40

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CONSORT AND QUALITY OF RCTS IN FEMALE PELVIC MEDICINE 2012- 2013

Hypothesis / aims of study

Randomized Controlled Trials (RCTs) are considered the best method to conduct a fair test between two (or more) clinical interventions. (1) Critical characteristics of RCTs include random allocation, allocation concealment and blinding. There is evidence that insufficient attention towards these methodological aspects leads to an exaggeration of treatment effects, making a study less reliable and reducing internal validity. (2)

The CONSORT statement was first proposed in 1996 and updated in 2001 and 2010. The checklist of the CONSORT reporting guideline for RCTs includes 25 items covering all aspects of the reporting of a RCT. (3) Adherence to this guideline facilitates critical appraisal of a manuscript for reviewers and readers.

The aim of this study was to identify, whether the reporting of important features of the CONSORT statement regarding randomization, allocation and blinding, has become more common in articles of RCTs in the sub- specialty of female pelvic medicine.

Study design, materials and methods

All randomized trials published in 3 urogynecology journals (Neurourology and Urodynamics, International Urogynecology Journal, Female Pelvic Medicine and Reconstructive Surgery) and 3 general gynecology journals (Obstetrics & Gynecology, AJOG, BJOG) in the years 2012 and 2013 were included. Each article was checked for reporting of randomization (items 8a and 8b of the CONSORT checklist), allocation concealment mechanism and implementation (items 9 and 10) and blinding (items 11a and 11b). The results were categorized as following: no reporting (0), insufficient or inadequate reporting (1), complete reporting / could be replicated (2). In addition, articles were checked for the inclusion of a participants flow chart (items 13a and 13b), and whether adherence to the CONSORT guidelines was specifically mentioned and referenced in the article.

Results

Table 1 Total number of published urogynecology RCTs in 2012- 2013 and total number of RCTs in the category "complete reporting / could be replicated"

	RCTs (n)	**Randomization (8a, 8b)***	**Allocation (9, 10)***	**Blinding (11a,11b)***	**Flowchart (13a, 13b)**	**CONSORT****
NAU	11	6	1	3	9	2
IUJ	27	16	8	12	25	11
FPMRS	6	4	4	4	4	0
OBGYN	9	8	8	6	9	3
AJOG	4	2	1	1	3	1
BJOG	1	0	1	0	1	0

* according to the CONSORT checklist items ; ** CONSORT guidelines explicitly mentioned in the article text or references; (NAU) Neurourology and Urodynamics, (IUJ) International Urogynecology Journal, (FPMRS) Female Pelvic Medicine and Reconstructive Surgery, (OBGYN) Obstetrics & Gynecology, (AJOG) American Journal of Obstetrics and Gynecology, (BJOG) British Journal of Obstetrics and Gynecology

Table 2 Change of implementation of CONSORT checklist items 2012-13 in the category "complete reporting / could be replicated"

	2012		**2013**		**Difference 2012-13**
Total number of RCTs*	25	**%**	33	**%**	
Randomization (8a, 8b)**	13	**52**	23	**70**	**+18%**
Allocation (9, 10)**	8	**32**	15	**45**	**+13%**
Blinding (11a, 11b)**	9	**36**	17	**52**	**+16%**
Flowchart (yes)	21	**84**	30	**91**	**+7%**
CONSORT (yes)***	6	**24**	12	**36**	**+12%**

* includes RCTs in NAU, IUJ, FPMRS, OBGYN, AJOG, BJOG; **according to the CONSORT checklist item no.; ***CONSORT guidelines explicitly mentioned in the article text or references

Changes of implementation of CONSORT checklist items between 2012 and 2013 in the categories "no reporting" and "Insufficient or inadequate reporting" (%): □randomization (-2), allocation (-27), blinding (-4)□ and □randomization (-12), allocation (+5), blinding (-11)□, respectively.

Interpretation of results

Adherence to the CONSORT guidelines varied depending on the journal and the respective CONSORT checklist item. The majority of urogynecology RCTs was published in NAU and IUJ (11 and 27 respectively), whereas the number ranged between 1-9 among the remaining journals. Comparing the years 2013 and 2012, all investigated items for quality and reproducibility (randomization, allocation, blinding, inclusion of flowchart, referencing CONSORT) seemed to have been reported more adequately and frequently. In 2013, randomization was sufficiently reported ("complete reporting / could be replicated") in 70% of

the published urogynecology articles in the investigated journals, whereas reporting of blinding and allocation still ranged on a lower scale (52% vs. 45% respectively). These results are particularly relevant, as the method of allocation concealment is considered even more important and determinant to the quality of a RCT than randomization or blinding. (2) A participants flowchart was presented in 91% of RCTs, although this number includes any type of flowchart and not necessarily the CONSORT template. The CONSORT guidelines were explicitly cited only in 36% of RCTs. However, the higher proportion of reported CONSORT checklist items in all articles suggests a higher implementation of CONSORT than cited.

Concluding message

Complete and reproducible reporting of urogynecology RCTs based on the CONSORT checklist has generally increased between 2012 and 2013. However, there is still a relevant number of published RCTs, which do not fulfil these criteria. Reporting according to the CONSORT guidelines, specifically focused on allocation concealment, should be further enforced in order to improve quality and reliability of RCTs in female pelvic medicine.

References

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