

## THE STANDARD OF REPORTING OF RANDOMISED TRIALS IN UROGYNAECOLOGY

### Hypothesis / aims of study

Randomised controlled trials (RCTs) represent the gold standard of evidence in research. The processes of randomisation and blinding serve to minimise bias, to allow the greatest sensitivity to detect real change. However, the quality of the data depends upon rigorous and robust design and conduct of the trial. To assist in the assessment of reporting of RCTs, journal editors produced a list of minimum criteria which should be included in any report published in the medical literature ( the CONSORT statement)<sup>1</sup>. We have searched for RCTs in two specialist urogynaecology journals and in two general gynaecology and urology journals to assess the degree of compliance with the CONSORT statement.

### Study design, materials and methods

Papers in two specialist urogynaecology journals, the International Urogynaecology Journal (IUGA J) and Neurology and Urodynamics (N&U) and general journals British Journal of Obstetrics and Gynaecology (BJOG) and Journal of Urology (J Urol) published during 2001-2003 were examined. RCTs were assessed for meeting each criterion of CONSORT completely, partially (items within the CONSORT statement had subsections, and each of these were assessed) or not at all.

### Results

	IUGAJ	N&U	BJOG	J Urol
No of papers examined	96	86	179	2274
No of RCTs	7	2	30	32
No of urogynaecology related RCTs	7 (7.2%)	2 (2.3%)	2 (0.01%)	2 (0.0008%)

	IUGA J	N&U	BJOG	J Urol
Any reference to CONSORT	0	0	0	0
All criteria fully met	0	0	0	0
All criteria at least partially met	0	0	1	2
50% criteria at least partially met	4	1	2	2
Sample size calculation reported	3	1	2	1
Effect size reported	4	1	2	1
Method of randomisation reported	4	0	1	2
Intention to treat analysis stated	4	1	1	1

### Interpretation of results

There were few RCTs reported, and the quality of reporting of them was poor. It is possible that the editorial process for these journals requires adherence to the CONSORT principles, without publication of the checklist or a flow diagram. Alternatively, it is possible that the well-designed trials are published in more prestigious journals. We also acknowledge that the lack of quality may be due to other factors including lack of resources to conduct large trials, or the logistics of conducting RCTs for surgical procedures.

### **Concluding message**

Our data demonstrate that the rigour demanded by CONSORT is not uniformly applied within our speciality. It is critically important that we strive as a speciality to ensure that we have robust evidence from which we can properly counsel our patients.

1. The revised CONSORT statement for reporting randomised trials : explanation and elaboration. Annals Int Med 2001;132:663-94.