A high degree of variability exists in how “safety and efficacy” is defined and reported in growing rod surgery for early-onset scoliosis: A systematic review

Pooria Hosseini, Areian Eghbali, Jeff Pawelek, Karen Heskett, Gregory M. Mundis, Behrooz A. Akbarnia

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Introduction

- Several publications have reported the safety and efficacy of traditional growing rods (TGR) and magnetically controlled growing rods (MCGR) using **various parameters**.

- **Radiographic parameters** are most commonly used to measure efficacy, while **incidence and type of complications** are used to assess safety.

- A systematic review of peer-reviewed articles was performed to identify whether a consensus exists in how safety and efficacy parameters are reported in EOS patients treated with TGR and MCGR.

Methods

Four databases (PubMed, Embase, Web of Science, and CINAHL) were searched on November 10, 2016 to identify all qualified peer-reviewed articles using specific keyword searches.

Keywords:

adverse effects, complications, risk, treatment outcome, safety, efficacy, effectiveness, magnetically controlled growing rod, MCGR, traditional growing rod, conventional growing rod, TGR, CGR, growing spinal implant, growing rod implant, growing rod surgery, magnetic expansion control rod, magnetic driven growing rod, MAGEC, and early onset scoliosis.

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Methods

Inclusion criteria

1) Studies published in peer-reviewed journals with full-text available in English with any study design
2) Studies that reported safety and efficacy of TGR or MCGR.

Minimum requirements for safety and efficacy

Efficacy- Any report that at least contained one of the following radiographic measurements: major coronal curve size, major sagittal curve size (maximum kyphosis), T1-T12 height, or T1-S1 height.

Safety- Safety was defined as any reported information on complications.

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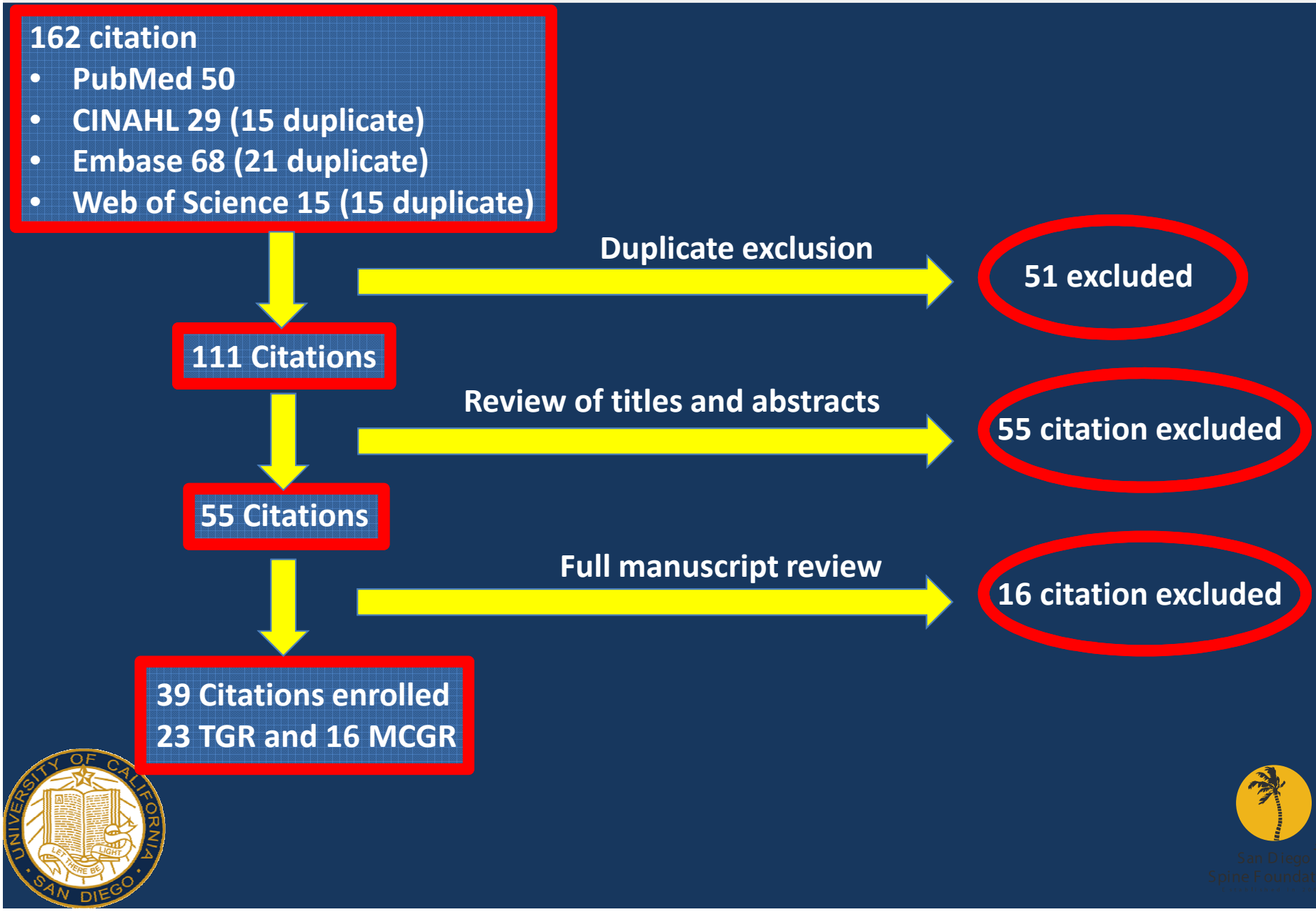
Results

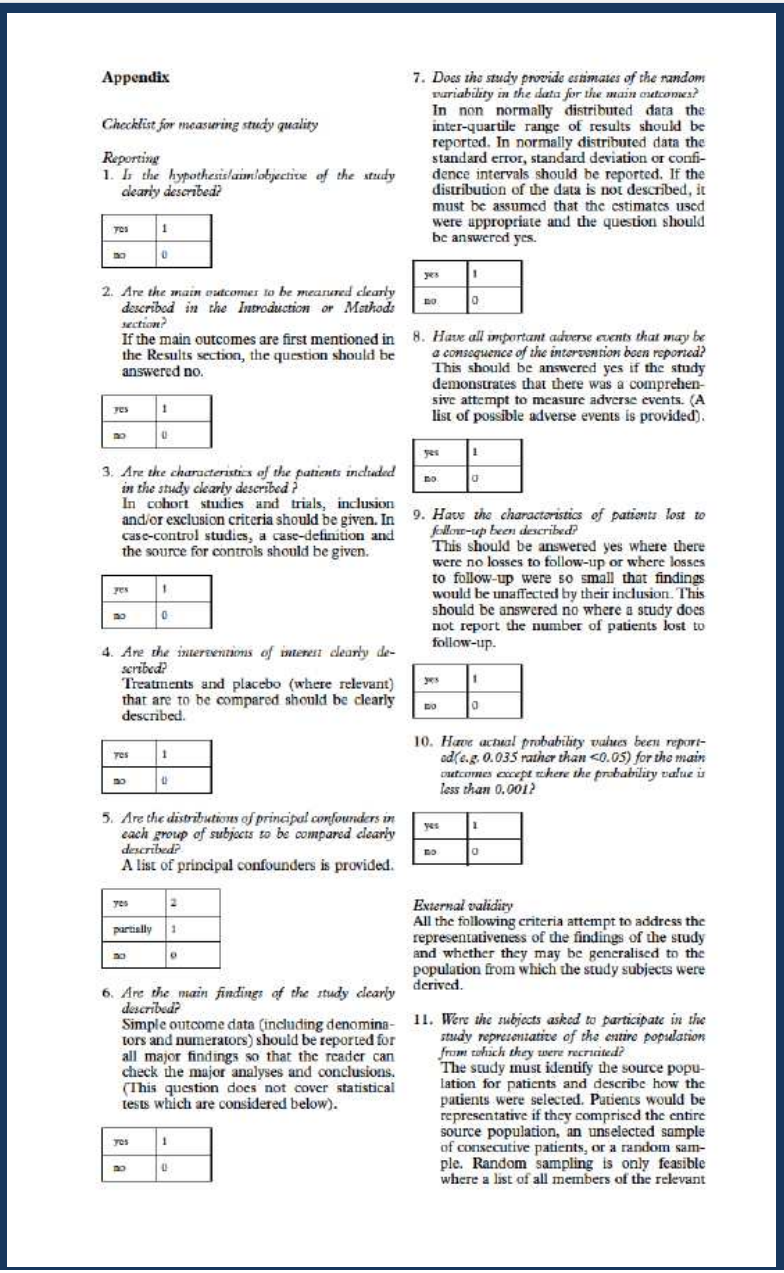

162 citation
• PubMed 50
• CINAHL 29 (15 duplicate)
• Embase 68 (21 duplicate)
• Web of Science 15 (15 duplicate)
Duplicate exclusion
51 excluded
111 Citations
Review of titles and abstracts
55 citation excluded
55 Citations
Full manuscript review
16 citation excluded
39 Citations enrolled
23 TGR and 16 MCGR

Downs and Black scoring

J. Epidemiol Community Health, 1998

- **Evaluates level 3 -5 studies**
- 27 questions
- Three domains:
  - Reporting
  - Internal validity
  - External validity

} Overall score



Appendix

Checklist for measuring study quality

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

yes	1
no	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
If the main outcomes are first mentioned in the Results section, the question should be answered no.

yes	1
no	0

3. *Are the characteristics of the patients included in the study clearly described?*
In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. *Are the interventions of interest clearly described?*
Treatments and placebo (where relevant) that are to be compared should be clearly described.

yes	1
no	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*
A list of principal confounders is provided.

yes	2
partially	1
no	0

6. *Are the main findings of the study clearly described?*
Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

yes	1
no	0

9. *Have the characteristics of patients lost to follow-up been described?*
This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

yes	1
no	0

External validity
All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

Quality of papers

The overall Downs and Black score was 63.9 for TGR papers vs. 64.0 for MCGR papers (p>0.05)

Study title	Reporting (%)	External validity (%)	Internal validity (%)	Overall quality score (%)	TGR overall score
TGR (Reference)					63.9 ± 6.9 %
Thompson 2007 (21)	87.5	33	22	50	
Akbarnia 2008 (3)	100	100	33	70	
Sponseller 2009 (19)	87.5	67	44	65	
Bess 2010 (6)	75	100	44	65	
Farooq 2010 (9)	100	67	33	65	
Sankar 2010 (16)	75	67	33	55	
Sankar 2011 (17)	87.5	100	55	75	
Chandran 2011 (7)	75	67	33	55	
Elsebai 2011 (8)	87.5	67	33	60	
McElroy 2011 (14)	100	100	33	70	
Yang 2011 (24)	87.5	100	33	65	
Zhao 2012 (25)	100	67	44	70	
Schroerlucke 2012 (18)	75	100	55	70	
McElroy 2012 (15)	87.5	67	33	60	
Caniklioglu 2012 (12)	62.5	67	44	55	
Greggi 2012 (10)	50	67	44	55	
Wang 2012 (22)	87.5	67	44	65	
Watanabe 2013 (23)	100	67	44	70	
Akbarnia 2014 (4)	87.5	100	33	65	
Akgül 2014 (5)	100	67	44	70	
Kamaci 2014 (11)	75	67	33	55	
Sun 2015 (20)	100	67	44	70	
Li 2016 (13)	100	67	44	70	
MCGR (Reference)					MCGR overall score
Cheung 2012 (27)	87.5	67	33	60	64.0 ± 6.3 %
Akbarnia 2013 (26)	75	67	44	60	
Dannawi 2013 (30)	75	67	44	60	
Akbarnia 2014 (4)	87.5	100	33	65	
Hicky 2014 (31)	75	67	44	60	
Yoon 2014 (35)	100	67	44	70	
Cheung 2014 (28)	62.5	67	33	50	
Jones 2015 (33)	75	67	44	60	
La Rosa 2015 (37)	75	67	44	60	
Rolton 2015 (40)	75	67	44	60	
Choi 2016 (29)	87.5	100	44	70	
Heydar 2016 (36)	87.5	67	44	65	
Hosseini 2016 (32)	100	100	44	75	
Keskinen 2016 (34)	100	100	33	70	
Ridderbusch 2016 (38)	100	67	44	70	
Thompson 2016 (39)	100	67	44	70	

Overview of included studies

Parameter	TGR	MCGR	P value
Date of publication	2005-2016	2012-2016	
Country of publication	USA (52%)	UK (37.5%)	
Randomization	0%	0%	
Study design	Retrospective (96%)	Retrospective (69%)	P < 0.05
Control group	Yes (17.3%)	Yes (12.5%)	P < 0.05
Sample size	45 (5-327)	15 (1-34)	P < 0.05
Mean index age	6.5 (5.1-8.7)	8.0 (4.5-12)	P < 0.05
Length of follow up	4.6 (2.3-7.2)	1.8 (0.2-2.5)	P < 0.05

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Efficacy measures

Efficacy measures were not consistently reported among the publications. The only consistently reported efficacy parameter in majority (>90%) of papers was coronal curve magnitude.

Parameter	TGR	MCGR	P value
Coronal curve magnitude	91%	94%	P > 0.05
Kyphosis	43%	50%	P > 0.05
T1-T12 height	13%	56%	P < 0.05
T1-S1 height	43%	69%	P > 0.05

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Safety measures

- Although some implant-related complications (IRCs), neurological complications, wound complications, and medical complications were reported, such reporting was unmethodical and at the discretion of the respective writers.

- **Therefore, there is a clear lack of a standard classification system.**

- **Note:** Proposed Smith et al complication classification does not cover devices like MCGR or Shilla

Less reported data for safety and efficacy

Miscellaneous data	Articles reported
Single rod versus dual rod	8/39 (20%)
Pulmonary function tests and space available for lungs (SAL)	7/39 (18%)
Final fusion results	6/39 (15%)
Primary versus conversion cases	5/39 (13%)
Instrumentation levels	4/39 (10%)
Outcome measures (VAS, ODI, SF-30)	2/39 (5%)
Foundation type	2/39 (5%)
Different levels of coronal and sagittal curve	2/39 (5%)
Length of hospital Stay	2/39 (5%)
Apical vertebral rotation (AVR)	1/39 (2.5%)
Rib vertebral angle (RVA)	1/39 (2.5%)
Coronal balance (C7PL-CSVL)	1/39 (2.5%)
Sagittal balance	1/39 (2.5%)

Conclusion

- **Major curve size** was the only consistent parameter to report efficacy in peer-reviewed TGR and MCGR publications.

- **Complications** were not consistently reported, thus assessing safety of either treatment was infeasible.

Future recommendations

- **Safety -** Establishing a comprehensive complication classification system **(URGENT NEED)**

- **Efficacy-** In addition to common radiographic parameters consideration of less reported parameters (sagittal balance, HRQoL, AVR, PFTs, …) might help to raise the expectation bars in terms of efficacy.

Thank you

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