



The Cochrane
Renal Group

Review Checklist

Title:

Each review needs to be explicit and comprehensive. At each part of the review, the referee should ask the questions:-

- “Did the authors do what the protocol said they planned to do?”
- “Have they done it correctly?”
- Please enter;
 - Y (yes),
 - N (no),
 - ? (unsure),
 - or NA (not applicable) in the right-hand column.
- Please include comments at the end of the checklist.

Abstract

Does each section of the abstract accurately reflect the equivalent section in the review	
• Background	
• Objectives	
• Search strategy	
• Selection criteria	
• Data collection and analysis	
• Main results	
• Reviewers' conclusions	

Background

• Does the background support the need for a systematic review by providing sufficient information on the frequency and severity of the clinical problem and the uncertainties in its management?	
• Does the background address the important issues for consumers?	

Objective/s

<ul style="list-style-type: none"> • Was the main objective of the review specified in terms of intervention(s), clinical problem, population and outcomes (both beneficial and harmful)? <p><i>Example: To evaluate the benefits (reduction in number of children who relapse) and harms (serious infections, cystitis) of different agents, other than corticosteroids, that are used in children who pursue a relapsing course of steroid responsive nephrotic syndrome</i></p>	
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Selection criteria

Types of participants:

<ul style="list-style-type: none"> • Were the characteristics of the clinical problem and the population with the clinical problem described? <i>Example Children aged 3 months to 18 years with steroid responsive nephrotic syndrome who have suffered one or more relapses</i> 	
<ul style="list-style-type: none"> • Was a clear case definition for establishing the presence of the clinical problem included? <i>Example The child, who becomes free of oedema and whose urine protein is $\leq 1+$ on dipstick or $< 4\text{mg}/\text{m}^2/\text{hr}$ for 3 consecutive days after receiving corticosteroid therapy.</i> 	
<ul style="list-style-type: none"> • Were the population groups to be excluded specified? <i>Example Children in their first episode of nephrotic syndrome, children with steroid resistant nephrotic syndrome, children with congenital nephrotic syndrome and children with other renal or systemic forms of nephrotic syndrome defined on renal biopsy, clinical features or serology</i> 	
<ul style="list-style-type: none"> • Were the appropriate population groups excluded? 	

Types of studies:

<ul style="list-style-type: none"> • Did the authors include randomised controlled trials? 	
<ul style="list-style-type: none"> • Did the authors include quasi-randomised trials? 	

Types of interventions and comparisons

<ul style="list-style-type: none"> • Were the study interventions described? 	
<ul style="list-style-type: none"> • Were the control interventions described? 	
<ul style="list-style-type: none"> • Were all relevant interventions for the clinical problem and question asked identified? <i>Example</i> <ul style="list-style-type: none"> - Non corticosteroid agent versus placebo - Non-corticosteroid agent versus prednisone used alone. - Two different non-corticosteroid agents - Different doses and durations of the same non-corticosteroid agent 	
<ul style="list-style-type: none"> • Were the interventions excluded described? 	
<ul style="list-style-type: none"> • Were the interventions excluded appropriate? 	

Types of outcomes:

<ul style="list-style-type: none"> • Were the outcome measures for benefits and harms of the intervention(s) clearly defined in nature and in timing? 	
<ul style="list-style-type: none"> • Were the outcome measures used important to the population with the clinical problem? 	
<ul style="list-style-type: none"> • Were all relevant outcomes (beneficial and harmful) included? <i>Example</i> <ul style="list-style-type: none"> - The prevention of relapse in steroid responsive nephrotic syndrome as measured by the numbers of children with and without relapse at 6 months, 12 months and 2 years - Mean relapse rates per patient per year - Serious adverse effects of therapy 	
<ul style="list-style-type: none"> • If specific outcomes have been included, did they conform with the question asked? 	

Search strategy

• Was the search strategy included?	
• Were the dates that each source was searched indicated?	
Were the following data sources searched?	
• Cochrane Controlled Trials Register (most recent)	
• MEDLINE (from 1966 – most recent)	
• EMBASE (from 1980 – most recent)	
• Reference lists of textbooks, reviews (including previous systematic reviews), and previous trials	
• Conference proceedings	
• Did the authors contact experts in the field?	
• Were the appropriate subject headings, key words and text words for the clinical problem and population used?	
• Was the Cochrane Collaboration search strategy to identify RCTs used?	
• Did the reviewers contact the Trials Search Coordinator?	
• Were studies in languages other than English included?	
• Did the reviewers identify and deal with duplicate publications of the same trial in the way that they said they would in the protocol?	
• If not, did they deal with duplicate publications in a way that would reduce bias?	

Assessment of quality

• Were the criteria used to assess study quality reported?	
Did the criteria used to assess study quality include:-	
• Allocation concealment	
• Blinding of participants	
• Blinding of investigators	
• Blinding of outcome assessment	
• Intention to treat analysis	
• Completeness of follow-up	
• Were these items assessed separately rather than 'combined' in a scoring system?	

Methods of the Review

Did at least two authors of the review:-	
• Perform the literature search?	
• Determine study eligibility?	
• Assess study quality?	
• Extract data?	
• Enter data in RevMan?	
• Did reviewers work independently?	
• Was there consensus and/or liaison with a third reviewer to resolve disagreement between the primary reviewers?	
• Were authors of primary studies contacted for clarification of unclear data or to obtain missing information?	
• If so, was this information provided to the reviewers?	
• Did the reviewers attempt to analyse for possible publication bias using funnel plots or other methods?	
• If not, did the reviewers state why this could not be done?	

Statistical analysis

• Were the results of primary studies reported with 95% CI using relative risk (RR) for dichotomous outcomes and weighted mean difference (WMD) for continuous outcomes?	
• Were the RR and WMD summary statistics calculated using a random effects model? <i>Example: Statistical analysis was performed using RevMan. For dichotomous outcomes (relapse or no relapse) results were expressed as RR with 95% CI. Data was pooled using the random effects model. Where continuous scales of measurement were used to assess the effects of treatment (number of relapses/year), the WMD was used, or the standardised mean difference if different scales were used.</i>	
• Did the reviewers test for heterogeneity as pre-specified in the protocol? <i>Example: Heterogeneity was analysed using the Cochran Q test on N-1 degrees of freedom, with an α of 0.1 used for statistical significance</i>	
• Were plausible explanations for variations in treatment effect explored using subgroup analysis based on study quality, population and interventions? <i>Example: Sub-group analysis was planned based on study quality, patient-type (age, presence of abnormal radiological findings) and intervention (type of antibiotic used) as we postulated that the relative treatment effect could vary these factors.</i>	
• Did the reviewers attempt to determine the applicability of the results to individual patients? <i>Example: Calculation of absolute risk reductions with therapy in relation to different baseline risk of the event with no treatment or a different therapy.</i>	

Description of studies, Characteristics of included studies/Characteristics of excluded studies

• Were the important details of the included studies summarised in the text of the review?	
• Were the important details of study design, participants, interventions and definitions of outcomes included in the table “Characteristics of included studies”?	
• Were the reasons for excluding any studies clearly reported in the text and in the table “Characteristics of excluded studies”?	
• If studies were excluded, are the reasons for exclusion consistent with the inclusion/exclusion criteria in the section on “Criteria for considering studies for the review”?	
• Are you aware of any other studies that should have been included?	

Methodological quality of the included studies

• Was there a table listing the quality items for each included study?	
• Was a short summary of the quality assessment of the included studies included in the text?	

Results/comparison table

Key results

• Are the key results of the review provided in the text?	
• Did the key results address the objectives of the review?	

Meta analysis

• If results were pooled, was this appropriate?	
• Did between study heterogeneity exist?	
• If yes, was it appropriately explained?	

Outcomes

• Were all outcomes described in the protocol included in the results?	
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Subgroup analysis

• Were planned subgroup analyses included? <i>Example: Sub-group analysis showed that there was no difference in relative treatment effects (recurrence of urinary tract infections) between sulphonamide containing antibiotics (RR 1.20; 95% CI 0.47,3.10) and non-sulphonamide based antibiotics (RR 1.77; 95% CI 0.96,3.29).</i>	
• If planned subgroup analyses were not included, did the reviewers explain the reasons for this?	
• Were subgroup analyses that were not specified in the protocol performed (post hoc analysis)?	
• If so, were these analyses described as being post hoc?	

Discussion

Key results

• Were the principal results (both benefits and harms) summarised?	
• Was the potential clinical importance of these results discussed?	
• Are the conclusions of the study consistent with the results?	

Consistency of results

• Was the consistency/inconsistency of trial results discussed?	
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Limitations of the study

Were the implications of the following methodological problems discussed:

• Publication bias	
• Trial quality	
• Impression of results (sample size, CI)	
• Uncertainty of harms	

Comparison with other data

• Were the review findings discussed in relation to relevant evidence from other studies or reviews?	
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Reviewers' conclusions

Implications for practice

• Did the reviewers attempt to demonstrate the applicability of the results of benefits and risks to patients of low medium and high risk of adverse outcomes? (see table below)	
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Implications for research

• Did the reviewers determine which questions had been answered by the review?	
• If so, do you agree?	
• Did the reviewers determine which questions require further trials?	
• If so, do you agree?	
• Did the reviewers suggest new studies based on the reviewed research?	
• If so, do you believe that these studies are appropriate?	
• Can you suggest further studies that should be done?	

Table demonstrating applicability of results to patients at different risks of disease where trial intervention is more effective than control

Comparison of effects of using cyclophosphamide (CPA) in three patient groups with steroid responsive nephrotic syndrome at different risks of relapse over 12 months when treated with prednisone alone (assumes the same relative treatment effect with relative risk for relapse after cyclophosphamide being 0.4 ie 60% reduction in risk)

Patient subgroups	Risk of relapse without CPA	Risk of relapse with CPA	No. patients without relapse for 100 treated	No. with severe infection for 100 treated	No. with cystitis for 100 treated
Low risk	10%	4%	6	1	4
Medium risk	50%	20%	30	1	4
High risk	100%	40%	60	1	4

Comments

Abstract

Background

Objectives

Selection criteria

Search strategy

Assessment of quality

Methods of review

Statistical analysis

*Description of studies /Characteristics of included studies
/characteristics of excluded studies*

Methodological quality of included studies

Results/ comparison table

Discussion

Reviewers' conclusion

General comments (style and readability)

Name _____

Date: _____