College of Osteopathic Medicine

Evaluating the Reporting of Patient-Reported Outcomes in Surgical Management of Stress Urinary Incontinence in Females: a cross-sectional analysis of randomized controlled trials

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Background

Stress urinary incontinence (SUI) significantly reduces a woman's quality of life (QoL). Use of patient-reported outcomes (PROs) is increasing in randomized control trials RCTs and standardization is paramount. We aim to evaluate completeness of reporting of RCTs for surgical management of SUI in females based on an adaptation of the Consolidated Standards of Reporting Trials statement with PRO extension (CONSORT-PRO).

Methods

A literature search was conducted and returns were screened using Rayyan. After title and abstract screening, a full-text screen was conducted for final inclusions. All RCTs meeting inclusion criteria were evaluated using an adaptation of the CONSORT-PRO extension checklist and the Cochrane Collaboration risk of bias assessment tool (RoB). Completion percentages of CONSORT-PRO were calculated and a bivariate regression evaluated associations between trial characteristics and CONSORT-PRO adaptation completeness.

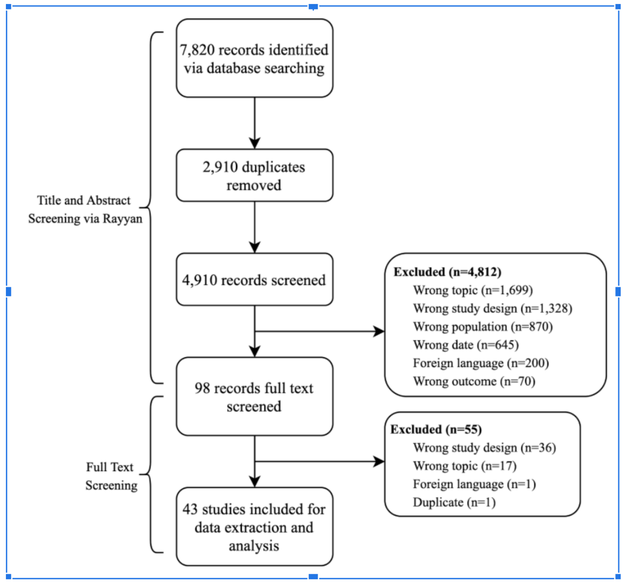

Figure 1: PRISMA diagram for analyzed studies

Results

After full-text screening, 43 RCTs were included for data extraction and analysis. Mean completion percentage of the CONSORT-PRO adaptation was 50.53% (SD=15.63). A total of 38 (of 43; 88.37%) RCTs received a RoB 2.0 rating of 'some concern'. RCTs with follow-up longer than 3 months had higher CONSORT-PRO adaptation completion of statistical significance: 3-6 months (P=0.049), 6-12 months (P=0.009), greater than 12 months (P=0.021). Reporting a conflict of interest (P<0.001) and reporting no conflict of interest (P=0.048) also had statistically significant results with higher reporting completeness when compared to studies without a conflict of interest statement.

Table 1: Baseline Characteristics of Randomized Controlled Trials and associations by PROs being a primary or secondary outcome.

Characteristic	Total 43 (100)	Coef. (SE)	t	*P*
Year of publication, No. (%)				
< 2014	25 (58.14)	1 (Ref)	-	-
≥ 2014	18 (41.86)	5.51, (4.81)	1.14	0.259
Intervention of RCT, No. (%)				
Surgical	43 (100)	1 (Ref)	-	-
Includes COI statement, No. (%)				
No statement	7 (16.28)	1 (Ref)	-	-
Reports COI	15 (34.88)	27.99, (5.49)	5.09	**<.001**
Reports No COI	21 (48.84)	10.68, (5.24)	2.04	**0.048**
Journal Requirement of Reporting Guidelines, No. (%)				
Not Mentioned	6 (13.95)	1 (Ref)	-	-
Recommended	22 (51.16)	5.05, (7.24)	0.7	0.49
Required	15 (34.88)	9.08, (7.59)	1.2	0.239
Mention of CONSORT or CONSORT-PRO within RCT, No. (%)				
No	38 (88.37)	1 (Ref)	-	-
Yes	5 (11.63)	3.75, (7.5)	0.5	0.62
PRO as a primary or secondary outcome, No. (%)				
Primary	28 (65.12)	1 (Ref)	-	-
Secondary	15 (34.88)	-2.74, (5.04)	-0.54	0.59
Overall ROB, No. (%)				
High	2 (4.65)	1 (Ref)	-	-
Some Concern	38 (88.37)	-6.82, (11.44)	-0.6	0.554
Low	3 (6.98)	2.7, (14.39)	0.19	0.852
Length of PRO Follow-up				
3 months or less	4 (9.30)	1 (Ref)	-	-
3+ to 6 months	3 (6.98)	23, (11.31)	2.03	**0.049**
6+ months to 1 year	27 (62.79)	21.66, (7.93)	2.73	**0.009**
1 years +	9 (20.93)	21.46, (8.9)	2.41	**0.021**
Sample size,				
Mean (SD)	163.02 (112.03)	0, (0.02)	0.06	0.956

References

Mercieca-Bebber R, Friedlander M, Calvert M, et al. A systematic evaluation of compliance and reporting of patient-reported outcome endpoints in ovarian cancer randomised controlled trials: implications for generalisability and clinical practice. *J Patient Rep Outcomes*. 2017;1(1):5.

Summary

PROs are used as measures to understand a patient's experience with a condition. Our results suggest CONSORT-PRO adaptation reporting completeness of RCTs about surgical management of SUI in women is suboptimal. Improving reporting completeness through adherence to the CONSORT-PRO extension checklist can better inform clinical decision making and lead to improved QoL.

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