European Association of Urology

Platinum Priority – Statistics in Urology
Editorial by Richard J. Sylvester on pp. 1050–1051 of this issue

Improved Reporting of Randomized Controlled Trials in the Urologic Literature

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Abstract

Background: Well-designed randomized controlled trials (RCTs) have the potential to provide high-quality evidence to inform questions of therapy and prevention, but this potential is contingent on the use of appropriate methods and transparent reporting.
Objective: To systematically assess the quality of urology RCT reporting and identify trends over time.
Design, setting, and participants: All RCTs published in four leading urology journals in 2013 were identified and compared to a prior analysis of studies from 1996 and 2004. Two reviewers abstracted data based on the Consolidated Standards of Reporting Trials (CONSORT) checklist.
Outcome measurements and statistical analysis: A summary reporting score (range: 0–22) for each study was determined. Mean overall scores for 1996, 2004, and 2013 were compared using analysis of variance. We used χ^2 to compare the reporting frequency of individual criteria.
Results and limitations: Mean CONSORT scores for RCTs were 15.6 ± 2.0 in 2013 ($n = 82$), 12.0 ± 0.3 in 2004 ($n = 87$), and 10.2 ± 0.3 in 1996 ($n = 65$); $p < 0.01$. Key deficiencies remain in reporting methods of allocation concealment and group assignment (selection bias), and blinding of participants, personnel, and outcome assessors (performance and detection bias). Study limitations are potential reviewer bias resulting from lack of journal deidentification and the relatively low number of studies reviewed.
Conclusions: There has been a substantial improvement in reporting quality of RCTs in urology since CONSORT. Some methodological criteria remain underreported, and increased efforts are necessary to further this improvement.
Patient summary: Treatment decisions are often based on data from randomized controlled trials. We looked at whether these trials in urology are transparent in reporting their design and conduct using a framework known as the CONSORT criteria and found significant improvements over time. Some areas of deficiency remain, and our paper aimed to highlight these drawbacks to promote continued high-quality research.

Published by Elsevier B.V. on behalf of European Association of Urology.

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1. Introduction

Well-designed randomized controlled trials (RCTs) have the potential to provide the highest level of evidence to evaluate therapeutic interventions and support clinical decision making [1]. Transparent reporting of RCTs is important for critical appraisal. With its release in 1996, the first Consolidated Standards of Reporting Trials (CONSORT) statement established a standardized checklist of items critically important for appraisal and interpretation of RCTs [2]. Since then, there have been two revisions, released in 2001 and 2010 [3,4]. CONSORT is currently endorsed by more than 600 journals, and its use has been shown to improve the quality of reporting [5,6].

We previously performed a systematic assessment of the quality of RCT reporting within the urology literature using the CONSORT criteria and found significant deficiencies [7]. Since the publication of these findings in 2007, other studies that have looked at reporting quality, including those of abstracts presented at major urologic conferences, have found similar shortcomings [8,9]. *BJU International, European Urology*, and *Urology* currently require formal reporting of the CONSORT criteria in their respective authorship guidelines. Given the nearly 10 yr that have passed since the last formal assessment of published RCTs and the increased emphasis on evidence-based clinical practice in urology since that time, we performed an updated analysis to assess the current status.

2. Materials and methods

2.1. Study selection

As previously published [7,10], *randomized control trial* was defined as a prospective study that assesses health care interventions with therapeutic intent in human participants who were randomly allocated to study groups. We identified eligible studies published in four major general urology journals—specifically, *BJU International, European Urology, The Journal of Urology*, and *Urology*—in 2013, with exclusions for studies of cost-effectiveness and diagnostic properties as well as secondary analyses or subset analyses of previously reported RCTs. We performed a Medline search with restrictions on year of publication (2013) and publication type (RCT). We also manually reviewed the tables of contents for the four journals for the year 2013 to identify any RCTs that Medline had not otherwise indexed as such. An author (D.S.) not participating in the formal review redacted authorship and institutional information from each study. These studies were then combined with our previous database of articles from 1996 and 2004 that followed the same inclusion criteria.

2.2. Reporting quality assessment

Two trained investigators (E.B.C., V.M.N.) independently reviewed and abstracted data from each deidentified publication. To allow direct comparison of findings, we used the same standardized evaluation as in our prior assessment [11], which was based on the 2001 CONSORT checklist, and supplemented it with new or revised items from the 2010 version. We scored each item as *met* or *not met*. We pilot-tested the data-abstraction forms in two sets of four studies to ensure clarity and consistency of interpretation.

2.3. Data collection

Each reviewer independently assessed and entered each criterion into a dedicated electronic study database that was blinded from the other's review during the period of data entry. After all data had been collected, each reviewer's assessment merged into a single database, and the results were compared. Discrepancies were reviewed and settled by consensus and mediation by a third party (C.D.S., P.D.).

2.4. Analysis

The primary objective of this study was to compare the quality of RCT reporting in the urology literature in 2013 with those published in 1996 and 2004 based on the mean number of checklist criteria met. Because the 2010 CONSORT statement included 25 total items (compared to 22 criteria with the 2001 statement), we elected to report both scores (on a scale of 0 to 22 and 0 to 25) for the 2013 RCTs to permit comparison with our previous data sets from the earlier years, and to allow contemporary comparisons using the latest data. We assigned 1 point per criterion. For criteria that included two, three, or four components, we assigned a half, third, or quarter point, respectively, to maintain overall weighting, which was consistent with our prior study. We compared mean number of CONSORT criteria reported using analysis of variance (ANOVA), the frequency of individual criterion reporting using the χ^2 test, and subgroup means using either ANOVA or the independent samples t test. Statistical analysis was performed using SPSS version 23.0 software (IBM Corp., Armonk, NY, USA). We did not adjust for multiple statistical testing for individual CONSORT criteria.

3. Results

From 8800 urology articles indexed in Medline in 1996, 2004, or 2013, 297 articles were indexed as RCTs, from which 234 were determined to be eligible for review. A total of 63 studies were excluded because they were secondary or subset analyses of other RCTs ($n = 18$), were meta-analyses ($n = 14$), were not randomized ($n = 8$), or had nonclinical outcomes ($n = 3$). An additional 20 studies were not analyzed because they did not assess interventions that had therapeutic intent.

Table 1 lists the characteristics of the studies we reviewed. The overall number of RCTs published in the urology literature has remained largely stable in the recent past, with 82 studies reviewed in 2013 compared with 87 in 2004 and 65 in 1996. Among those published in 2013, the most common topic of study was voiding dysfunction (43.9%), followed by oncology (23.1%). The median overall sample size of RCTs increased over the study time period, and studies in 2013 tended to more often be multicenter. In 2013, 12 studies (15%) aimed to show noninferiority or equivalence, while the remainder were trials in which the primary hypothesis was to test superiority. Among RCTs that reported sources of funding, industry remained the primary source, making up 41.5% of studies in 2013. Nearly two-thirds (67.1%) of studies in 2013 provided information about their funding source, representing an improvement from 2004 and 1996, where less than half (46% and 31%, respectively) of studies provided information on funding.

Overall reporting of CONSORT criteria improved from 1996 to 2013 (Fig. 1). The mean score (using the 2001 CONSORT scoring system on a scale of 0 to 22) was