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

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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)

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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

- Unlike definitive RCTs, pilot studies aim to determine feasibility, not treatment, diagnostic, or policy outcomes
  - Will not provide meaningful effect size estimates

OBJECTIVE

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.**

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METHODS

Study Design:

- A comprehensive search was conducted through MEDLINE® and EMBASE®
- 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%)

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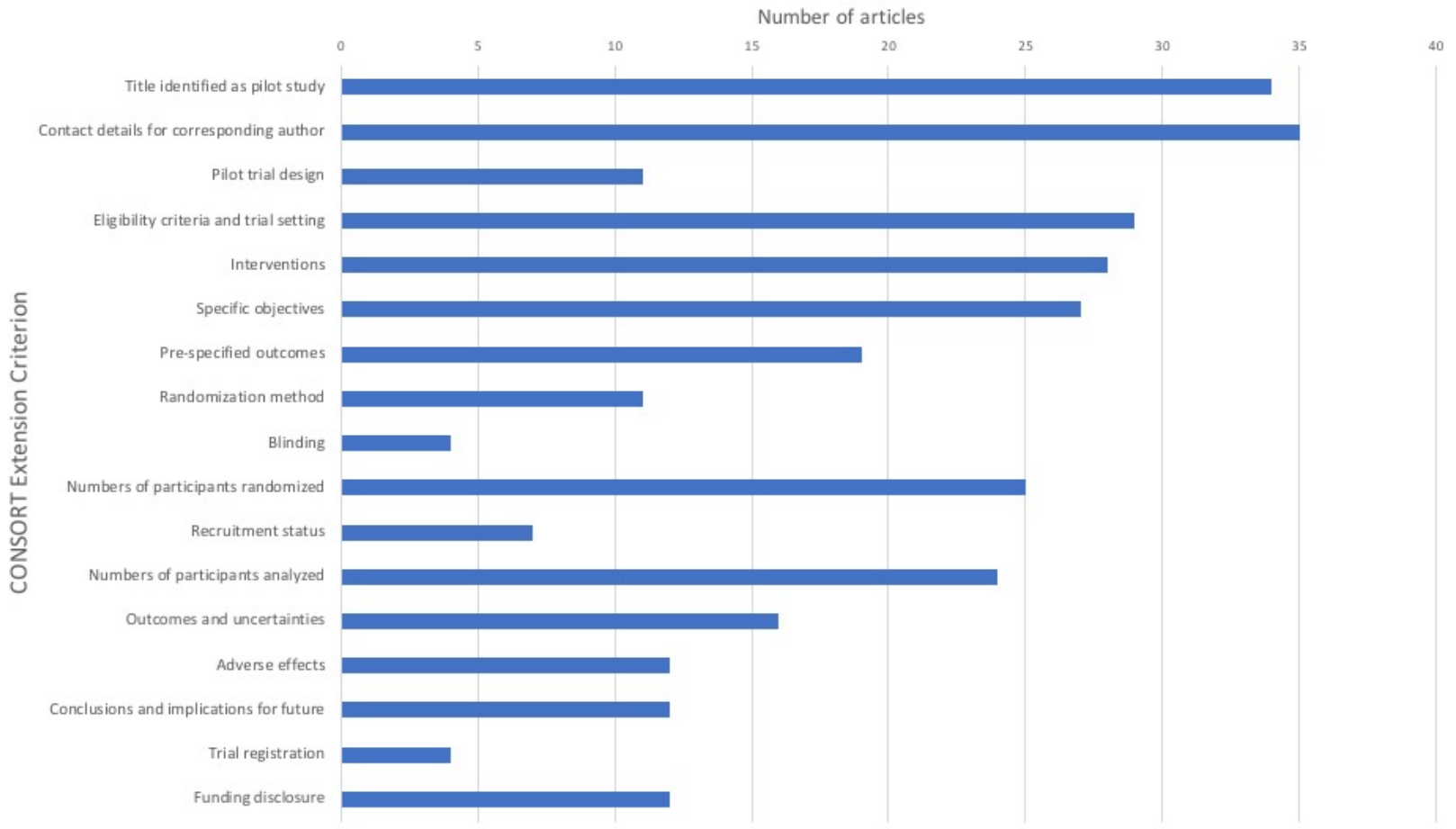
METHODS

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 -



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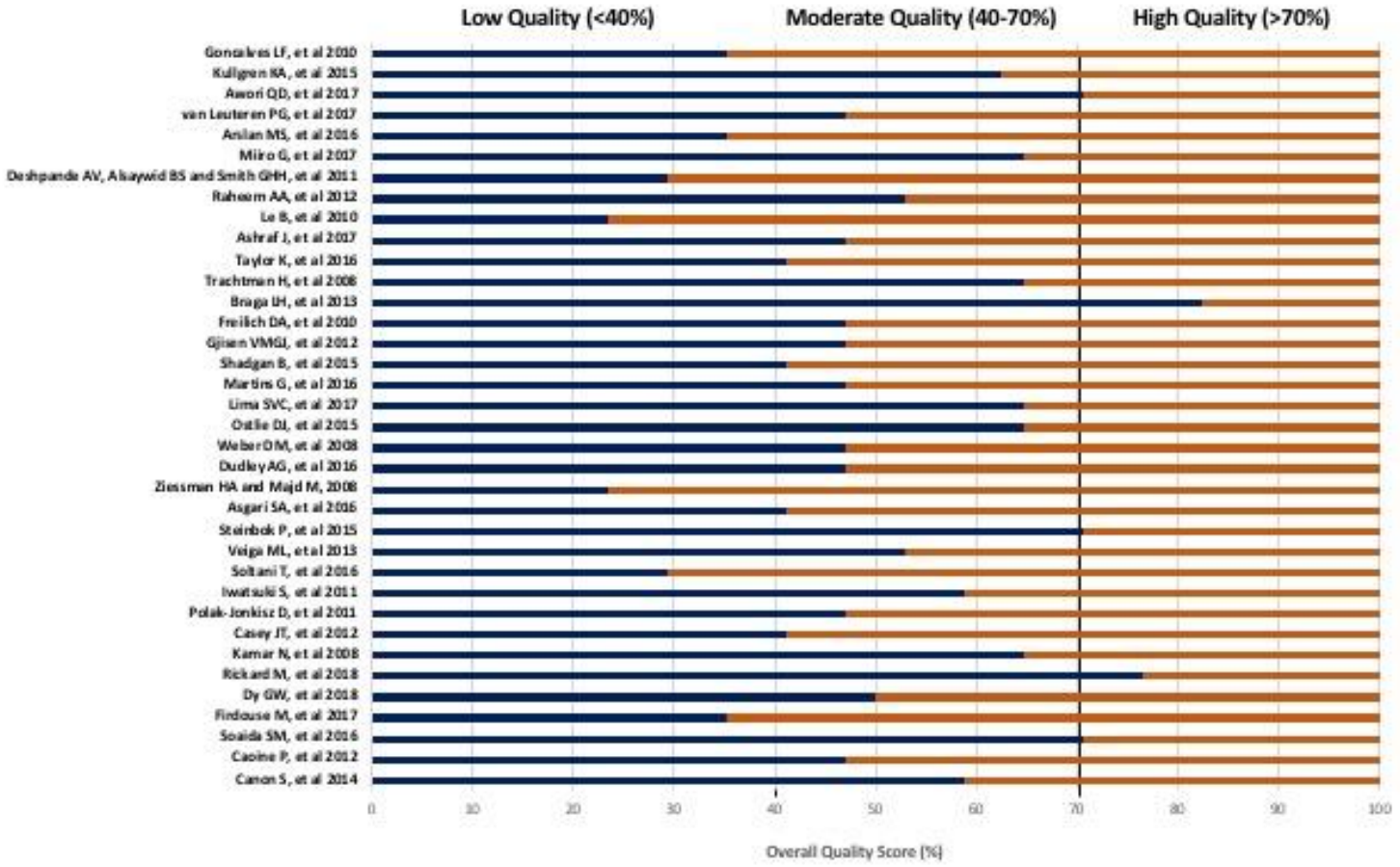
RESULTS –



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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	45 ± 18.5%	
2010-15 (n=6)	52 ± 14%	
Biostatistician support		
Yes (n=4)	69 ± 10%	
No (n=32)	49 ± 14%	0.01
Method of randomization described		
Yes (n=-11)	63 ± 11%	
No (n=25)	45 ± 13%	0.01
Sample size justification		
Yes (n=6)	69 ± 11%	
No (n=30)	47 ± 13	0.01

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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.

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THANK YOU

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