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Reporting of Harms in RCTs published in Urology Journals: An Updated Analysis

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INTRODUCTION

In 2004, the Consolidated Standards for Reporting Clinical Trials (CONSORT) group published a Harms extension to their checklist to ensure RCTs properly report on adverse events within trials. In 2010, Breau et. al found sub-optimal reporting of harms within studies published in top urology journals in 1996 and 2004. Our objective was to determine whether their study influenced the completeness of harm reporting in subsequently published RCTs within the same journals.

OBJECTIVES

We sought to conduct a follow-up analysis to determine 1) how well the top Urology journals meet CONSORT-Harms criteria for reporting and 2) to what extent has Harms reporting improved since the original publication by Breau et. al in 2010

METHODS

PubMed was searched to identify all RCTs published within *The Journal of Urology*, *Urology*, *European Urology*, *and BJU International* from 2012 and 2020. These years were selected to provide eight-year intervals from the original publication. In a similar methodology to Breau et. al (2010), two authors independently evaluated each RCT meeting inclusion criteria according to the CONSORT-Harms checklist. Using Stata 17.0, we analyzed trends in reporting and factors associated with completeness of reporting.

RESULTS

Table 1. Characteristics of Included Studies

	2012 (n=87)	2020 (n=45)
Topic	n (%)	n(%)
Oncology	24 (28)	23 (51)
Endourology	19 (22)	4 (9)
Trauma/reconstruction	4 (5)	2 (4)
Voiding dysfunction	24 (28)	12 (27)
Infection/inflammation	9 (10)	2 (4)
Infertility/erectile function	7 (8)	2 (4)
Randomization of:		
Drug	38 (44)	12 (27)
Chemotherapeutic agent	2 (2)	7 (16)
Procedure/surgery	30 (35)	20 (44)
Device	9 (10)	5 (11)
Other	8 (9)	1 (2)
No. multicenter trials	49 (56)	28 (62)
No. reporting source of funding	47 (54)	29 (64)

Table 2. Harm reporting criteria based on CONSORT-recommendations

	2012 n (%)	2020 n (%)	p-value
No. Studies	87	45	
Title + Abstract			
1a – Harm, safety, or similar term used in title	12 (13.8)	7 (15.6)	0.785
1b–Harm addressed in abstract	55 (63.2)	32 (71.1)	0.365
Introduction			
2–Harm addressed in introduction	56 (64.4)	28 (62.2)	0.808
Methods			
3–Authors report which harms were assessed	46 (52.9)	29 (64.4)	0.203
4a–When harm information was collected	50 (57.5)	26 (57.8)	0.973
4b–Methods to attribute harm to intervention	45 (51.7)	30 (66.7)	0.100
4c–Stopping rules	4 (4.6)	1 (2.2)	0.661
5–Plan to compare harm between groups	45 (51.7)	33 (73.3)	0.017
Results			
6–Reason for pt withdrawal	69 (79.3)	37 (82.2)	0.690
7–Denominators provided for harm outcomes	45 (51.7)	43 (95.6)	< 0.005
8a–Effect sizes for harms	62 (71.3)	37 (82.2)	0.168
8b–Stratified serious + minor harms	43 (49.4)	33 (73.3)	0.008
9–Description of subgroup analysis for harm outcomes*	2* (2.3)	2* (4.4)	0.702
Discussion			
10a–Interpret harm outcomes	57 (65.5)	35 (77.8)	0.146
10b–Discuss generalizability	53 (60.9)	34 (75.6)	0.093
10c–Discuss current evidence	64 (73.6)	42 (93.3)	0.007

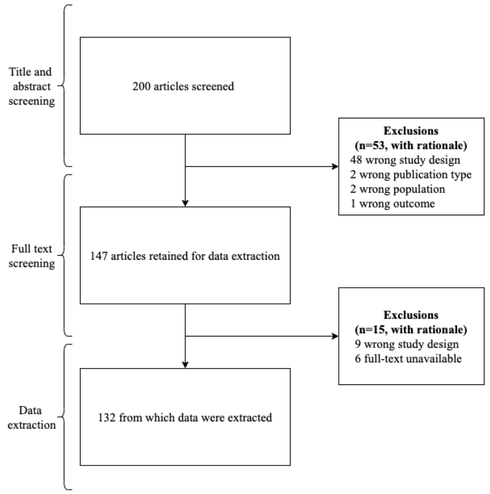

Figure 1. PRISMA Flow Diagram for Study Selection

Table 3. Total number of harm criteria reported

	Median No. Criteria (IQR)	*p-value*
Publication Year		
2012	5.3 (2.3, 7.8)	0.0133
2020	7.0 (4.2, 8.2)	
Journal		
1	2.1 (2.6, 7.2)	0.31
2	4.7 (2.8, 8.2)	
3	6.7 (4.7, 8.2)	
4	6.9 (3.3, 7.8)	
Topic		
Endourology/laparoscopy	7.2 (3.7, 8.2)	0.31
Infection/inflammation	5.7 (3.3, 7.7)	
Infertility/erectile function	6.3 (3.5, 7.3)	
Oncology	4.3 (2.3, 7.2)	
Trauma/reconstruction	7.2 (5.3, 8.2)	
Voiding dysfunction	7.2 (4.5, 8.2)	
Randomization of		
Drug	6.5 (3.5, 8.2)	0.09
Chemotherapeutic agent	7.2 (6.7, 8.2)	
Procedure/surgery	5.7 (3.0, 7.8)	
Device	7.4 (4.7, 8.2)	
Other intervention	3.2 (1.0, 4.8)	
Sample Size		
0 – 49	4.2 (3.0, 7.2)	0.14
50 – 90	6.8 (4.2, 8.2)	
91 – 220	7.2 (4.7, 8.2)	
221 – Max	5.3 (2.5, 7.7)	
Funding		
Industry	7.2 (4.3, 8.2)	0.33
Government	6.8 (3.7, 8.2)	
Institutional	5.3 (2.3, 6.8)	
Not reported	6.2 (3.2, 7.8)	
Participating centers		
Single-institution	6.2 (3.0, 8.2)	0.73
Multiple institutions	6.5 (3.5, 7.8)	

Maximum number of criteria was 9.
* Journal names purposely concealed and correspond with data by Breau et al. (2010)
† Stratified by quartiles according to the original study by Breau et al. (2010)

CONCLUSION

Overall, adherence to the CONSORT-Harms checklist improved since the original publication in The Journal of Urology. Completeness of Harms reporting is imperative for clinicians to make the most informed decisions for their patients well-being. Our analysis found significant improvements in the RCTs published by top Urology journals and we commend the authors and editors for their part in ensuring better reporting since the initial publication in 2010.

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