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LONG TERM RESULTS OF A RANDOMIZED CONTROLLED TRIAL OF THE NURSE CONTINENCE ADVISOR VERSUS THE UROGYNAECOLOGIST IN CONSERVATIVE THERAPY

Aims of the study

Several studies have provided objective evidence that conservative therapy for incontinence is effective in the short term (at 6-12 week review) Long term follow-up of the conservative regimes has shown that cure rates range from 11% at a median of 4 3 years[1] to 30% (at 1 year[2] and at 5 years[3]) up to 34% at 1 year[4] Follow-up methods have included postal survey[1], short pad test at the clinic[3], a 3 point incontinence score[2] and a 12 point incontinence score[4]

In 1998, the twelve-week objective outcome for a randomised controlled trial of conservative therapy was reported, in 147 women with mild to moderate incontinence (1 hour pad test 2-9 9g and 10 –50g respectively This study revealed a 65% objective cure rate (defined as a dry 1 hour pad test) in mild cases and a 35% dry rate for moderate incontinence, regardless of the treatment arm

The aim of the present study was to objectively measure the improvement/disimprovement that occurred over a minimum follow-up of 2 years using measures originally employed in the original study

Methods

After history, physical examination, grading of pelvic floor strength on vaginal examination and full urodynamic investigation patients were randomised to treatment by a nurse continence advisor (NCA) or an urogynaecologist (UG) Patients were stratified with respect to mild or moderate losses on 1 hour pad tests, severe leakage was not accepted Exclusion criteria were previous pelvic radiotherapy, faecal incontinence, recurrent bacterial cystitis, prolapse beyond the introitus, uterine enlargement greater than 12 weeks size and voiding difficulty (Qmax <15 ml sec @200mls, residual > 100 ml) At baseline a one hour standardised pad test was carried out with an ultrasound bladder volume >200 ml A validated 20-point incontinence score was performed Other baseline outcomes were voids/ 24 hours and leaks per day on fluid volume chart, VAS, self-administered cost survey and quality of life questionnaires (QOL) (UDI, IIQ and SF-36)

Those women randomised to standard UG out-patient regime were given a pelvic floor exercise (PFE) program based on initial pelvic floor grading Patients with detrusor instability (DI) or sensory urgent (SI) were given standard written information on bladder training (BT) with a videotape on the subject and those with DI were prescribed anti-cholinergic therapy Women with a main diagnosis of GSI were also asked to visit a physiotherapist, in accordance with unit standard practice At 6 week follow-up these therapies were reviewed and intensified

Women randomised to the NCA arm were given a detailed PFE program and BT plan, with weekly 30 minute follow-up visits, then the program was tailored to their progress For DI, an anticholinergic prescription was attached to the notes and given to the patients at the NCA's discretion, with dose titration Those who could not contract their pelvic floor underwent electrotherapy by the NCA. Motivation to follow the program and discard continence pads was emphasised.

The long term follow-up was performed by blinded independent observer who had not been part of the original treatment team The unit case notes of all recruits were reviewed, to check whether initial dropouts or initial completing patients had or had not re-attended the unit for further treatment of their incontinence The remaining patients were then sent an explanatory letter enclosing the original 20 point incontinence score and original short

form QOL questionnaires, and these were discussed in a telephone conversation 3-4 days later

Absolute cure was defined as no leakage whatsoever, relative cure was defined as leakage of less than once per month with no impact on lifestyle Greater than 50% benefit was defined as a 50% reduction in the original St.George score, failure defined as less than 50% benefit Quality of life scores were compared for statistical change over the period of follow-up and patients were also questioned regarding persistence with treatment

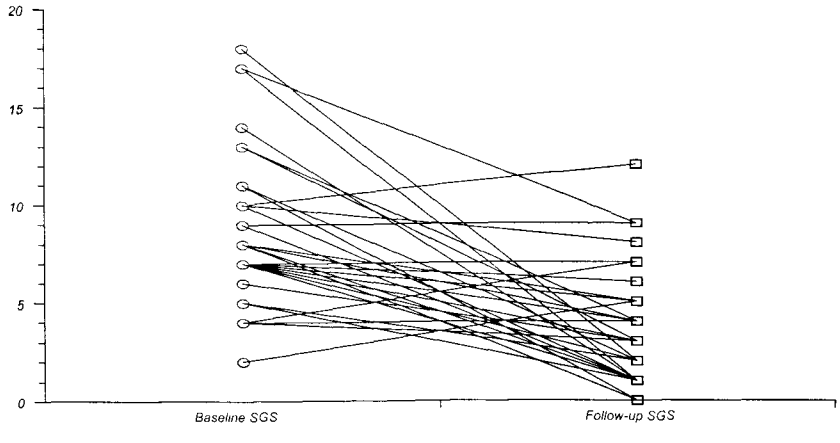
Results

Of the initial 147 recruits, a total of 75(52%) had either withdrawn prior to 3 month follow-up or subsequently failed to attend for treatment after the initial study period was over, despite many being improved. Another 15 (12%) had continence devices fitted or underwent continence procedures (colposuspensions or TVT's) or had alternative management regimes (SANS, TENS, etc)

Of those who could be contacted (n=57), a total of 40 (32%) completed telephone questionnaires The median 20-point incontinence score, St George Score (SGS)[6], was 3 (IQR 1-5), with no significant difference between those in the UG arm (median 3, IQR 1-4 5 n=17) versus those in the NCA arm (median 3, IQR 2-5 75, n=23) There were however significant differences overall between the 20-point incontinence scores taken at baseline and at 2 years follow-up (median 5, IQR 3 5-6 5, p<0 0001) (Fig 1)

Figure 1.

20 point continence scores at baseline and 2 years



Absolute cure occurred in a total of 12 (9%) at 2 years, 8 (13%) of the NCA arm, 4 (7%) of the UG arm Relative cure occurred in a total of 20(16%) women with no significant differences between UG and NCA arms Greater than 50% benefit occurred in the remaining 8 patients (NCA v's UG p=0.04)

Quality of life scores were derived from the short forms of sf-36 (sf-12) and UDI (UDI-6) All patients had completed these at baseline and during telephone conversation There was significant difference between mental and physical component score of the sf-12 at baseline or 2 years (p=0 04), this was also true for UDI-6 (p=0 02)

Of those questioned, only 50% had persisted with their treatment regimes, falling equally into UG (n=10) and NCA (n=10) arms

Conclusion

There is wide variability in the long-term success rates with conservatively managed urinary incontinence This study originally highlighted the differences that occurred between groups conservatively managed by either an NCA or UG After at least 2 years follow-up there were large dropout rates (43%) and low overall cure rates (9%), with little difference between those managed by an NCA or UG A urinary incontinence specific score (SGS) was used with effect to detect overall improvement following treatment, with no significant difference between UG and NCA Quality of life scores also improved over the treatment and follow-up period

References

[1] *BJU* 72 421-427, 1993
[2] *Neurourol & Urod* vol, 374-376,1995
[3] *BJU* 68, 32-37, 1991
[4] *Family Practice* 9, 284-289, 1992