life. Also, there is a paucity of information on QOL in non-Western women suffering from urinary incontinence. The aim of this study was to translate the original English version of the I-QOL and to assess the reliability and validity of this questionnaire in Iranian patients with urinary incontinence. METHODS: Four hundred women with urinary incontinence completed the Persian version of the questionnaire. By Cronbach's alpha coefficient, the intraclass correlation coefficient, and confirmatory factor analysis, the reliability and validity of the questionnaire were assessed. RESULTS: The median age of the respondents was 48 years (range 27-90). The overall I-QOL summary score showed internal consistency of 0.96 (Cronbach's alpha). The intraclass correlation coefficient was 0.96 for the total score. The range of correlation between the I-QOL total score and the subscales of the Sf-36 and the Psychological General Well-Being (PGWB) questionnaires were between 0.47 to 0.59 and 0.52 to 0.61 respectively. CONCLUSION: The Persian version of the I-QOL can be used for measuring QOL in urinary incontinent women in Iran.

Oh, S. J. and J. H. Ku (2006). "Is a generic quality of life instrument helpful for evaluating women with urinary incontinence?" Qual Life Res **15**(3): 493-501.

OBJECTIVES: The aim of this study was to determine whether a generic health outcome instrument would be helpful for evaluating women with stress urinary incontinence (UI) combined with or without urge UI. **METHODS:** A total of 109 women with UI and 80 controls participated in the study. Health-related quality of life (QOL) was measured using the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) and the Incontinence Quality of Life (I-QoL) questionnaire. **RESULTS:** Among eight domains of the SF-36 questionnaire, only four domains, namely, 'role-physical functioning' ($p < 0.05$), 'vitality' ($p < 0.05$), 'mental health' ($p < 0.05$) and 'bodily pain' ($p < 0.05$) were significantly different between the groups. Comparing the I-QoL scores in the two groups, patients with UI had significantly poorer subscale scores of I-QoL than the controls ($p < 0.05$ for all domains). When women with UI were subdivided into groups of stress and mixed UI, only 2 domains of the SF-36 questionnaire, 'role-physical functioning' ($p < 0.05$) and 'bodily pain' ($p < 0.05$), were significantly different. The mixed UI group had higher scores only on these two domains compared to the stress UI group. In the 'role-physical functioning' domain, there was no significant difference between the mixed UI group and the controls. In 'bodily pain' domain, there was no significant difference between the stress UI group and the controls. The mixed group had the highest scores observed. Patients with mixed UI had significantly lower total scores compared to those with stress UI, including the subscale score of 'avoidance behavior' of the I-QoL. Among eight domains of the SF-36, only 'physical functioning' ($r = 0.281$, $p < 0.01$) and 'social functioning' ($r = 0.239$, $p < 0.05$) were weakly correlated with 'psychological impact' of the I-QoL. **CONCLUSION:** Our findings show that the generic QOL instrument is not sensitive measure of QOL in women with UI.

Oh, S. J. and J. H. Ku (2007). "Comparison of three disease-specific quality-of-life questionnaires (Bristol Female Lower Urinary Tract Symptoms, Incontinence Quality of Life and King's Health Questionnaire) in women with stress urinary incontinence." Scand J Urol Nephrol **41**(1): 66-71.

OBJECTIVES: To examine the impact of stress urinary incontinence (UI) on quality of life (QOL) using three disease-specific QOL instruments and compare the results obtained with these instruments. **MATERIAL AND METHODS:** A total of 28 women (age range 36-74 years) with stress UI were included in the study. To obtain QOL assessments, patients were asked to complete the Bristol Female Lower Urinary Tract Symptoms (BFLUTS), Incontinence Quality of Life (I-QoL) and King's Health Questionnaire (KHQ) instruments. **RESULTS:** One domain in the BFLUTS (Incontinence symptoms) and one in the KHQ (Severity measures) correlated inversely with the Valsalva leak point pressure and the cough leak point pressure, respectively; however, other domains in the three questionnaires did not correlate with objective data. Two BFLUTS domains (Incontinence symptoms and QOL) correlated weakly or moderately with six KHQ domains; however, other BFLUTS domains did not correlate with most KHQ domains. Significant negative correlations were noted between two BFLUTS domains (Incontinence symptoms and QOL) and most I-QoL domains; however, other BFLUTS domains did not correlate with the I-QoL. Role limitations, Emotional

problems and Severity measures in the KHQ correlated weakly or moderately with the I-QoL; however, General health and Personal relationships did not correlate significantly with the I-QoL. CONCLUSIONS: Subjective QOL results of stress UI using condition-specific QOL questionnaires may differ because there are a plethora of measurement instruments that vary in terms of their scope and content. Our findings suggest that, before deciding on an instrument, its contents should be thoroughly reviewed to ensure that a particular aspect of QOL does not need additional assessment.

Oh, S. J., J. H. Ku, et al. (2005). "Factors influencing self-perceived disease severity in women with stress urinary incontinence combined with or without urge incontinence." Neurourol Urodyn **24**(4): 341-347.

AIMS: The aim of this study was to assess the impact of patient-perceived disease severity (PPDS) on the quality of life (QoL) of women with urinary incontinence (UI) and to identify factors predicting PPDS. METHODS: A total of 109 women (mean age 54.9; range 31-77) with stress UI combined with or without urge UI were included in the primary analyses. The incontinence quality of life (I-QoL) devised during the course of this study was used to assess the QOL impact of UI. RESULTS: PPDS of women with UI increased as I-QoL scores decreased ($P < 0.001$). When analyzed by patient characteristics and objective test results, PPDS increased only with the number of episodes ($P = 0.005$) and pad test weight increased ($P = 0.010$). By multivariate regression analysis, patients who complained of UI "three to four times a day or more" had 6.4-fold higher risk ($P = 0.027$) of perceiving that their symptoms were more severe than those who complained of a UI "one to two times per week or less." Patients with a pad test weight of >25 g had a 4.7-fold higher risk of perceiving their symptoms were more severe than those with a pad test weight of <15 g. CONCLUSIONS: Our results suggest that the frequency of UI episodes and the volume of urine loss are associated with PPDS. In addition, the I-QoL scores deteriorated significantly as the PPDS of incontinence increased. Thus, PPDS may impact on the QoL of women with stress UI combined with or without urge UI.

Ozkan, S., F. Ogce, et al. (2011). "Quality of life and sexual function of women with urinary incontinence." Jpn J Nurs Sci **8**(1): 11-19.

AIM: The aim of this study was to examine the urinary incontinence (UI) types on the sexual function and quality of life (QOL) of women with UI and the correlation between sexual function and QOL. METHODS: The sample for this descriptive study was comprised of 122 women who presented to obstetrics and gynecology and urology outpatient clinics at university hospitals in Denizli and Izmir, Turkey, who had UI, who were sexually active, who volunteered to participate in the study, and who were chosen by a convenience sampling method. A sociodemographic data collection form, the Female Sexual Function Index (FSFI), and the Incontinence Quality of Life (I-QOL) questionnaire were used for data collection in the study. RESULTS: The mixed type of incontinence had an effect on the women's quality of life, mixed and stress incontinence affected the

FSFI's pain subscale, and the total sexual functioning score was lower for the women with mixed incontinence. Even though the correlation values were low, it was clear that there was a positive correlation between sexual function and quality of life. CONCLUSIONS: Among the incontinence types, a significant difference was determined by the FSFI and I-QOL. Urinary incontinence seems to be the predictor of sexual function and quality of life. As a result, a comprehensive assessment of patients with UI is recommended because this condition has a negative influence on their sexual function and quality of life.

Paick, J. S., M. C. Cho, et al. (2007). "Influence of self-perceived incontinence severity on quality of life and sexual function in women with urinary incontinence." Neurourol Urodyn **26**(6): 828-835.

AIMS: We examined the impact of patient-perceived incontinence severity (PPIS) on health-related quality of life (QoL) and sexual function in women with urinary incontinence (UI). METHODS: Patients were recruited from clinic practices at one hospital. Between May 2004 and June 2006, 353 women 27-79 years old (mean 55.7) underwent detailed evaluations. To obtain health-related QoL and sexual function assessments, the patients were asked to fill the questionnaires including the incontinence quality of life (I-QoL) and female sexual function index (FSFI). Patients were categorized into the three groups according to the PPIS; 'mild,' 'moderate,' and 'severe.' RESULTS: Among groups, the duration of symptoms, rate of mixed UI, mean number of treatment visits over the past year, rate of UI associated without any activity, and Valsalva leak point pressure (VLPP) was significantly different ($P < 0.05$). The I-QoL total score and subscale scores deteriorated significantly as the PPIS increased ($P < 0.001$). Of the six domains in the FSFI questionnaire, four domains, namely, 'arousal' ($P = 0.026$), 'lubrication' ($P = 0.012$), 'orgasm' ($P = 0.017$), and 'pain' ($P = 0.037$) as well as the FSFI total score ($P = 0.004$) were significantly different among the groups. CONCLUSIONS: Our findings suggest that PPIS significantly influences health-related QoL and sexual function, and that strategies for assessing PPIS should be incorporated for assessing patients with UI.

Papanicolaou, S., S. Hunskaar, et al. (2005). "Assessment of bothersomeness and impact on quality of life of urinary incontinence in women in France, Germany, Spain and the UK." BJU Int **96**(6): 831-838.

OBJECTIVE: To assess the bothersomeness and impact on quality of life (QoL) of urinary incontinence in community-dwelling women in France, Germany, Spain and the UK. SUBJECTS AND METHODS: A detailed follow-up questionnaire was mailed to 2960 randomly-selected women who had reported symptoms of urinary incontinence in an earlier survey of 29,500 representative households in four European countries. In the second questionnaire, women were asked about the severity of their symptoms, the impact of urinary incontinence on their QoL, and how bothersome their incontinence was. RESULTS: A total of 1573 women responded to the follow-up questionnaire, of which >80% reported that their urinary incontinence symptoms were bothersome. The greatest negative effect appeared to be on physical activities, confidence, self-perception and social

activities, with a statistically significant correlation between an increase in bothersomeness and an increase in severity of symptoms. Similarly, a negative impact on QoL was associated with an increase in severity of incontinence. The variables: country, urinary incontinence type, severity, age, number of medical conditions and number of leakages had a statistically significant influence on the bother and the validated incontinence QoL (I-QoL) questionnaire scores. CONCLUSION: The extent to which women are bothered by their urinary incontinence and report that their symptoms have a negative impact on their QoL is largely subjective. In determining the most appropriate management, physicians should consider the experience of being incontinent as unique to each individual.

Patrick, D. L., M. Martin, et al. (1996). Urinary Incontinence-Specific Quality of Life Instrument. Boston, MA, Medical Outcomes Trust.

Patrick, D. L., M. L. Martin, et al. (1999). "Cultural adaptation of a quality-of-life measure for urinary incontinence." Eur Urol **36**(5): 427-435.

OBJECTIVES: To translate and validate a urinary incontinence-specific measure of quality of life (I-QOL) in French, Spanish, Swedish, and German and provide translations only into seven other languages and variants of these languages. METHODS: Quality of life and linguistic experts prepared two forward translations from American English to their native languages and helped to harmonize these translations at a meeting. In the four European countries, the adapted versions of the I-QOL were administered to 259 women with stress, urge, and mixed incontinence. Principal component analyses were used to confirm the proposed measurement model suggested by patient interviews. Psychometric testing was conducted using standardized procedures. RESULTS: Translation procedures resulted in a change in the original instrument's Likert response scale from 4 to 5 points. Principal component analyses confirmed three patient-derived subscales and higher-order factor analysis confirmed a total summary score. In all countries, the internal consistency (alpha) and reproducibility (ICC) were high (alpha ranged between 0.87 and 0.93); (ICC ranged between 0.92 and 0.95). In all countries, I-QOL scores were significantly worse ($p < 0.001$) as perceived severity of incontinence, use of services, and number of incontinent episodes increased. CONCLUSIONS: The I-QOL has been adapted successfully into eleven languages and six variants of these languages. The cross-sectional psychometric properties of the US version were confirmed in four European countries. The I-QOL fills the need for a valid, international quality-of-life instrument for incorporation in clinical trials covering patients with varying types and severity of urinary incontinence.

Patrick, D. L., M. L. Martin, et al. (1999). "Quality of life of women with urinary incontinence: further development of the incontinence quality of life instrument (I-QOL)." Urology **53**(1): 71-76.

OBJECTIVES: To report on the further development of the Incontinence Quality of Life Instrument (I-QOL), a self-report quality of life measure specific to urinary

incontinence (UI), including its measurement model, responsiveness, and effect size. METHODS: Incontinent female patients (141 with stress, 147 with mixed UI) completed the I-QOL and comparative measures at screening, pretreatment, and four subsequent follow-up visits during participation in a multicenter, double-blind, placebo-controlled, randomized trial assessing the efficacy of duloxetine. Psychometric testing followed standardized procedures. RESULTS: Factor analysis confirmed an overall score and three subscale scores (avoidance and limiting behaviors, psychosocial impacts, and social embarrassment). All scores were internally consistent ($\alpha = 0.87$ to 0.93) and reproducible ($ICC = 0.87$ to 0.91). The pattern of previously reported correlations with the Short-Form 36-item Health Survey and Psychological Well-Being Schedule were confirmed. Responsiveness statistics using changes in the independent measures of stress test pad weight, number of incontinent episodes, and patient global impression of improvement ranged from 0.4 to 0.8 . Minimally important changes ranged from 2% to 5% in association with these measures and effect sizes. CONCLUSIONS: In a clinical trial, the I-QOL proved to be valid, reproducible, and responsive to treatment for UI in women.

Ross, S., D. Soroka, et al. (2006). "Incontinence-specific quality of life measures used in trials of treatments for female urinary incontinence: a systematic review." Int Urogynecol J Pelvic Floor Dysfunct **17**(3): 272-285.

This systematic review examined the use of incontinence-specific quality of life (QOL) measures in clinical trials of female incontinence treatments, and systematically evaluated their quality using a standard checklist. Of 61 trials included in the review, 58 (95.1%) used an incontinence-specific QOL measure. The most commonly used were IIQ (19 papers), I-QoL (12 papers) and UDI (9 papers). Eleven papers (18.0%) used measures which were not referenced or were developed specifically for the study. The eight QOL measures identified had good clinical face validity and measurement properties. We advise researchers to evaluate carefully the needs of their specific study, and select the QOL measure that is most appropriate in terms of validity, utility and relevance, and discourage the development of new measures. Until better evidence is available on the validity and comparability of measures, we recommend that researchers consider using IIQ or I-QOL with or without UDI in trials of incontinence treatments.

Roupret, M., F. Richard, et al. (2005). "[Place of duloxetine in the treatment of stress urinary incontinence]." Prog Urol **15**(4): 689-692.

Urinary incontinence is a public health problem, as more than three million women in France are concerned by this problem. The prevalence of stress urinary incontinence is about 40% among these women. Duloxetine is a molecule developed for the oral treatment of stress urinary incontinence. It is a serotonin and norepinephrine reuptake inhibitor, which acts by increasing urethral sphincter tone. In several phase III trials, duloxetine administered orally at a high dose of 80 mg per day, significantly reduced episodes of incontinence. Total scores on the Incontinence Quality of Life questionnaire (I-QOL) were more markedly improved by duloxetine than by placebo. Nausea was an adverse effect

observed in more than 25% of cases and required discontinuation of treatment in some patients. However, the encouraging preliminary results of duloxetine in this indication must be confirmed during phase IV post-marketing clinical trials.

Santos, P. F., E. Oliveira, et al. (2009). "[Electrical stimulation of the pelvic floor versus vaginal cone therapy for the treatment of stress urinary incontinence]." Rev Bras Ginecol Obstet **31**(9): 447-452.

PURPOSE: to compare the effects of functional electrostimulation of the pelvic floor and therapy with cones in women with stress urinary incontinence (SUI). **METHODS:** randomized clinical study for which 45 patients with SUI were selected. The effects of functional electrostimulation of the pelvic floor were evaluated in the SUI treatment of 24 women, with the use of clinical data (micturition diary, pad test and a questionnaire about quality of life - I-QoL). The patients were submitted to two 20' weekly sessions for four consecutive months, under the supervision of a physiotherapist. The electrode used had 10 cm length and 3.5 cm width with a double metallic ring and a cylindrical shape, positioned in the medium third of the vagina. The electric parameters used were: intensity varying from 10 to 100 mA and 50 Hz of fixed frequency, with pulse duration of 1 ms. Also, we evaluated 21 patients who were submitted to vaginal cone treatment. The cone therapy was done with two 45 minute sessions per week. The cones' weight varied from 20 to 100 gr. **RESULTS:** there was no difference between the outcomes of electrostimulation of the pelvic floor and the vaginal cones for the treatment of SUI ($p>0.05$). After four months, there was a significant improvement in the I-QoL index of the patients treated both with electrostimulation (40.3 versus 82.9) or with the cones (47.7 versus 84.1). There was a significant decrease in pad weight in both groups, measured before and after the treatment (28.5 and 32 g versus 2.0 and 3.0 g for the electrostimulation and cone group, respectively). Finally, there was a significant decrease in the number of urinary leakage evaluated by the micturition diary in both groups ($p<0.0001$). **CONCLUSIONS:** both electrostimulation and vaginal cones were effective in the treatment of women with SUI.

Sar, D. and L. Khorshid (2009). "The effects of pelvic floor muscle training on stress and mixed urinary incontinence and quality of life." J Wound Ostomy Continence Nurs **36**(4): 429-435.

OBJECTIVE: To evaluate the effects of pelvic floor muscle (PFM) training on urinary incontinence (UI) and quality of life in women diagnosed with stress or mixed UI. **DESIGN:** We completed a parallel group, randomized clinical trial evaluating the effectiveness of PFM training in women with stress or mixed UI. **SETTINGS AND PARTICIPANTS:** We recruited consecutive cases of women with stress or mixed UI from outpatient urology clinics attached to a county hospital and a university hospital in Izmir, Turkey. **METHODS:** After baseline evaluation, 41 women were randomly assigned to either the PFM training group or the control group. Muscle training included 3 sets of daily fast and slow contractions in lying, sitting, and standing positions. Participants were also taught the knack. The intervention period was 8 weeks, and the women in the exercise

group telephoned once a week to provide motivation. The untreated control group had no contact during the intervention period. Outcome measures were Incontinence Quality of Life (I-QOL) Questionnaire, episodes of leakage in 3-day bladder diary, 1-hour pad test, and PFM strength. RESULTS: Thirty-four women completed the trial. The mean age of women was 41.82 +/- 8.65 years in the exercise group and 44.64 +/- 6.90 years in the control group. The 2 groups were statistically similar regarding key demographic and clinical characteristics. After 8 weeks, significant differences in the 1-hour pad test, episodes of leakage in 3-day bladder diary, PFM strength, and I-QOL scores ($P = .01$) were noted when participants in the PFM training group were compared to control group participants. CONCLUSION: An 8-week trial of PFM training significantly increased PFM strength, improved quality of life, and reduced the frequency of UI episodes.

Schagen van Leeuwen, J. H., R. R. Lange, et al. (2008). "Efficacy and safety of duloxetine in elderly women with stress urinary incontinence or stress-predominant mixed urinary incontinence." Maturitas **60**(2): 138-147.

OBJECTIVES: To evaluate the efficacy and safety of duloxetine in community-dwelling women $> \text{ or } = 65$ years with stress urinary incontinence (SUI) or stress-predominant mixed urinary incontinence (S-MUI) versus placebo. METHODS: Patients were randomly assigned for 12 weeks to placebo ($N=134$) or duloxetine ($N=131$) (20mg twice daily [BID] for 2 weeks and 40 mg BID for an additional 10 weeks), followed by a double-blind 4-week dose de-escalation/discontinuation phase. The primary efficacy variable was the percent change in incontinence episode frequency (IEF) from baseline to endpoint. Other variables included absolute IEF change, responder rate, changes in mean time between voids (MTBV), weekly continence pad usage, the impact of treatment on quality of life, patient's global impression of improvement (PGI-I), and changes in depression and cognition. RESULTS: Duloxetine-treated patients had a significantly greater decrease from baseline to endpoint in mean IEF/week than placebo-treated patients (-52.47% vs. -36.70%, $P<0.001$). The IEF responder rate ($> \text{ or } = 50\%$ reduction in IEF/week) was 57.1% in the duloxetine group and 35.2% in the placebo group ($P<0.001$). Significant benefits of duloxetine were also demonstrated for weekly continence pad usage ($P=0.011$), MTBV ($P<0.001$), incontinence quality of life questionnaire (I-QOL) scores ($P<0.001$), and PGI-I ratings ($P<0.001$). Patients with depressive symptoms and cognitive impairments were few and changes were insignificant. The proportion of patients with $> \text{ or } = 1$ treatment-emergent adverse event (TEAE) was similar with both treatments, but dry mouth, fatigue, constipation, and hyperhidrosis were significantly more common in women taking duloxetine. CONCLUSIONS: Duloxetine is a safe and effective treatment for elderly women with symptoms of SUI or S-MUI.

Schurch, B., P. Denys, et al. (2007). "Reliability and validity of the Incontinence Quality of Life questionnaire in patients with neurogenic urinary incontinence." Arch Phys Med Rehabil **88**(5): 646-652.

OBJECTIVE: To assess the reliability, validity, responsiveness, and minimally important difference (MID) of the Incontinence Quality of Life (I-QOL) questionnaire in patients with urinary incontinence due to neurogenic detrusor overactivity. **DESIGN:** Randomized, double-blind, multicenter, placebo-controlled study. **SETTING:** Eight centers across Belgium, France, and Switzerland. **PARTICIPANTS:** Patients with urinary incontinence due to neurogenic detrusor overactivity inadequately managed on oral anticholinergics. Fifty-nine patients (spinal cord injury, n=53; multiple sclerosis, n=6) were enrolled. **INTERVENTION:** Single dose of botulinum toxin type A (Botox) (200 or 300 U) or placebo. **MAIN OUTCOME MEASURES:** I-QOL questionnaire completed at screening and over a 24-week post-treatment period. **RESULTS:** The Cronbach alpha ranged from .79 to .93, indicating that I-QOL is a reliable measure of QOL in neurogenic urinary incontinence patients. No item had more than 5.1% missing or out of range values. With the exception of 2 items, questions showed acceptable item-scale correlation and scaling success results varied by domain. Post-treatment correlations indicated acceptable construct validity. The I-QOL was responsive to improvements in symptoms. MID values ranged from 4 to 11 points. **CONCLUSIONS:** Results suggest that I-QOL is a reliable, valid, and responsive measure of incontinence-related QOL in neurogenic patients.

Schurch, B., P. Denys, et al. (2007). "Botulinum toxin A improves the quality of life of patients with neurogenic urinary incontinence." Eur Urol **52**(3): 850-858.

OBJECTIVE: To evaluate the impact of botulinum toxin type A (BoNTA) on health-related quality of life in patients with neurogenic urinary incontinence (UI) using the Incontinence Quality of Life questionnaire (I-QOL). **METHODS:** Randomized, double-blind, multicenter, placebo-controlled study involving eight centers across Belgium, France, and Switzerland. Patients (n = 59) with UI due to neurogenic detrusor overactivity (spinal cord injury, n = 53; multiple sclerosis, n = 6) who were inadequately managed on oral anticholinergics received a single dose of BoNTA (200U or 300U, Botox) or placebo. I-QOL scores at screening and after treatment at weeks 2, 6, 12, 18, and 24 were recorded. **RESULTS:** Median total and subscale I-QOL scores increased significantly from screening with BoNTA 300U compared with placebo at all time points (p<0.05) and with BoNTA 200U compared with placebo at all time points for total score and the Avoidance Limiting Behavior subscale (p<0.05), and at weeks 2, 6, 12, and 18 (p<0.05), but not 24 for the Psychosocial Impact and Social Embarrassment subscales. Approximately twice as many BoNTA recipients as placebo recipients achieved at least a minimal important difference in total I-QOL score at 2, 6, 12, and 24 wk. **CONCLUSIONS:** BoNTA significantly improves UI-associated health-related quality of life in patients with neurogenic UI.

Shin, Y. S., J. S. Cha, et al. (2011). "Efficacy and safety of the TVT-SECUR(R) and impact on quality of life in women with stress urinary incontinence: a 2-year follow-up." Korean J Urol **52**(5): 335-339.

PURPOSE: As recently reported, the short-term results of the tension-free vaginal tape SECUR(R) (TVT-S) procedure seem to be similar to those of the

conventional transobturator tape (TOT) procedure. However, results of efficacy and satisfaction with TVT-S are insufficient in patients with more than 1 year of follow-up. Therefore, we evaluated the results of the TVT-S procedure in women with stress urinary incontinence (SUI) during 2 years. **MATERIALS AND METHODS:** We evaluated 51 patients with clinical and urodynamic diagnoses of SUI who underwent the TVT-S procedure from March 2008 to February 2009. Preoperative evaluation included a history, cough stress test with full bladder, urodynamic study, and incontinence quality of life (I-QoL) questionnaire. Following the postoperative period, urinary incontinence status was examined through a physical examination and the I-QoL questionnaire was completed in an outpatient setting or by telephone. **RESULTS:** Data from 2 years of follow-up were available for 46 of 51 patients. The cure rate was 80.4% at 1 month after TVT-S and 76.0% at 2 years after TVT-S. The cure or improvement rate was 93.5% at 1 month after TVT-S and 86.8% at 2 years after TVT-S. The mean total I-QoL score increased by 42 points at 1 month after TVT-S ($p < 0.026$) and by 32 points at 2 years after TVT-S ($p < 0.013$). Most patients reported significant improvements in quality of life. At the 2-year follow-up, there were no significant complications related to TVT-S. **CONCLUSIONS:** The results of this study suggest that TVT-S is an efficient and safe procedure for the improvement of both the quality of life of the patients and the SUI itself.

Slack, M., P. Culligan, et al. (2004). "Relationship of urethral retro-resistance pressure to urodynamic measurements and incontinence severity." *Neurourol Urodyn* **23**(2): 109-114.

AIMS: The urethral retro-resistance pressure (URP) is a retrograde urethral pressure profile measured by a new urodynamic measurement system. 1GYNECARE MoniTorr Urodynamic Measurement System (ETHICON, Inc., Somerville, NJ). URP is the pressure required to achieve and maintain an open sphincter. This clinical investigation focused on a comparison of URP to standard urodynamic measurements and an examination of their relationship to incontinence severity. **METHODS:** Twenty-two centers enrolled 258 stress incontinent women in a randomized, crossover study of two groups: (1) test procedure followed by multichannel urodynamics, (2) multichannel urodynamics followed by test procedure. We defined incontinence severity categories using 24 hr urine loss and assessed these categories using incontinence quality of life (I-QOL), urinary incontinence severity score (UISS), incontinence visual analogue score (VAS), URP, maximum urethral closure pressure (MUCP), and leak point pressure (LPP). **RESULTS:** The mean age was 56.2 (+/-12) years. No order effect was present. The correlation coefficient between URP and MUCP was 0.31 (95% CI 0.19-1, $P < 0.0001$); between URP and LPP was 0.28 (95% CI 0.12-1, $P = 0.003$); and between MUCP and LPP was 0.14 (95% CI-0.04-1, $P = 0.101$). The mean values for URP across symptom severity categories were significantly different ($P = 0.028$) and decreased with increasing severity. The mean values for MUCP and LPP did not decrease with increasing severity. **CONCLUSIONS:** The study demonstrated that URP had a consistent relationship with incontinence severity. The data suggested that URP is a physiological

measure of urethral function and may have clinical utility as a diagnostic tool. Future outcomes-based research is necessary to establish the predictive value of URP, MUCP, and LPP measurements in terms of incontinence cure rates and diagnosis of sphincter dysfunction.

Souza, C. C., A. M. Rodrigues, et al. (2009). "Portuguese validation of the Urinary Incontinence-Specific Quality-of-Life Instrument: I-QOL." Int Urogynecol J Pelvic Floor Dysfunct **20**(10): 1183-1189.

INTRODUCTION AND HYPOTHESIS: Our objective was to translate and validate a Portuguese version of the Urinary Incontinence-Specific Quality-of-Life Instrument (I-QOL), a questionnaire that is widely used in clinical trials.

METHODS: Fifty patients completed the same questionnaire twice at a 2-week interval. During the first visit, we conducted a face-to-face interview and collected demographic data. The King's Health Questionnaire was completed during the same visit for comparisons. **RESULTS:** The results showed that the Portuguese version of the I-QOL has very good psychometrics properties. Reliability was assessed by Cronbach's alpha (0.93), reproducibility was calculated through the intraclass correlation coefficient (0.88), construct validity was determined by comparing the I-QOL scores and King's Health scores, and discriminant validity was calculated by comparing the total I-QOL scores with measures of gravity.

CONCLUSIONS: We conclude that the Portuguese version of the I-QOL is a very good tool for the evaluation quality-of-life in women with urinary incontinence in Portuguese-speaking countries.

Steers, W. D., S. Herschorn, et al. (2007). "Duloxetine compared with placebo for treating women with symptoms of overactive bladder." BJU Int **100**(2): 337-345.

OBJECTIVE: To evaluate duloxetine (a serotonin-noradrenaline reuptake inhibitor) in women with symptoms of overactive bladder (OAB), as it has been shown to increase the bladder capacity in an animal model. **PATIENTS AND**

METHODS: In all, 306 women (aged 21-84 years) were recruited and randomly assigned to placebo (153) or duloxetine (80-mg/day for 4 weeks increased to 120-mg/day for 8 weeks; 153). Symptoms of OAB were defined as bothersome urinary urgency and/or urge urinary incontinence (UI) for > or =3 months.

Participants were also required to have a mean daytime voiding interval (VI) of < or =2 h and urodynamic observations of either detrusor overactivity (DOA) or urgency which limited bladder capacity to <400 mL, both with no stress UI (SUI). The primary efficacy analysis compared the treatment effects on mean change from baseline to endpoint in the mean number of voiding episodes (VE)/24 h.

The secondary efficacy analyses compared the treatment effects on the number of UI episodes (IE)/24 h, in the Incontinence Quality of Life questionnaire (I-QOL) score, and on the mean daytime VI. Safety was assessed with vital signs, adverse event reporting, routine laboratory testing, electrocardiogram, and the measurement of postvoid residual urine volumes (PVR). **RESULTS:** Patients randomized to duloxetine had significant improvements over those randomized to placebo for decreases in VE and IE, for increases in the daytime VI, and for improvements in I-QOL scores at both doses of duloxetine. Urodynamic studies

showed no significant increases in maximum cystometric capacity or in the volume threshold for DOA. The most common treatment-emergent adverse events with duloxetine (nausea, 31%; dry mouth, 16%; dizziness, 14%; constipation, 14%; insomnia, 13%; and fatigue, 11%) were the same as those reported by women with SUI and were significantly more common with duloxetine than placebo. Laboratory assessments, vital signs and electrocardiograms were stable relative to baseline, with no relevant differences detected between groups. There was a significant difference in the change in PVR with duloxetine (<5 mL mean increase) but no patient reported hesitancy or retention. CONCLUSION: In this trial, duloxetine was better than placebo for treating women with 'wet' and 'dry' symptoms of OAB associated with DOA or a bladder capacity of <400 mL.

Sussman, D., V. Patel, et al. (2012). "Treatment satisfaction and improvement in health-related quality of life with onabotulinumtoxinA in patients with urinary incontinence due to neurogenic detrusor overactivity." Neurourol Urodyn.

AIMS: OnabotulinumtoxinA significantly reduces urinary incontinence (UI) and improves bladder management in patients with neurogenic detrusor overactivity (NDO). We evaluated the impact of onabotulinumtoxinA on patient-reported outcomes (PROs) in patients with UI due to NDO in a double-blind, placebo-controlled study. METHODS: Patients with UI due to NDO (from multiple sclerosis or spinal cord injury) were randomized to intradetrusor placebo (n = 92) or onabotulinumtoxinA 200 U (n = 92) or 300 U (n = 91). PROs included Incontinence Quality of Life (I-QOL) Questionnaire to assess health-related quality of life (HRQoL), the 16-item modified Overactive Bladder-Patient Satisfaction with Treatment Questionnaire (OAB-PSTQ) to assess treatment satisfaction, and Patient Global Assessment to assess treatment goal achievement. RESULTS: Mean improvement in I-QOL total score at weeks 6 and 12 was significantly greater with both onabotulinumtoxinA 200 U and 300 U versus placebo (Delta12.3 for 200 U and Delta14.9 for 300 U vs. placebo; P < 0.001), and was clinically meaningful. For those patients who completed the OAB-PSTQ, improvement in satisfaction at weeks 6 and 12 was significantly greater for onabotulinumtoxinA versus placebo (P < 0.001, all comparisons). At 6 weeks, greater proportions of onabotulinumtoxinA-treated patients than placebo reported being somewhat or very satisfied (200 U, 77.5% and 300 U, 67.8% vs. placebo, 39.5%), and significant progress toward or complete achievement of primary treatment goal (200 U, 62.9% and 300 U, 61.6% vs. placebo, 16.5%). CONCLUSIONS: NDO patients treated with onabotulinumtoxinA 200 or 300 U had significantly greater improvement in HRQoL and greater treatment satisfaction compared with placebo-treated patients, with no clinically relevant differences between onabotulinumtoxinA doses. *Neurourol. Urodynam.* (c) 2012 Wiley Periodicals, Inc.

Terlikowski, R., B. Dobrzycka, et al. (2013). "Transvaginal electrical stimulation with surface-EMG biofeedback in managing stress urinary incontinence in women of premenopausal age: a double-blind, placebo-controlled, randomized clinical trial." Int Urogynecol J.

INTRODUCTION AND HYPOTHESIS: The aim of this study was to evaluate the results of conservative treatment of urodynamic stress urinary incontinence (SUI) using transvaginal electrical stimulation with surface-electromyography-assisted biofeedback (TVES + sEMG) in women of premenopausal age. **METHODS:** One hundred and two patients with SUI were divided into two groups: active (n = 68) and placebo (n = 34) TVES + sEMG. The treatment lasted for 8 weeks and consisted of two sessions per day. Women were evaluated before and after the intervention by pad test, voiding diary, urodynamic test, and the Incontinence Quality of Life Questionnaire (I-QOL). **RESULTS:** Mean urinary leakage on a standard pad test at the end of 8th week was significantly lower in the active than the placebo group (19.5 +/- 13.6 vs. 39.8 +/- 28.5). Mean urinary leakage on a 24-h pad test was significantly reduced in the active group at the end of 8th and 16th weeks compared with the placebo group (8.2 +/- 14.8 vs. 14.6 +/- 18.9 and 6.1 +/- 11.4 vs. 18.2 +/- 20.8, respectively). There was also a significant improvement in muscle strength as measured by the Oxford scale in the active vs the placebo group after 8 and 16 weeks (4.2 vs 2.6 and 4.1 vs 2.7, respectively). No significant difference was found between groups in urodynamic data before and after treatment. At the end of 8th week, the mean I-QOL score in the active vs the placebo group was 78.2 +/- 17.9 vs 55.9 +/- 14.2, respectively, and at the end of 16th week 80.8 +/- 24.1 vs. 50.6 +/- 14.9, respectively. **CONCLUSION:** Our study showed that TVES + sEMG is a trustworthy method of treatment in premenopausal women with SUI; however, its reliability needs to be established.

Tommaselli, G. A., A. D'Afiero, et al. (2012). "Efficacy of a modified technique for TVT-O positioning: a twelve-month, randomized, single-blind, multicenter, non-inferiority study." Eur J Obstet Gynecol Reprod Biol.

OBJECTIVE: To evaluate the impact of a more limited paraurethral dissection, avoidance of perforating the obturator membrane with scissors or guide, and a more medial trajectory of the trocar in positioning the TVT-O device on stress urinary incontinence cure rates. **STUDY DESIGN:** One hundred and ten patients were recruited for this randomized, single blind, multicenter, non-inferiority study, with a 1:1 ratio to undergo the traditional (n=55) or the modified (n=55) technique. Preoperatively, patients underwent POP-Q staging, Q-tip test, challenge stress test and urodynamics, and completed the I-QoL, PISQ-12, and PGI-S questionnaires. During the post-operative period, patients attributed a pain VAS score 1, 3, 6, 12 and 24h after the procedure and were followed up at 12 months, undergoing the same baseline evaluations. The primary outcome was the cure rate (absence of urine leaks at the challenge stress test or urodynamic testing) one year after the procedure. The primary outcome was evaluated using a non-inferiority test. **RESULTS:** No differences were observed in cure rates (traditional technique 92.3% vs. modified technique 88.8% and non-inferiority P<0.05) and in questionnaire scores between the two groups. Post-operative pain was significantly lower in the modified technique group at each time point assessed, with the exception of 12h post-operatively. No differences between the two groups were observed in the number of analgesic vials administered.

CONCLUSIONS: The modified technique does not seem to reduce the efficacy of TVT-O, but induces a reduction of post-operative pain.

Tsai, Y. C. and C. H. Liu (2009). "Urinary incontinence among Taiwanese women: an outpatient study of prevalence, comorbidity, risk factors, and quality of life." Int Urol Nephrol **41**(4): 795-803.

The objective of this study was to evaluate comorbidity and risk factors associated with female urinary incontinence and to assess quality of life for women with different types of urinary incontinence. Subjects included 551 consecutive females who attended the outpatient clinic from 9 March to 8 July 2006 and did not have a chief complaint of incontinence. A four-item incontinence questionnaire and a Chinese version of the Incontinence-Quality of Life (I-QOL) questionnaire were completed in the waiting room. Patient characteristics and medical conditions were summarized from outpatient electronic databases. A total of 371 females were included for statistical analysis. Among them, 114 patients (30.7%) did not indicate any urinary incontinence, while 257 (69.3%) patients indicated symptoms of urge incontinence, stress incontinence, or mixed incontinence. Comorbidities significantly associated with incontinence included osteoarthritis ($P = 0.001$), peptic ulcer disease ($P = 0.031$), obesity ($P < 0.001$), and cardiac disease ($P < 0.001$). After multiple logistic regression analysis, obesity (OR 3.38, 95% CI 1.94-6.98) and postmenstrual status (OR 2.17, 95% CI 1.35-3.50) were found to be risk factors of incontinence ($P < 0.001$). Mixed incontinence patients exhibited the least satisfaction in quality of life, while no significant differences were observed between patients with urge incontinence and stress incontinence. In conclusion, the incidence of urinary incontinence may be greater in the outpatient population than previously thought. Osteoarthritis, peptic ulcer disease, and cardiac disease are more common in women with urinary incontinence, obesity and postmenopausal status appear predictive of incontinence, and women with mixed incontinence exhibit the least satisfying quality of life.

van de Vaart, H., C. Falconer, et al. (2010). "Patient reported outcomes tools in an observational study of female stress urinary incontinence." Neurourol Urodyn **29**(3): 348-353.

AIMS: To determine which patient characteristics, incontinence and non-incontinence related, are associated with the symptom severity scores of the Urogenital Distress Inventory (UDI) and the International Consultation on Incontinence Questionnaire Urinary Incontinence (ICIQ-UI); and to determine the association of both patient characteristics and symptom severity scores with quality-of-life scores of the Incontinence Impact Questionnaire (IIQ) and the Incontinence-Quality of Life (I-QOL) questionnaire. **METHODS:** Women presenting with stress urinary incontinence (SUI) symptoms in primary and secondary care entered the Stress Urinary Incontinence Treatment Study (SUIT), an observational study evaluating the cost-effectiveness of duloxetine compared to other non-surgical treatments for SUI. At enrollment patients completed the UDI-6, the short form ICIQ-UI, the IIQ-7 and the I-QOL. Multivariate linear

regressions were performed with the UDI-6, ICIQ-UI SF, IIQ-7, and I-QOL as outcomes. RESULTS: The total number of incontinence episodes is the most significant explanatory variable of the two symptom questionnaire scores, but the UDI-6 score also reflects the type of incontinence. The variability of the condition-specific quality-of-life questionnaires is primarily explained by the symptom severity questionnaire scores. Although there is a high intercorrelation, both these symptom questionnaires independently contributed significantly to the IIQ-7 and I-QOL total scores. CONCLUSIONS: The UDI-6 and ICIQ-UI SF can be regarded as scientifically sound symptom questionnaires in UI evaluation; but they have differences. Since the UDI-6 and ICIQ-UI SF independently contribute to the quality-of-life scores, this suggests that in incontinence research symptom questionnaires should not focus only on incontinence, but on a broader range of urogenital symptoms.

van der Pal, F., M. R. van Balken, et al. (2006). "Percutaneous tibial nerve stimulation in the treatment of refractory overactive bladder syndrome: is maintenance treatment necessary?" *BJU Int* **97**(3): 547-550.

OBJECTIVE: To determine the effect of a pause in percutaneous tibial nerve stimulation (PTNS) in successfully treated patients with an overactive bladder (OAB), and the reproducibility of successful treatment when restored. PATIENTS AND METHODS: Eleven patients (mean age 51 years) with refractory OAB (more than seven voids and/or three or more urge incontinence episodes per day) were successfully treated with PTNS, and then discontinued treatment. Patients completed bladder diaries and quality-of-life (QoL) questionnaires (Short Form-36 and I-QoL) before (T1) and after a 6-week pause (T2) of maintenance PTNS, and again after re-treatment (T3). The first objective was defined as a $>$ or $=$ 50% increase in the incontinence episodes and/or voiding frequency in the bladder diary after T2. The second objective was defined as $>$ or $=$ 50% fewer incontinence episodes and/or voiding frequency in bladder diary after T3. RESULTS: At T2, seven of the 11 patients had a $>$ or $=$ 50% increase in incontinence episodes and/or voiding frequency in the bladder diary. The mean voided volume, nocturia, number of incontinence episodes and incontinence severity deteriorated significantly ($P < 0.05$). At T3, nine patients had $>$ or $=$ 50% fewer incontinence episodes and/or voiding frequency in the bladder diary. Nocturia, the number of incontinence episodes, incontinence severity, mean voided volume and quality of life improved significantly ($P < 0.05$). CONCLUSIONS: Continuous therapy is necessary in patients with OAB treated successfully by PTNS. The efficacy of PTNS can be reproduced in patients formerly treated successfully.

van Kerrebroeck, P., P. Abrams, et al. (2004). "Duloxetine versus placebo in the treatment of European and Canadian women with stress urinary incontinence." *BJOG* **111**(3): 249-257.

OBJECTIVE: To assess the efficacy and safety of duloxetine in women with stress urinary incontinence. DESIGN: Randomised double-blind, placebo-controlled clinical trial. SETTING: Fort-six centres in seven European countries

and Canada. **POPULATION:** Four hundred and ninety-four women aged 24-83 years identified as having predominant symptoms of stress urinary incontinence using a clinical algorithm that was 100% predictive of urodynamic stress urinary incontinence in a subgroup of 34 women. **METHODS:** The case definition included a predominant symptom of stress urinary incontinence with a weekly incontinence episode frequency ≥ 7 , the absence of predominant symptoms of urge incontinence, normal diurnal and nocturnal frequencies, a bladder capacity ≥ 400 mL and both a positive cough stress test and positive stress pad test. Subjects completed two urinary diaries prior to randomisation and three diaries during the active treatment phase of the study, each completed during the week prior to monthly visits. Subjects also completed quality of life questionnaires at each visit. Safety was assessed by the evaluation of treatment-emergent adverse events, discontinuation of treatment because of adverse events, serious adverse events, vital sign measurements, electrocardiograms (ECG) and clinical laboratory tests. **INTERVENTION:** After a two-week placebo lead-in, women received placebo or duloxetine 40 mg BD for 12 weeks. **MAIN OUTCOME MEASURES:** The percentage decrease in incontinence episode frequency and the change in the Incontinence Quality of Life (I-QOL) questionnaire total score were prespecified as co-primary outcome variables in the protocol. **RESULTS:** Incontinence episode frequency decreased significantly with duloxetine compared with placebo (median decrease of 50% vs 29%; $P = 0.002$) with comparable improvements in the more severely incontinent subgroup (those experiencing at least 14 incontinence episodes per week at baseline; 56% vs 27% decreases; $P < 0.001$). The primary analysis of I-QOL scores did not reveal a significant difference between treatment groups, due primarily to the carrying forward of low scores from patients who discontinued treatment very early due to duloxetine-associated adverse events. The increase in I-QOL scores was significantly greater for duloxetine than for placebo at each of the three postrandomisation visits after 4, 8, and 12 weeks of treatment. Discontinuation rates for adverse events were higher for duloxetine (22% vs 5%; $P < 0.001$) with nausea being the most common reason for discontinuation (5.3%). Nausea tended to be mild to moderate, not progressive, and transient. **CONCLUSIONS:** The findings support duloxetine as a potential treatment for women with stress urinary incontinence.

Vandoninck, V., M. R. Van Balken, et al. (2003). "Posterior tibial nerve stimulation in the treatment of urge incontinence." *Neurourol Urodyn* **22**(1): 17-23.

AIMS: The objective of this study was to evaluate the effect of posterior tibial nerve stimulation (PTNS) for treatment of urge incontinence. **METHODS:** In a prospective multicentre study, 35 patients with complaints of urge incontinence underwent 12 weekly sessions of PTNS at one of five sites in the Netherlands and one site in Italy. Frequency/volume charts and I-QoL and SF-36 questionnaires were completed at 0 and 12 weeks. Success was analysed by using subjective and objective criteria. Overall subjective success was defined as the willingness to continue treatment, whereas objective success was defined as a significant decrease (to $< 50\%$) in total number of leakage episodes. **RESULTS:**

Twenty-two patients (63%) reported a subjective success. Twenty-four patients (70%) showed a 50% or greater reduction in total number of leakage episodes. Sixteen (46%) of these-patients were completely cured (i.e., no leakage episodes) after 12 sessions. Quality of life parameters improved significantly. CONCLUSIONS: We conclude that posterior tibial nerve stimulation is an effective, minimally invasive option for treatment of patients with complaints of urge incontinence, as improvement was seen in subjective as well as objective parameters.

Vidhubala, E., Latha, et al. (2011). "Validation of cancer institute quality of life questionnaire version II for cancer patients in India." Indian J Cancer **48**(4): 500-506.

BACKGROUND: The Quality of Life (QOL) questionnaire version I consisted of 38 items that were validated using 392 patients. The experiences gained through the interaction with the patients during the administration of the questionnaire provided a lot of inputs for the improvization of the tool. AIM: The current study is aimed at certain modifications of the QOL questionnaire version I and standardization of the same. MATERIALS AND METHODS: The modifications of version I QOL scale included the change of verbatim, splitting, deleting, and adding of new items. Finally, version II included 42 items. It was administered to 183 cancer patients irrespective of their demographic details for further standardization. STATISTICS: The principal component method with varimax rotation was used. Spearman's product moment correlation and Cronbach's alpha coefficient were used for reliability analysis. RESULTS: The data were subjected to factor analysis to explore the factors. Eleven factors emerged with the eigenvalue ranging from 8.03 to 1.10 and accounted for 66.7% variance. The first factor contributed maximally, 19.5%, and the remaining 10 factors contributed a total of 46.2% variance on QOL. They are general well-being, physical well-being, psychological well-being, familial relationship, sexual and personal ability, cognitive well-being, optimism and belief, economical well-being, information support, patient-physician relationship, and body image. The Cronbach alpha of 0.90 and split-half reliability of 0.80 indicated a high reliability of the tool. CONCLUSION: The factor structure showed that QOL is a multidimensional concept having different aspects. The Cancer Institute QOL Questionnaire version II for cancer patients is found to be a valid and reliable tool and feasible to administer at the clinical settings.

Viktrup, L. and I. Yalcin (2007). "Duloxetine treatment of stress urinary incontinence in women: effects of demographics, obesity, chronic lung disease, hypoestrogenism, diabetes mellitus, and depression on efficacy." Eur J Obstet Gynecol Reprod Biol **133**(1): 105-113.

OBJECTIVE: To identify poor responders, we evaluated the impact of demographic characteristics and comorbidities on efficacy using an integrated database including data from four large randomized controlled trials. Duloxetine has been shown to be effective in women with stress urinary incontinence (SUI). STUDY DESIGN: A total of 1913 women 22-83 years of age with predominant SUI (diagnosed using a validated clinical algorithm) were randomly assigned to

receive placebo (n = 955) or duloxetine (n = 958) for 12 weeks. Efficacy outcome variables included a weekly incontinence episodes frequency (IEF) from patient-completed diaries, the Incontinence Quality-of-Life (I-QOL) questionnaire score, and a Patient Global Impression of Improvement rating. Subgroups selected a priori included: ethnicity, age, body mass index (BMI), chronic lung disease, hypoestrogenism, diabetes mellitus, and depression. For safety comparisons, adverse events were compared across age and ethnicity subgroups. RESULTS: Reduction in IEF was minimal and not significantly different between duloxetine and placebo in women with chronic lung disease. The decrease in IEF for women > or =65 years of age was slightly diminished for duloxetine and placebo groups, but the treatment differences were maintained. There was a significantly different I-QOL improvement by BMI subgroup, with greater increases in scores associated with a higher BMI (>28 kg/m²). There were no other notable subgroup impacts on efficacy. CONCLUSIONS: With the possible exception of chronic lung disease, no characteristic was identified that predicted a lack of treatment response with duloxetine in the treatment of women with SUI. Elderly patients may experience lower response rates to duloxetine presumably due to age related changes in the lower urinary tract.

Wagner, T. H., D. L. Patrick, et al. (1996). "Quality of life of persons with urinary incontinence: development of a new measure." Urology **47**(1): 67-71; discussion 71-62. OBJECTIVES: Our objective was to develop a self-report quality of life measure specific to urinary incontinence (I-QOL) that could be used as an outcome measure in clinical trials and in patient care centers. METHODS: The I-QOL was developed from interviews of 20 individuals with urinary incontinence. Refining the questionnaire was accomplished by structured interviews of 17 individuals with urinary incontinence. Testing the I-QOL's psychometric properties involved two administrations (n = 62) along with measures of psychologic well-being and functional status. RESULTS: The rigorous development process ensured that the measure was complete and understandable. The I-QOL proved to be internally consistent (alpha 0.95) and highly reproducible (r = 0.93; 18 days; SD 4). For discriminant validity, severity of incontinence (P < 0.0001) and number of medical appointments in the past year to treat incontinence (P < 0.0001) significantly predicted I-QOL scores. Convergent validity analyses confirmed our predictions that the I-QOL scores were more closely related to overall well-being than bodily pain. CONCLUSIONS: The I-QOL proved to be valid and reproducible as a self-administered measure for assessing quality of life of patients with urinary incontinence.

Wagner, T. H., D. L. Patrick, et al. (2007). "Incontinence Quality of Life--French Version." Reliability and validity of the Incontinence Quality of Life questionnaire in patients with neurogenic urinary incontinence **98**: 646-652.

Wagner, T. H., D. L. Patrick, et al. (1999). "Incontinence Quality of Life Instrument." Quality of life of women with urinary incontinence: Further development of the Incontinence Quality of Life Instrument (I-QOL) **53**: 71-76.

Incontinence Quality of Life Instrument (I-QOL) reported by Patrick, Martin, Bushnell, Yalcin, Wagner, and Buesching (1999) presents further development of the initial measure by Wagner, Patrick, Bavendam, Martin, and Buesching (1996)

Wagner, T. H., D. L. Patrick, et al. (2007). "Incontinence Quality of Life--Dutch Version." Reliability and validity of the Incontinence Quality of Life questionnaire in patients with neurogenic urinary incontinence **98**: 646-652.

Wagner, T. H., D. L. Patrick, et al. (2007). "Incontinence Quality of Life--German Version." Reliability and validity of the Incontinence Quality of Life questionnaire in patients with neurogenic urinary incontinence **98**: 646-652.

Wagner, T. H., D. L. Patrick, et al. (1996). "Quality of Life Measure Specific to Urinary Incontinence. [Now denoted: Incontinence Quality of Life Instrument]." Quality of life of persons with urinary incontinence: Development of a new measure **47**(1): 67-72.

Quality of Life Measure Specific to Urinary Incontinence is developed to 'be used as an outcome measure in clinical trials and in patient care centers' (p. 67). 'Incontinence type (stress, urge, or mixed) is identified by collecting self-report symptoms data as defined by Fultz and Herzog (1991). Urge incontinence is defined as losing urine before the person can get to the bathroom. Stress incontinence is identified as losing urine when the person coughs, sneezes, runs, walks, jumps, or does some other specific activity. People are classified as having mixed incontinence if they report having both stress and urge symptoms. Questions about undergarment use and altering physical or social life provide the primary measure of incontinence severity....Mild incontinence [is defined] as those who say they do not wear protection or wear it only when needed and do not alter their social activities' (p. 68)

Ware, J. E., Jr., B. Schurch, et al. (2007). "SF-36 Health Survey--Dutch Version." Reliability and validity of the Incontinence Quality of Life questionnaire in patients with neurogenic urinary incontinence **98**: 646-652.

Ware, J. E., Jr., B. Schurch, et al. (2007). "SF-36 Health Survey--French Version." Reliability and validity of the Incontinence Quality of Life questionnaire in patients with neurogenic urinary incontinence **98**: 646-652.

Ware, J. E., Jr., B. Schurch, et al. (2007). "SF-36 Health Survey--German Version." Reliability and validity of the Incontinence Quality of Life questionnaire in patients with neurogenic urinary incontinence **98**: 646-652.

Ware, J. E., Jr., C. D. Sherbourne, et al. (1999). "MOS 36-Item Short-Form Health Survey." Quality of life of women with urinary incontinence: Further development of the Incontinence Quality of Life Instrument (I-QOL) **53**: 71-76.

Wattanayingcharoenchai, R., J. Manonai, et al. (2007). "Impact of stress urinary incontinence and overactive bladder on quality of life in Thai women attending the urogynecology clinic." J Med Assoc Thai **90**(1): 26-31.

OBJECTIVE: To investigate the impact of stress urinary incontinence (SUI) and overactive bladder (OAB) on the quality of life (QOL) using disease specific health-related QOL questionnaire. **MATERIAL AND METHOD:** Three hundred and nineteen women with SUI and/or OAB, attending the urogynecology clinic, Ramathibodi Hospital were recruited in the present study. Information on QOL was collected, using the Thai version of modified incontinence-specific quality of life questionnaire (I-QOL) and short form incontinence impact questionnaire (IIQ-7). **RESULTS:** In 319 cases, the diagnosis of SUI, OAB, and both were 55 cases, 78 cases, and 186 cases, respectively. There was no statistically significant difference in patients' characteristics in three groups. The patients with both SUI and OAB showed significantly lower scores in all domains of I-QOL than the SUI and OAB groups, whereas QOL, assessed by IIQ-7, showed significant impairment in the combined SUI and OAB group, only in the emotional health domain. **CONCLUSION:** Stress urinary incontinence and overactive bladder have a detrimental impact on patient health-related QOL. Women with a combination of SUI and OAB have the greatest impairment in QOL.

Yalcin, I., D. L. Patrick, et al. (2006). "Minimal clinically important differences in Incontinence Quality-of-Life scores in stress urinary incontinence." Urology **67**(6): 1304-1308.

OBJECTIVES: To determine the clinically relevant reference points for the Incontinence Quality of Life (I-QOL) questionnaire scores in women with stress urinary incontinence and compare them with the treatment effects observed with duloxetine and placebo. **METHODS:** Using data from 1133 women with predominant stress urinary incontinence in two randomized, placebo-controlled duloxetine studies, the within-treatment and between-treatment minimal clinically important differences (MCIDs) were obtained by anchoring the I-QOL scores to the validated Patient Global Impression of Improvement scale (PGI-I). The within-treatment MCID (mean I-QOL for women rating their condition "a little better" with treatment) and between-treatment MCID (difference in scores between the group ratings of "no change" and "a little better") were derived. The treatment effects were compared with these MCIDs. Real-time urinary diaries were completed, along with the I-QOL and PGI-I. **RESULTS:** The within-treatment and between-treatment MCID for the I-QOL total score was 6.3 and 2.5, respectively. The total and subscale scores had almost identical MCIDs. Duloxetine 80 mg significantly improved the I-QOL total and subscale scores. Treatment differences in the I-QOL scores exceeded the between-treatment MCID and the duloxetine I-QOL treatment effect exceeded the within-treatment MCID. The number of patients needed to treat to gain an additional I-QOL responder was 6.8. **CONCLUSIONS:** Improvements in I-QOL scores should be greater than the within-treatment MCID, and differences between two treatments should be greater than the between-treatment MCIDs, for statistically significant differences to be considered clinically meaningful. We propose 2.5 points as a reasonable guide

for the I-QOL between-treatment MCID and 6.3 points for the within-treatment MCID.

Yalcin, I., G. Peng, et al. (2010). "Reductions in stress urinary incontinence episodes: what is clinically important for women?" Neurourol Urodyn **29**(3): 344-347.

AIM: To expand our understanding of the clinical importance to patients with stress urinary incontinence (SUI) of reductions in incontinence episode frequency (IEF) that fall short of a complete cure. METHODS: We used an integrated database that included data from 1,913 women with SUI who were enrolled in four randomized, placebo-controlled pharmaceutical clinical trials and examined the relationship between various levels of reduction in IEF and minimally clinical important difference (MCID) levels established for the validated Incontinence Quality of Life (I-QOL) questionnaire. The first decile of IEF reduction to exceed the within-group MCID was considered to be the point at which the reduction in IEF first became clinically important. The between-group MCID was then used to determine when further reductions in incontinence represented clinically relevant incremental improvements for patients. RESULTS: Improvements in condition-specific quality of life were not clinically important until the fifth decile of IEF reduction, representing a reduction in IEF >40% to <or=50%. Patients appreciated incremental clinically important benefits when IEF reductions exceeded 70%, with progressive improvements in condition-specific quality of life with higher levels of IEF reduction. The difference between a >70% to <or=80% reduction and a >90% to <or=100% reduction was clinically important. CONCLUSION: Reductions in IEF <or=40% do not appear to be clinically important for women with SUI. Patients appear to recognize important clinical value at reductions of approximately 50% and important incremental clinical value at reductions of approximately 75% and 90-100%. These thresholds may not apply to women seeking non-pharmaceutical treatments for SUI.

Yoshida, M., R. Murayama, et al. (2012). "Reliability and validity of the Japanese version of the pelvic floor distress inventory-short form 20." Int Urogynecol J.

INTRODUCTION AND HYPOTHESIS: The aim of this study was to translate the Pelvic Floor Distress Inventory-Short Form 20 (PFDI-20) into Japanese and test its reliability and validity among Japanese women. METHODS: Fifty-nine women with and without pelvic floor disorders (age 55.8 +/- 16.8 years, mean +/- SD) completed the Japanese PFDI-20 (J-PFDI-20) questionnaire at baseline and 2 weeks later. Intraclass correlation coefficients (ICC) and the Bland and Altman method for test-retest reliability and Cronbach's alpha for internal consistency of the J-PFDI-20 were used. Scores of total and subscales were compared between women with and without pelvic floor disorders for known-groups validity. Spearman's correlation coefficients between the J-PFDI-20 and the severity of pelvic floor disorders and Urinary Incontinence Quality of Life Scale (I-QOL) were used for construct validity. RESULTS: The PFDI-20 was successfully translated from English into Japanese with face validity through rigorous cross-cultural validation. Test-retest reliability of the J-PFDI-20 and three subscales was good to excellent (ICC = 0.77-0.90). The Bland and Altman analysis showed that

differences between the first and second scores of total J-PFDI-20 and its subscales were not significantly different from 0 and largely fell within the range of 0 +/- 1.96 SD. Cronbach's alpha values were 0.52-0.83. Analysis of known-groups validity showed differences in scores of the J-PFDI-20 between women with and without pelvic floor disorders. Acceptable construct validity was found in J-PFDI-20 total and subscale scores with positive correlations to severity of pelvic floor disorders ($\rho > 0.35$) and negative correlations to I-QOL ($\rho < -0.39$). CONCLUSIONS: The results suggest that the J-PFDI-20 is a reliable and valid condition-specific quality of life instrument for women with pelvic floor disorders.