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IS THE CONSORT CHECKLIST CRITERIA INCLUDED IN THE ABSTRACTS OF RANDOMIZED CONTROLLED TRIALS PUBLISHED IN INTERNATIONAL CONTINENCE SOCIETY CONFERENCE- 2011?

Hypothesis / aims of study

Every year many articles are presented in International Continence Society (ICS) conferences which are concentrated by most of the specialists around the world who may treat their patients by confidence on integrity of these articles .Since complete and informative reporting can lead to better decisions in health care, adherence to CONSORT (CONsolidated Standards of Reporting Trials) check list for Randomized Controlled Trials (RCTs) is considered useful for appraising the strengths and weaknesses of RCT reports. Regretfully it seems that not all the RCT abstracts published by ICS have a suitable level of reporting quality and almost most of them do not mention some important items of CONSORT check list. The aim of this study is to determine the reporting quality of published RCT abstracts in ICS 2011.

Study design, materials and methods

From January to March 2012, of 287 abstracts published in ICS 2011, all of the RCTs (n=37) were enrolled to this study. Recognition of RCTs (Randomized Controlled Trials) was easy due to the fact that at the end of each abstract it is determined by authors whether or not the article is an RCT. Each RCT was inspected by two reviewers independently. The reviewers compared and scored the abstracts using the CONSORT statement extension for reporting abstracts of Randomized Controlled Trials which consists of 17 items instead of 25 in the CONSORT statement for the full text articles. Data were extracted independently by reviewers onto data extraction files; If any disagreements arose, they were resolved either by discussion between the reviewers or the supervisor of the study. Where it was not possible to obtain the necessary information, it was marked as “unclear”. We gave 1 point to each item that met the expectations of the checklist and 0 to the ones that didn’t match the criteria or were unclear. Using SPSS 13 non parametric statistical tests were done, calculating the total sum of the scores for each article and each item of the checklist.

Table1: Analysis of the collected data on the matching of RCTs with CONSORT checklist

Items	yes		no		unclear		PV
	number	percent	number	percent	number	percent	
Title	21	56.8	16	43.2	0	0	NS
Authors	0	0	37	100	0	0	NS
Trial Design	13	35.1	24	64.9	0	0	NS
Methods							
Participant	21	56.8	10	27.0	6	16.2	0.008
Intervention	36	97.3	1	2.7	0	0	0.00
Objective	32	86.5	4	10.8	1	2.7	0.00
Outcome	22	59.5	14	37.8	1	2.7	0.00
Randomization	27	73.0	10	27.0	0	0	0.005
Blinding	11	29.7	26	70.3	0	0	0.014
Results							
Numbers Randomized	21	56.8	16	43.2	0	0	NS
Recruitment							
Numbers Analyzed	24	64.9	12	32.4	1	2.7	0.00
Outcome	27	73.0	9	24.3	1	2.7	0.00
Harms							
Conclusion	11	29.8	24	64.9	2	5.4	0.00
Registration							
Funding	18	48.6	13	35.1	6	16.2	0.05
	36	97.3	1	2.7	0	0	0.00
	28	75.7	9	24.3	0	0	0.002
	30	81.1	7	18.9	0	0	0.00

Results

The mean score of the articles was 10.70 out of 17.The scores ranged from a minimum of 6 to a maximum of 15 (SD 2.22).The least scored items were the second and ninth items (Authors and Blinding respectively) which scored 0 and 29.7% respectively .The most scored items were Interventions and Conclusions each included in 97.3 % of the abstracts .Other significant results are as follows(Table1): Title 56.8% , Design 35.1% , Participant 56.8% ,Objective 86.5% , Randomization 73% , Numbers Randomized 56.8% , Numbers Analyzed 73% , Harms 48.6% , Registration 75.7% and Funding 81.1%. More than eighty

percent (81.08%) of the abstracts were met positively with more than 50% of the items in CONSORT statement. In the result part of the most of the abstracts, Risk difference, Relative risk and NNT were not reported clearly and estimation of the results was incomplete (PV=0.00). Only few studies reported the application of intention to treat analysis (PV<0.01). However about 65% of the abstracts scored between10 to 13 (59% to 76% of the items of the checklist) with a mode of 11.

Interpretation of results

The overall scoring of the abstracts shows that the chosen articles for publication match moderately with the criteria defined by the items of CONSORT checklist. The poor reporting of the Authors' part might be due to ICS abstract rolls .Also a lack of accuracy in matching with the criteria of CONSORT checklist in some other important items such as Blinding, Participants, Trial Design, Harms, and method of the analysis which are essential in extending even more the reporting quality of the gold standard RCTs was observed widely. Blinding is a cornerstone of therapeutic studies, it is not possible all the times to mask patient, physician or investigator, but any lack of blinding may bias treatment effect estimates. Properly done, blinding leads to more accurate trial results. The result has to be presented clearly, objectively, and in sufficient detail to enable the readers to draw their own conclusions, which in most of the abstracts was not emphasized. It was not clear how "P values" were calculated and whether or not they were interpreted appropriately. It wasn't clear what level of difference between the groups, outcomes, or interventions constituted a statistically and clinically significant effect. Also confidence intervals were not calculated, and the authors' conclusions did not reflect them. Another main issue is adverse effects or harms that can change the "clinically significance" of the results. This too was not reported in majority of the abstracts.

Concluding message

This study shows that the inclusion of CONSORT checklist in the RCTs published in ICS 2011 was not as much as expected of a high ranking society as ICS .Therefore we recommend that ICS take under consideration the inclusion of CONSORT checklist for accepting the future RCTs for publication .We do also recommend that further studies on this subject be done annually for evaluation of reporting quality and even critical appraisal of the submitted RCTs.

Disclosures

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