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Original Research Article

Assessment of quality of reporting of *Helicobacter pylori* related randomized controlled trials: a focus on highly ranked gastroenterology journals

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ABSTRACT

Background: Randomized controlled trials are often considered as the gold standard for measuring the effectiveness of an intervention. However, inappropriate or poor reporting in randomized controlled trials can produce biased estimates of treatment effects. Clinical trials that do not use the CONSORT statement for reporting their findings will have limited value to the clinicians and researchers due to the risk of bias in their results. This review aims to assess the quality of reporting of randomized controlled trials in *Helicobacter pylori* associated infections by using the CONSORT 2010 checklist.
Methods: All issues of 20 highly ranked gastroenterology journals published from Jan 2011 up to November 2017 were searched. Searches were conducted in November 2017. Randomized controlled trials reporting on *Helicobacter pylori* associated infections were included in the review.
Results: 21 randomized controlled trials published in gastroenterology journals were included in the study. All included studies adequately reported (100%) on items including description of interventions, outcomes assessed, total number of participants analysed, baseline characteristics and results of outcome assessed. However, items including blinding and mechanism of allocation concealment were reported in only 12 randomized controlled trials (50%). The maximum and minimum scores and percentage of compliance of included randomised controlled trials were 24 (100%) and 15 (62.5%) respectively.
Conclusions: The finding of this review suggests that the overall quality of reporting in the included randomized controlled trials was adequate. However, items including trial design, trial registration and protocol and sample size calculations should be reported adequately in the future randomized controlled trials to improve the quality of reporting and replicability of clinical trials.

Keywords: Randomized controlled trials, *Helicobacter pylori*, CONSORT

INTRODUCTION

Helicobacter pylori (*H. pylori*) has been estimated to affect more than half of the world's population.[1] It is a major cause of majority of gastroduodenal diseases.[2] The prevalence of *H. pylori* associated infections is extremely variable and mostly depends on various factors including geographical location, socioeconomic factors, and personal hygiene.[3]

Treatment of *H. pylori* associated infections involves the use of antibiotics. However, such treatments are prone to failure for a number of reasons. One of the reasons for failure is the potential resistance of *H. pylori* towards one

of the antibiotics used in the treatment regimens.4 Therefore, randomized controlled trials (RCTs) are needed to make comparisons between these regimens and achieve a maximum eradication rate for *H. pylori* especially in high resistance areas.

Randomized controlled trials (RCTs) are a type of scientific experiments that are often considered as the gold standard for measuring the effectiveness of an intervention.[5] However, inappropriate or poor reporting of RCTs can produce biased estimates of treatment effects.[6-8]

The consolidated standards of reporting trials (CONSORT) statement is a reporting guideline that was developed to help the researchers in improving the reporting of RCTs. It was first published in 1996 and was further updated in 2001 and 2010. It consists of a 25-item checklist and was the first reporting guideline to be widely published and adopted.[9-11]

Evidence suggests that the methodological quality of reporting of RCTs published in major hepato-gastroenterology journals improved after the first revision of CONSORT in 2001.[12] However, to the best of authors' knowledge, no review has been done that has assessed the quality of reporting of RCTs published in gastroenterology journals since the last revision of CONSORT in 2010. This review therefore, aims to assess the quality of reporting of *H. pylori* specific randomized controlled trials published in highly ranked gastroenterology journals by using the CONSORT 2010 checklist.

METHODS

Data sources

All issues of 20 gastroenterology journals published from Jan 2011 up to November 2017 were searched. Since the CONSORT statement was last updated in the year 2010, the authors limited the search to six years (2011-2017). The included journals were top ranked according to Thomson Reuter journal citation report 2014 (see Table 1 for the description of included journals). All these journals endorse the CONSORT (Consolidated Standards of Reporting Trials) as stated in their author guidelines.[13] Searches were conducted in November 2017.

Study selection

All RCTs that included *H. pylori* infection in the title and abstract were included in the study and were retrieved as a full paper through hand flipping. Authors excluded non-inferiority RCTs, phase I or phase II studies, community-based studies, observational studies, meta-analysis, diagnostic or screening tests, follow-up studies of previously reported RCTs, editorials and letters to editor.

Data extraction and analysis

Descriptive data were analysed by SPSS software (version 16, IBM SPSS). All included studies were evaluated against the CONSORT 2010 checklist to evaluate the quality of reporting in RCTs by evaluating the internal and external validity of all sections of RCTs, including introduction, methods, results and conclusions.[10] The CONSORT 2010 checklist consists of 25 items. However, authors only used a revised 24 items checklist after excluding one item (see appendix 1 for CONSORT checklist). Items that were included in the checklist were critical to the strength of the RCTs based on the current evidence and exclusion of any of these items would have been associated with a greater level of bias.[14]

Each item of CONSORT checklist was assessed by indicating "Yes" if it was reported in the study and "No" if it was either not reported or was unclear. For items that were not applicable to the study were reported as "Not applicable" e.g. for an open label study, blinding was reported as not applicable. An individual score and percentage was calculated for all the 24 items in the checklist.[15] The possible score range was between 0 and 24.

Data extraction was carried out independently on each article by three authors (MM, AM and JS). Any differences were resolved through discussion and further resolved through the involvement of a fourth reviewer (ME).

RESULTS

Initial searches in the included gastroenterology journals identified 89 studies. Of these 89, 68 were excluded due to ineligibility (52 Not RCTs, 2 Inferior studies, 1 Abstract, and 13 Editorials). Finally, 21 studies were included in the review.[16-36]

Study characteristics

Of the 21 included studies, eight were published in journal of gastroenterology, six in alimentary pharmacology and therapeutics, three in GUT, three in the American journal of gastroenterology, followed by one in the Clinical Gastroenterology and Hepatology (see Table 1 for description of included RCTs). 12 of the included RCTs were conducted in multicentre and seven used a single centre. The two remaining studies did not report their setting. Seven of the included studies were conducted in Japan, four each in China and South Korea, two in Hong Kong followed by one each in USA, Israel, Spain and United Kingdom (see Table 2 for characteristics of included RCTs).

Reporting of CONSORT items in the included studies

All included studies adequately reported (100%) on items including description of interventions, outcomes

assessed, total number of participants analysed, baseline characteristics and results of outcome assessed. However, items including blinding and mechanism of allocation concealment was reported in only 12 randomized controlled trials (50%). Details of trial design were provided in 11 (45.8%) studies. 14 (58.3%) studies reported how sample size was calculated. Statistical methods used for comparison of outcomes between the treatment groups were reported in 23 (95.8%) studies while 10 (41.6%) studies provided the details of additional analysis including subgroup analysis in their study (see Table 3 for the assessment of compliance of included RCTs with the CONSORT checklist).

Table 1: Description of journals included in the review.

Journal name	Impact factor*	Number of articles identified (n=89)	Number of included articles (n=21)
Gastroenterology	16.716	29	0
GUT	14.660	22	3
Nature reviews gastroenterology and hepatology	13.678	0	0
Hepatology	13.246	0	0
Journal of hepatology	12.486	0	0
American journal of gastroenterology	10.755	13	3
Clinical gastroenterology and hepatology	7.398	10	1
Liver Cancer	7.854	0	0
Alimentary pharmacology & therapeutics	7.286	6	6
Gastrointestinal endoscopy	6.501	0	0
Endoscopy	6.107	0	0
Journal of crohns & colitis	5.813	0	0
Seminars in liver disease journal	5.5	0	0
Gastric cancer	5.454	0	0
Inflammatory bowel diseases	4.525	0	0
Journal of gastroenterology	4.493	9	8
Journal of viral hepatitis	4.122	0	0
Liver international	4.116	0	0
Clinical and translational gastroenterology	3.923	0	0
Liver transplantation	3.910	0	0

*The impact factor according to web of Science-ISI Thomson Reuters 2014.

Table 2: Characteristics of included RCTs.

Characteristic	n= 21 (%)
Number of authors	
6	1 (4.7)
7	1 (4.7)
8	3 (14.3)
9	2 (9.5)
10	1 (4.7)
11	2 (9.5)
13	2 (9.5)
14	5 (23.8)
15	1 (4.7)
5	1 (4.7)
23	1 (4.7)
29	1 (4.7)
Center	
Single	7 (33.33)
Multicenter	12 (57.14)
Not reported	2 (9.5)

Characteristic	n= 21 (%)
Year of publication	
2011	6 (28.5)
2012	5 (23.8)
2013	5 (23.8)
2014	5 (23.8)
Type of intervention	
Active control	15 (71.4)
Placebo control	6 (18.6)
Type of funding	
Government	5 (23.8)
Academic & research centers	4 (19)
Not reported	6 (28.5)
Pharmaceutical companies & others	6 (28.5)
Study design	
Crossover	1 (4.7)
Parallel	19 (90.5)
Factorial 2x2	1 (4.7)
Randomization	
Block	11 (52.3)
Stratified block	1 (4.7)
Computer generated or 3rd party	6 (28.5)
Unknown	3 (14.3)
Blinding	
Open label	12 ((57.14)
Single-blind	1 (4.7)
Double-blind	7 (33.33)
Double-dummy	1 (4.7)
Impact factor	
4.493	8 (38.1)
7.286	6 (28.5)
7.896	1 (4.7)
10.755	3 (14.3)
14.660	3 (14.3)
Country of study	
Hong Kong	2 (9.5)
Spain	1 (4.7)
China	4 (19)
South Korea	4 (19)
USA	1 (4.7)
UK	1 (4.7)
Israel	1 (4.7)
Japan	7 (33.33)

Table 3: Assessment of compliance of included studies with the CONSORT checklist.

Section	Item No	Assessment of included RCTs (n=21) (%)
Title and abstract		
	1	18 (75)
	2	21 (87.5)
Methods		
Trial design	3	11 (45.8)
Participants	4	18 (75)
	5	13 (54.1)
Interventions	6	24 (100)
Outcomes	7	24 (100)
Sample size	8	14 (58.3)

Section	Item No	Assessment of included RCTs (n=21) (%)
Randomization		
Sequence generation	9	12 (50)
	10	11 (45.8)
Allocation concealment mechanism	11	12 (50)
Blinding	12	12 (50)
Statistical methods	13	23 (95.8)
	14	10 (41.6)
Results		
Participant flow (a diagram is strongly recommended)	15	19 (79.1)
	16	17 (70.8)
Recruitment	17	19 (79.1)
Baseline data	18	24 (100)
Numbers analyzed	19	24 (100)
Outcomes and estimation	20	24 (100)
Discussion		
Limitations	21	18 (75)
Other information		
Registration	22	11 (45.8)
Protocol	23	4 (16.6)
Funding	24	18 (75)

Table 4: Scores and percentage of compliance of included studies with CONSORT checklist.

No.	Included RCTs	Journal	Score	Percentage of compliance (%)
1	Liu et al.	GUT	24	100
2	McNicholl et al.	GUT	24	100
3	Wong et al.	GUT	18	75
4	Park et al.	American Journal of Gastroenterology	18	75
5	Zhou et al.	American Journal of Gastroenterology	20	83.33
6	Basu et al.	American Journal of Gastroenterology	15	62.50
7	Liang et al.	Clinical Gastroenterology and Hepatology	19	79.17
8	Cho et al.	Alimentary Pharmacology and Therapeutics	18	75
9	Huang et al.	Alimentary Pharmacology and Therapeutics	17	70.83
10	Lane et al.	Alimentary Pharmacology and Therapeutics	22	91.66
11	Kim et al.	Alimentary Pharmacology and Therapeutics	21	87.5
12	Park et al.	Alimentary Pharmacology and Therapeutics	18	75
13	Nseir et al.	Alimentary Pharmacology and Therapeutics	18	75
14	Murakami et al.	Journal of Gastroenterology	14	58.33
15	Sugano et al.	Journal of Gastroenterology	19	79.17
16	Sanuki et al.	Journal of Gastroenterology	17	70.83
17	Sugano et al.	Journal of Gastroenterology	16	66.66
18	Fujiwara et al.	Journal of Gastroenterology	18	75
19	Tominaga et al.	Journal of Gastroenterology	21	87.5
20	Tan et al.	Journal of Gastroenterology	17	70.83
21	Nagahara et al.	Journal of Gastroenterology	16	66.66

The maximum scores and percentage of compliance of included RCTs were 24 and 100% respectively while the minimum scores and percentage of compliance were 15 and 62.50% respectively (see table 4 for scores and percentage of compliance of included RCTs with CONSORT checklist).

DISCUSSION

This is the first review that has assessed the quality of reporting of *H. pylori* related randomized controlled trials by using a 2010 CONSORT checklist. In general the overall quality of reporting of included RCTs was adequate. All included studies adequately reported on

items including description of interventions, outcomes assessed and baseline characteristics. However, items including trial design, trial registration and protocol were not reported adequately in the included studies.

This review reported a similar percentage of studies that reported the mechanism of allocation concealment (50%) as reported in previous studies.[37,38] Similarly, compliance of the studies included in this review with CONSORT items such as the reporting of flow diagram was higher (79.1%) as compared to earlier studies.[39,40] These findings suggest an increase in the compliance of RCTs with the CONSORT items in particular, reporting of flow diagram. However, fewer studies (45.8%) included in this review reported their trial design as compared to 100% of the studies included in another study.[15]

Only 12 (50%) of the included studies reported how sample size was calculated. Sample size calculations are critical to clinical research and ensure that sufficient number of participants required for determining the safety and efficacy of the study intervention have been enrolled in the study. Failure to report sample size calculations by authors raises the concern of the validity of their study findings and should therefore be reported adequately in the study.

Clinical trials that do not use the CONSORT statement for reporting their findings will have limited value to the clinicians and researchers due to the risk of bias in results. Authors of this review would therefore, recommend all gastroenterology journals to endorse the CONSORT statement on their websites to improve the reporting of RCTs. Authors should be required to submit the CONSORT checklist when submitting new manuscripts to ensure more accurate and robust reporting of RCTs. Indeed, reviewers and Editorial office should ensure that the CONSORT checklist is fulfilled.

This review has some limitations. Although rigorous and systematic, the reviewers did not include unindexed and unpublished research. Furthermore, the number of studies that were included in this review was low. The findings of this review are therefore only applicable to the included journals and cannot be extrapolated to other journals that may affect the generalizability of the findings of this review.

CONCLUSION

The findings of this review suggest that the overall quality of reporting of included RCTs was adequate. However, items including trial design, trial registration and protocol and sample size calculations should be reported adequately in the future RCTs to improve the quality of reporting.

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APPENDIX 1

24 item CONSORT checklist.

Section	Item no	Checklist item
Title and abstract		
	1	Identification as a randomised trial in the title
	2	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Methods		
Trial design	3	Description of trial design (such as parallel, factorial) including allocation ratio
Participants	4	Eligibility criteria for participants
	5	Settings and locations where the data were collected
Interventions	6	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	7	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Sample size	8	How sample size was determined
Randomisation		
Sequence generation	9	Method used to generate the random allocation sequence
	10	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	11	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Blinding	12	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
Statistical methods	13	Statistical methods used to compare groups for primary and secondary outcomes
	14	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow (a diagram is strongly recommended)	15	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	16	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	17	Dates defining the periods of recruitment and follow-up
Baseline data	18	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	19	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	20	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
Discussion		
Limitations	21	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Other information		
Registration	22	Registration number and name of trial registry
Protocol	23	Where the full trial protocol can be accessed, if available
Funding	24	Sources of funding and other support (such as supply of drugs), role of funders

*The descriptors describing each CONSORT item used are taken directly from the "CONSORT 2010 Statement: updated guidelines for reporting.