REporting quality of PilOt Randomized controlled Trials in Surgery according to the CONSORT checklist (REPORTS CONSORT): A Methodological Survey

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Background:

- Pilot and feasibility studies are not reported completely as per reporting guidelines in fields of study such as nephrology and psychiatry[1,2]
- The reporting completeness of these types of studies in surgery has never been examined
- We designed this study to evaluate previously published pilot and feasibility studies in surgery to assess their completeness of reporting





Methods:

- Included pilot and feasibility trials evaluating a surgical intervention published between Jan 1-Dec 31, 2011 or Jan 1-Dec 31, 2021
- **Primary outcome:** Completeness of reporting according to the CONSORT statement extension to randomized pilot and feasibility trials[3]
- **Secondary outcomes:** Completeness of reporting for each trial; research factors associated with reporting completeness
- **Descriptive statistics** used for the primary outcome
- **Poisson regression** was used to explore associations between research factors and reporting

The reporting completeness of surgical pilot and feasibility trials is poor and has not improved after the publication of the CONSORT extension



Studies registered in a clinical trial database and randomizing more than 50 patients had more complete reporting





Results:



72 pilot and feasibility trials included

- 34 published in 2021
- 38 published in 2011



- 26.4% general surgery
- 15.3% orthopedic surgery

0.59

Mean CONSORT reporting score 20.1/34 (0.59)

- 22.5/34 in 2021 (0.66)
- 18.0/34 in 2011 (0.53)



IRR 1.01 (95% CI 0.89-1.15)



IRR 1.29 (95% CI 1.12-1.48)



IRR 1.16 (95% CI 1.04-1.30)

Limitations and Future Directions:



- Sampling bias
- Lack of statistical power
- Heterogeneity



- Ongoing endorsement of CONSORT reporting checklists

1. Kosa SD, Monize J, Leenus A, et al. Reporting quality of pilot clinical trials in chronic kidney disease patients on hemodialysis: A methodological survey. Pilot Feasibility Stud. 2019;5(1). doi:10.1186/s40814-019-0436-3; 2. Bhatt M, Zielinski L, Sanger N, et al. Evaluating Completeness of Reporting in Behavioral Interventions Pilot Trials. Res Soc Work Pract. 2018;28(5):577-584. doi:10.1177/1049731517720033; 3. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239. doi:10.1136/bmj.i5239