QUALITY OF REPORTING FOR PILOT RANDOMIZED CONTROLLED TRIALS IN THE PEDIATRIC UROLOGY LITERATURE – A SYSTEMATIC REVIEW

MELISSA MCGRATH, CHEN CHEN, FOROUGH FARROKHYAR, LUIS H. BRAGA

McMaster University - Dept. of Surgery/Urology, Hamilton, Ontario

Authors have no conflict of interest to disclose







BACKGROUND

- Purpose of a pilot study is to examine the feasibility of conducting a larger definitive randomized controlled trial (RCT)
- The Consolidated Standards of Reporting Trials (CONSORT) statement extension (2016) to pilot/feasibility studies was developed in response to the growing number of publications in the literature described as pilot studies, but that did not have real feasibility outcomes or missed important reporting items.

(ref)







WHAT IS A PILOT STUDY?

- Pilot studies are: "...investigation designed to test the feasibility of methods and procedures for later use on a large scale or to search for possible effects and associations that may be worth following up in a subsequent larger study." (Everett, 2006)
 - Means of testing the water prior to full scale trial
 - Important step to determining if definitive RCT plan is feasible
- <u>Unlike</u> definitive RCTs, pilot studies aim to determine feasibility, not treatment, diagnostic, or policy outcomes
 - Will not provide meaningful effect size estimates









The aim of this systematic review was to assess the quality of reporting in pilot RCTs in the Pediatric Urology literature based on their adherence to the CONSORT extension for pilot/feasibility studies.







METHODS

Study Design:

- A comprehensive search was conducted through MEDLINE $\ensuremath{\mathbb{R}}$ and $\ensuremath{\mathsf{EMBASE}}\ensuremath{\mathbb{R}}$
- Pilot RCTs from 2010-2019 (n=1347)
- Two reviewers independently performed title and abstract screening as well as full text review, with discrepancies resolved by consensus (n=36)
- Quality appraisal, which was also done in duplicate, was performed using the 17 criteria CONSORT extension checklist







METHODS

- An overall quality of reporting score (OQS) was calculated by dividing the number of checklist items present in each study by the maximum possible score (17) and expressed as a percentage
- Studies were then classified as:
 - low (<40%)
 - moderate (40–70%)
 - high OQS (>70%)







METHODS

Mean OQS was compared with the presence or absence of four a priori key methodological factors

- Year
- Biostatistician
- Method of randomization
- Sample size justification
- Data were analyzed using SPSS version 22.0.







RESULTS -









RESULTS –

	Low Quality (<40%)	Mod	lerate Quality	(40-70%)	High Quali	ity (>70%)	
Gonsalves LF, et al 2000		-			_	-	· ·
Kuligren KA, et al 2015							
Awori QD, et al 2017							
van Leuteren PG, et al 2017			100				
Arsian MS, et al 2016							
Milro G, et al 2017							
rshpanda AV, Alsaywid BS and Smith GHH, et al 2011							
Raheem AA, et al 2012	and the second se			10 10		144	
Le B, et al 2010	the second se			A.0			
Astraf J, et al 2017			all of the second se				
Taylor K, et al 2016		_		-			
Trachtman H, et al 2008							
Braga UH, et al 2013							
Freilich DA, et al 2000			Contract of Contract of Contract	10.000			
Gjisen VMGI, et al 2012			and the second se	10 10	1		
Shadgan B, et al 2015							
Martins G, et al 2016							
Lima SVC, et al 2017				100			
Ostlie DJ, et al 2015				Comments Streements			
WeberDM, et al 2008			and the second se				
DudleyAG, et al 2016			10/1	20	111	111	
Ziessman HA and Majd M, 2008				10 20			
Asgari SA, et al 2016		_					
Steinbok P, et al 2015					_		
Veiga ML, et al 2013							
Soltani T, et al 2016							
Iwatsuki S, et al 2011			_	-		_	
Polak-Jonkisz D, et al 2011				-			
Casey JT, et al 2012		_	-				
Kamar N, et al 2008							
Rick and M, et al 2018 me							
Dy GW, et al 2018							
Findouse M, et al 2017			100	an 10		215	
Soaida SM, et al 2016				_	_	-	
Caoine P, et al 2012			100	10			
Canon S, et al 2014				-			
0.	30 20 30	40	50	50 70	80	90	
		0.000					
		Overall 0	Quality Score (%)				







RESULTS – MEAN OQS COMPARED WITH THE PRESENCE OR ABSENCE OF FOUR A PRIORI KEY METHODOLOGICAL FACTORS

Methodological Factor	Mean OQS	p-value
Year 2016-19 (n=30 2010-15 (n=6)	45 <u>+</u> 18.5% 52 <u>+</u> 14%	
Biostatistician support Yes (n=4) No (n=32)	69 <u>+</u> 10% 49 <u>+</u> 14%	0.01
Method of randomization described Yes (n=-11) No (n=25)	63 <u>+</u> 11% 45 <u>+</u> 13%	0.01
Sample size justification Yes (n=6) No (n=30)	69 <u>+</u> 11% 47 <u>+</u> 13	0.01







CONCLUSIONS

- The mean OQS of pilot studies in pediatric urology was suboptimal (51%)
- Key variables that were significantly associated with a higher OQS were biostatistician support, sample size calculation and method of randomization
- Therefore, adopting the CONSORT extension checklist as a prerequisite for submission of studies identified as 'pilot' may improve the reporting and transparency of pilot studies, leading ultimately to improved implementation of future RCTs.







THANK YOU







