Systematic review of shorter versus longer duration of bladder catheterization after surgical repair of urinary obstetric fistula

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Abstract
Background: Bladder catheterization duration after urinary obstetric fistula surgery varies widely.
Objective: To assess the effect of bladder catheterization duration after urinary obstetric fistula surgery.
Search strategy: Medline, EMBASE, CINAHL, GIM, and POPLINE databases were searched, without language restrictions, using "obstetric urinary fistula" and "catheterization" from inception to September 30, 2017.
Selection criteria: Randomized controlled trials comparing shorter versus longer (>10 days) bladder catheterization after urinary obstetric fistula repair were included.
Data collection and analysis: Data were extracted and meta-analyses were conducted. The GRADE system was used to assess evidence quality.
Main results: Two unblinded non-inferiority trials (684 patients combined) were included. There were no differences between shorter and longer bladder catheterization in the risk of fistula repair breakdown either before (relative risk [RR] 1.14; 95% confidence interval [CI] 0.49–2.64) or after (RR 1.64; 95% CI 0.81–3.31) hospital discharge. Similarly, urinary infection (RR 5.18; 95% CI 0.25–107.44); urinary incontinence before (RR 1.15; 95% CI 0.54–2.43) or after (RR 1.16; 95% CI 0.62–2.18) discharge; urinary retention (RR 1.34; 95% CI 0.79–2.27); or extended hospital stay (RR 9.33; 95% CI 0.51–172.41) were not associated with duration of catheterization. Evidence quality was low or moderate.
Conclusions: Shorter, compared to longer, bladder catheterization duration after urinary obstetric fistula surgery was not associated with significant outcome differences.

Keywords
Catheterization; Obstetric fistula; Systematic review; Urinary catheterization; Vaginal fistula; Vesicovaginal fistula
1 | INTRODUCTION

An obstetric fistula is an abnormal opening between a woman's vagina and her urinary tract and/or rectum caused by obstetric events. The main cause of obstetric fistula is very long or obstructed labor, usually due to lack of access to timely obstetric care. The continued pressure of the fetal head against the bladder or rectal wall leads to tissue necrosis and fistula formation. Owing to the constant uncontrolled passage of urine and/or feces, women with obstetric fistula are often ostracized and marginalized by their families and communities.

Most cases of obstetric fistula occur in low-income countries. A recent systematic review of population-based studies reported that the pooled prevalence of obstetric fistula was 1.60 (95% confidence interval [CI] 1.16–2.10) per 1000 reproductive-age women in Sub-Saharan Africa, and 1.20 (95% CI 0.10–3.54) in South Asia. This means that more than one million women have an obstetric fistula in these two regions, and thousands of new cases occur each year, making it an international public health problem.

In most cases, urinary obstetric fistula can be repaired surgically. Routine post-operative care of women who undergo surgery involves the use of an indwelling urinary catheter to promote continuous urine drainage and allow tension-free healing of the surgical repair. The duration of routine post-operative bladder catheterization is not standardized and varies widely in clinical practice, ranging from 5 to 42 days, with direct health and cost implications. Prolonged bladder catheterization translates into longer hospitalization, more discomfort and inconvenience to patients, increased risk of infection related to catheterization, more intensive nursing care, and increased costs. The unmet need for fistula repair is estimated to be as high as 99%; therefore, a shorter duration of hospitalization could translate into a substantially larger number of women receiving surgical treatment for obstetric fistula.

Some evidence suggests that shorter periods of routine post-operative bladder catheterization are both effective and cost-beneficial compared with longer periods. However, to the best of our knowledge, evidence concerning the potential benefits and harms of shorter versus longer duration of bladder catheterization has not been previously analyzed in a systematic review.

The aim of the present study was therefore to identify, critically appraise, and synthesize evidence on the effects of different durations of bladder catheterization after the surgical repair of urinary obstetric fistula. The results of the review will be useful to develop guidelines on the post-operative care of women with urinary obstetric fistula.

2 | MATERIALS AND METHODS

The present study followed standard methods recommended by the Cochrane Handbook for Systematic Reviews of Interventions and the PRISMA reporting guidelines. The search string included the following generic terms and Boolean operators: "vaginal fistula" OR "vesicovaginal fistula" OR "urinary fistula" OR "obstetric fistula" OR "female genital fistula" AND "catheterization" OR "catheter" OR "cannula" OR "Foley catheter" (Appendix S1). The search was run in five electronic databases (Medline, EMBASE, CINAHL, Global Index Medicus, and POPLINE) from their inception to September 30, 2017. Two of the databases (POPLINE and Global Index Medicus, which includes LILACS, WPRIM, AIM, IMEMR, and IMSEAR) have a focus on publications from low- and middle-income countries. Two major trial registration platforms (WHO International Clinical Trials Registry Platform and US National Trial Registry) were also searched for ongoing trials. The search was completed by reviewing the reference lists of all articles selected for full text reading and through personal communications with fistula experts known to the investigators. There were no language restrictions. Only randomized controlled trials or quasi-randomized controlled trials comparing different durations of bladder catheterization after urinary obstetric fistula surgery were included in the review. All participants had to be women in the post-operative period following surgery to repair urinary obstetric fistula.

Women with non-obstetric fistula, such as those induced by radiation, caused by gynecologic surgery or trauma, associated with cancer, or due to lymphogranuloma venereum, were not included. As a retrospective analysis of published data, the present systematic review was exempt from ethics approval. The protocol was registered in PROSPERO (CRD42017056320).

Citations were downloaded into reference manager (ENDNOTE version X7; Clarivate Analytics, New York, NY, USA) and duplicates were excluded. The process of study selection, data extraction, and quality assessment was performed in duplicate by two independent investigators (MRT and RR). Disagreements were discussed until consensus was reached; if necessary, a third reviewer was consulted (ER). The investigators screened the titles and abstracts of all unique citations, selected the full-texts of those deemed potentially eligible, read the selected articles, and included those that fulfilled the selection criteria. A form specifically designed for the systematic review was used to extract the following data from included studies: design, participants, intervention, comparators, and outcome measures. If information from an article was unclear or incomplete, the original authors were contacted by email to request additional details.

Different durations of routine post-operative bladder catheterization after obstetric fistula surgery were compared. The duration of catheterization after surgery was categorized as shorter (≤10 days) or longer (>10 days). The two primary outcomes of the review were fistula repair breakdown (FRB) after catheter removal before hospital discharge and after hospital discharge. The secondary outcomes were urinary tract infection, post-repair urinary incontinence (before or after hospital discharge), post-repair urinary retention before hospital discharge, and extended hospital stay for a medical reason possibly related to the study treatment.

Two reviewers (MR and RR) assessed the risk of bias for the outcomes of interest in each trial by using the tool recommended by the Cochrane Handbook. Random sequence generation (method used to generate the allocation sequence) and allocation concealment (method used to conceal allocation to interventions prior to assignment) were assessed at the study level. The following were assessed at the outcome level: masking of participants, personnel, and outcome assessors (methods used to ensure that participants, personnel and
outcome assessors did not know which intervention the participant had received; incomplete outcome data (completeness of data including attrition and exclusions from the analyses); selective reporting (whether all pre-specified outcomes were reported); and any other bias (important concerns about other potential sources of bias). The reviewers assigned one of three grades to each domain (low, high, or unclear risk of bias) in accordance with Cochrane recommendations.

Where appropriate, the results of individual studies were pooled and meta-analyses were performed. Statistical analyses were performed with Review Manager version 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). Combined effect estimates of categorical outcomes were assessed as relative risk (RR) and 95% CIs. For continuous outcomes, the use of mean differences (MDs) and 95% CIs was planned when the studies had similar measurement tools, and the use of standardized mean differences (SMD) and 95% CIs were planned to pool the results of studies that assessed outcomes by using different scales. A fixed-effects model was used to combine data where studies estimated the same type of participants and interventions. In case of clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected ($I^2$ value of >50%), a random-effects model was used to produce an overall summary of effect estimate.

The overall quality (certainty) of the body of evidence was assessed for the two primary and four secondary outcomes by using Grades of Recommendation, Assessment, Development and Evaluation (GRADE). To assess the certainty of the body of evidence for each outcome, the GRADE approach analyzes five aspects: study limitations, consistency of effect, imprecision, indirectness, and publication bias. The overall certainty of the evidence (confidence in cumulative evidence) for each outcome was classified as very low, low, moderate, or high.

3 | RESULTS

The search strategy yielded 1155 unique citations. After screening titles and abstracts, the reviewers selected 11 citations for full text reading (Fig. 1). Three citations were excluded and two randomized trials reported in eight publications were included in the systematic review. (Table S1). Both included studies open label, randomized, controlled, non-inferiority trials, and involved women in countries in Africa. The main characteristics of the two trials included are presented in Table 1. The authors of both trials were contacted for additional information and unpublished details were obtained from both.

The study by Nardos et al. was conducted during a 35-month period (2007–2010) at a single hospital in Bahir Dar, Ethiopia. A total of 189 participants were randomized to 10 days ($n=107$) or 14 days ($n=82$) routine bladder catheterization after surgery to repair urinary obstetric fistula. Women with a history of prior surgical fistula repair or with a vesicovaginal fistula with circumferential involvement of the urethra (complete detachment of the bladder neck from the urethra) were not eligible. There was no trial protocol publication or registration, but

in the methods section of their publication, Nardos et al. stated that their primary outcome was “cure, defined as absence of leakage from the fistula repair site after removal of the bladder catheter”; however, in the results section of their paper, they did not present these data but instead reported the number of women in each group who had FRB while the catheter was in place. The investigators were contacted to obtain data for FRB after catheter removal, but the author who replied was unable to provide this information with certainty; therefore, data for this outcome from Nardos et al. were not included in the review. The other outcomes assessed were urinary retention and incontinence, both assessed after catheter removal before hospital discharge. The study of Nardos et al. had a low risk of bias for random sequence generation and an uncertain risk of bias for allocation concealment (owing to lack of information). The study was categorized as having an uncertain or high risk of bias for most domains for the two outcomes reported (Figs S1 and S2; Table S2).

Barone et al. published a multicenter trial conducted over 14 months (2012–2013) in eight African countries, involving 525 participants with vesicovaginal fistula. The participants had a mean age of 31 years, 59% had no education, and 87% lived in rural areas. Women were not eligible to enter the trial if they were pregnant, if their fistula was not simple, if they had multiple fistulae (this last exclusion criterion was added after the study had started), or if the fistula was radiation-induced, associated with cancer, or due to lymphogranuloma venereum. Women were eligible if they had a simple fistula (as judged by the surgeon at the end of the operation) that was closed after surgery and remained closed 7 days after surgery while the catheter was still in place (confirmed through dye tests on both occasions). On post-operative day 7, after confirming that the repair was intact, the investigators randomized 524 women to 7 or 14 days of bladder catheterization; 7 days after removal of the catheter (i.e., on post-operative day 14 for participants in the 7-day catheterization group.
TABLE 1  Main characteristics of the trials included in review.

| Study            | Setting                                                                 | Participants                                                                                   | Inclusion criteria                                                                 | Exclusion criteria                                                                 | Intervention and comparison | Outcomes                                                                 | Outcome assessment                |
|------------------|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------|----------------------------------------------------------------------------|-----------------------------------|
| Barone et al., 2015<sup>11</sup> | 8 hospitals (Democratic Republic of Congo, Ethiopia, Guinea, Kenya, Niger, Nigeria, Sierra Leone, Uganda) | 495 women with OF<sup>a</sup>; 7-d catheterization (n=243), 14-d catheterization (n=252). 51% with genital cutting; 22% in each group with previous fistula repair attempts; 3%–4% in each group with circumferential fistula<sup>b</sup> | Simple fistula (as defined by surgeon at end of surgery) that was closed after surgery and remained closed 7 d after surgery (confirmed by dye tests) | (1) pregnancy; (2) fistula due to radiation, cancer, or lymphogranuloma venereum; (3) fistula that was multiple or not simple | 7 vs 14 d catheterization | Before hospital discharge: FRB after catheter removal, urinary infection, urinary retention, extended hospital stay. After hospital discharge (3 mo): FRB, urinary infection, urinary incontinence | FRB: dye test on all participants. Urinary retention: post-void residual volume >50% of voided volume (measured by urethral catheter on all participants at 1, 3 and 7 d post-catheter removal). Urinary incontinence: subjective report only. Urinary infection: symptoms only |
| Nardos et al., 2012<sup>12</sup> | 1 hospital (Ethiopia)                                                   | 189 women with OF; 10-d catheterization (n=107), 14-d catheterization (n=82). Groups similar in age, parity, duration of labor, and time from index injury to surgery | OF diagnosed on physical exam. Fistula closure confirmed at the end of surgery by dye test on all participants | (1) history of prior fistula repair; (2) current vesicovaginal fistula with circumferential fistula<sup>b</sup> | 10 vs 14 d catheterization | Before hospital discharge: cure—defined as "absence of leakage from the fistula repair site after removal of the bladder catheter", non-fistula-related incontinence, urinary retention | FRB: dye test performed only on symptomatic patients. Urinary retention: post-void residual volume >150 mL (confirmed only in symptomatic patients). Urinary incontinence: subjective report only |

Abbreviations: FRB, fistula repair breakdown; OF, obstetric fistula.

<sup>a</sup>The original trial randomized 524 women; 1 woman in the 14-day group was excluded from analyses (following recommendation of data monitoring committee because she was non-eligible) and 28 participants had non-obstetric fistulas. After contacting the authors, the data exclusively for the 495 women with obstetric fistula were obtained.

<sup>b</sup>Urethra completely detached from bladder neck.

<sup>c</sup>Authors described this outcome in methods but did not present it in the results.
and on post-operative day 21 for those in the 14-day catheterization group), the condition of the repair was re-assessed (with a dye test) before the women were discharged from hospital.

All participants in the Barone study were scheduled for a follow-up visit 3 months after surgery when they had another dye test to assess the condition of the repair. The authors excluded one patient because she was incorrectly randomized (ineligible). Of the 523 remaining participants, 28 had non-obstetric fistula. After contacting the investigators, data exclusively on eligible women with obstetric fistula (n=495) were obtained for the current six outcomes of interest. Barone et al.’s study was classified as having a low risk of bias for random sequence generation and allocation concealment, and as having a low or uncertain risk of bias for most other domains for all outcomes (Figs S1 and S2; Table S2).

Overall, there was no significant difference in the risk of FRB after catheter removal before hospital discharge between the groups with shorter versus longer duration of bladder catheterization (RR 1.14; 95% CI 0.49–2.64; 1 study, 495 participants) (Fig. 2A and Table 2). The quality of the evidence for this outcome was downgraded to low because of imprecision (low number of events and a wide CI) (Table 2 and Table S3). Similarly, the risk of FRB after hospital discharge did not differ significantly between the two groups. In the best-case scenario, which assumed that all dropouts did not have FRB, the RR was 1.17 (95% CI 0.46–2.97; 1 study, 495 participants); in the worst-case scenario, which assumed that all dropouts had FRB, the RR was 1.64 (95% CI 0.81–3.31; 1 study, 495 participants) (Fig. 2B). The quality of the evidence for this last outcome was downgraded to moderate because of imprecision (wide CI) (Table 2 and Table S3).

There were no significant differences in the risk of post-repair urinary infection, urinary incontinence before or after hospital discharge, urinary retention after catheter removal (data from 2 studies; I² 0%), or extended hospital stay (Table 2 and Fig. S3). The quality of the evidence for urinary infection and extended hospital stay was judged to be low because of imprecision (low number of events and wide CI). The quality of the evidence for urinary incontinence before hospital discharge was downgraded to very low because of imprecision (low number of events and wide CI) and because of the risk of bias in the only contributing study. For urinary incontinence after hospital discharge (worst case-scenario) and for urinary retention, the quality of the evidence was downgraded to moderate owing to imprecision (wide CI) (Table 2 and Table S3).

4 | DISCUSSION

The search identified two randomized trials (684 women) that assessed a shorter (≤10 days) versus a longer (>10 days) duration of bladder catheterization after surgical repair of urinary obstetric fistula. There were no significant differences between the groups in relation to FRB before or after hospital discharge, urinary tract infection, post-repair urinary incontinence before or after hospital discharge, urinary retention, or extended hospital stay. The quality of the evidence for...
TABLE 2 Summary of findings.

| Outcomes                                                                 | Anticipated absolute risk (95% CI)¹ | Long duration catheterization (>10 d) | Short duration catheterization (≤10 d) | Short vs long duration, RR (95% CI) | No. of patients (studies) | Quality of evidence² |
|--------------------------------------------------------------------------|-------------------------------------|---------------------------------------|---------------------------------------|---------------------------------|------------------------|---------------------|
| Repair breakdown after catheter removal, before hospital discharge       |                                     | 40 per 1000                           | 45 per 1000 (19–105)                  | 1.14 (0.49–2.64)               | 495 (1 RCT)           | Low²                |
| Repair breakdown after hospital discharge                                 |                                     |                                       |                                       |                                |                        |                     |
| Worst-case scenario³                                                     | 48 per 1000                         | 78 per 1000 (39–158)                  | 1.64 (0.81–3.31)                     | 495 (1 RCT)                    | Moderate³              |                     |
| Best-case scenario³                                                      | 32 per 1000                         | 37 per 1000 (15–94)                   | 1.17 (0.46–2.97)                     | 495 (1 RCT)                    | Low²                   |                     |
| Post-repair urinary tract infection                                      | 0 per 1000                          | 0 per 1000 (0–0)                      | 5.18 (0.25–107.44)                   | 495 (1 RCT)                    | Low²                   |                     |
| Post-repair UI after catheter removal before hospital discharge          | 122 per 1000                        | 140 per 1000 (66–296)                 | 1.15 (0.54–2.43)                     | 189 (1 RCT)                    | Very low³              |                     |
| Post-repair UI after hospital discharge                                   |                                     |                                       |                                       |                                |                        |                     |
| Worst-case scenario³                                                     | 67 per 1000                         | 78 per 1000 (42–147)                  | 1.16 (0.62–2.18)                     | 495 (1 RCT)                    | Moderate³              |                     |
| Best-case scenario³                                                      | 24 per 1000                         | 37 per 1000 (13–102)                  | 1.56 (0.56–4.30)                     | 495 (1 RCT)                    | Low²                   |                     |
| Post-repair urinary retention                                            | 66 per 1000                         | 88 per 1000 (52–150)                  | 1.34 (0.79–2.27)                     | 684 (2 RCTs)                   | Moderate³              |                     |
| Extended hospital stay                                                   | 0 per 1000                          | 0 per 1000 (0–0)                      | 9.33 (0.51–172.41)                   | 495 (1 RCT)                    | Low²                   |                     |

Abbreviations: CI, confidence interval; RCT, randomized controlled trial; RR, risk ratio; UI, urinary incontinence.

¹The risk (95% CI) in the intervention group is based on the assumed risk in the comparison group and the relative effect of the intervention (95% CI).

²GRADE classifications: High quality: very confident that the true effect lies close to that of the estimate of the effect. Moderate quality: moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Low quality: confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect. Very low quality: very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

³Assumes that women who were lost to follow-up developed the outcome.

⁴Assumes that women who were lost to follow-up did not develop the outcome.

⁵Wide CI, number of events <30.

⁶Wide CI.

The main limitations of the review were the small number of trials identified, their quality, the varied inclusion criteria, and the different methods used to assess FRB. For instance, whereas Barone et al. included women with prior history of fistula repair surgery and women with circumferential fistula, Nardos et al. excluded these women. In addition, Barone et al. assessed FRB with an objective method (dye test) for all participants after catheter removal, whereas Nardos et al. used the dye test only for patients who were symptomatic. The clinical heterogeneity of participants and differences in the methods used to assess outcomes in these two trials could affect the generalization of the review findings to all women with urinary obstetric fistula.

To the best of our knowledge, there are no previous systematic reviews on this specific topic. A 2006 Cochrane review of short-term urinary catheter policies after various urogenital surgeries identified 39 randomized trials; however, none of those studies included participants with urinary obstetric fistula. Short and long durations of catheter use were compared, and no significant differences were found in urinary retention or incontinence post-catheter removal, or in length of hospital stay. However, the data available suggested that removing the catheter after 1 day, instead of after 3 days, reduced the risk of urinary infection (odds ratio 0.50, 95% CI 0.29–0.87; 3 studies, 179 participants). Although the Cochrane review did not include participants with obstetric fistula, its main results are similar to the present findings.

Many countries in Africa and Asia offer surgical treatment for women with obstetric fistula, and several studies from these settings report success rates and factors that influence FRB and other clinically important outcomes. Although those studies provide useful information, most were limited by their retrospective, non-randomized, or uncontrolled designs.

In most facilities, duration of bladder catheterization is the main determinant of length of hospitalization and the single most important factor affecting patient outcomes.
contributor to treatment cost and efficient use of bed space. However, there is little evidence on which to base decisions about the duration of catheterization.\textsuperscript{5,9} At an international meeting in 2005, clinicians and public health professionals pinpointed an existing research gap as the identification of evidenced-based practice for the successful management of obstetric fistula.\textsuperscript{27} In 2008, a consultative panel of fistula clinicians from 10 countries\textsuperscript{29} identified bladder catheterization in fistula care management as a priority area for clinical trials. In a survey conducted in 2009 among a purposive sample of surgeons who performed fistula repair in Sub-Saharan Africa and South Asia, Arrowsmith et al.\textsuperscript{5} reported large disparities in clinical practices on duration of post-operative bladder catheterization. They recommended randomized trials to assess the effectiveness and safety of short-term catheterization as the first topic in a list of research agenda priorities.

The findings of the present systematic review, based on two randomized trials conducted between 2007 and 2012, indicate that duration of catheterization after the surgical repair of urinary obstetric fistula does not affect major clinical outcomes. The findings are important to inform guideline developers; however, no information was obtained on important aspects related to the GRADE Evidence to Recommendation framework.\textsuperscript{29} For example, neither the values placed by women or stakeholders on the review outcomes, nor their views about shorter versus longer bladder catheterization, were included in the review. Nevertheless, it can be presumed that most women with urinary obstetric fistula, irrespective of their nationality, are likely to place a high value on a shorter duration of bladder catheterization because this would mean less discomfort and a quicker return to health and their social roles.

Although acceptability and costs of the intervention were not included in the present review, a shorter duration of bladder catheterization is likely to be highly acceptable by key stakeholders; it would allow them to offer fistula repair services to more women because the post-operative nursing care would be shorter and the women would be discharged sooner from the hospitals. For patients, having the catheter in place for a shorter period of time would probably be well accepted, because it would represent potentially fewer adverse events associated with the catheterization, shorter hospital stays, and faster social re-integration. However, given that the evidence in the systematic review comes from low-resource settings, caution is warranted when extrapolating its results to other contexts with different backgrounds and causes of obstetric fistula.

5 | CONCLUSION

On the basis of the existing evidence, a shorter duration of bladder catheterization could be an option for women in the post-operative period of urinary obstetric fistula repair surgery because the harms and benefits of this intervention were not found to differ significantly from those of longer bladder catheterization. The quality of the evidence for most outcomes was moderate to low, mainly owing to imprecision.

The present findings were based on the only two trials existing on this topic, and most data come from one large multinational study. Additional trials would therefore be useful to improve the quality of the evidence and to validate the findings of the present review. Future studies should also include other important aspects associated with a shorter duration of bladder catheterization, such as women's satisfaction and costs.

AUTHOR CONTRIBUTIONS

MRT contributed to conceiving and planning the review, performing the study selection, data extraction, quality assessment, and meta-analyses, assessing evidence quality, and writing the manuscript. RR contributed to performing the study selection, data extraction, quality assessment, and meta-analyses, assessing evidence quality, analyses, and revising the manuscript. ER contributed to assessing evidence quality, analyses, and revising the manuscript. ÖT and AMG contributed to the analyses and revising the manuscript. MW contributed to conceiving and planning the review, and writing the manuscript. All authors read and approved the submitted manuscript and accept responsibility for the paper.

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CONFLICTS OF INTEREST

MW and MG were members of the steering committee of one of the studies included in the review and co-authors of that study (Barone et al.\textsuperscript{11}). However, they did not participate in data extraction or quality assessment for the present systematic review.

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