Assessment of quality of reporting of Helicobacter pylori related randomized controlled trials
Elrggal, Mahmood E.; Al-muwallad, Morooj; Al-otaibi, Areej; Alsiddik, Jomanah; Shahbar, Alaa; Cheema, Ejaz

DOI:
10.18203/2349-3259.ijct20180127

License:
Creative Commons: Attribution-NonCommercial (CC BY-NC)

Citation for published version (Harvard):
Elrggal, ME, Al-muwallad, M, Al-otaibi, A, Alsiddik, J, Shahbar, A & Cheema, E 2018, 'Assessment of quality of reporting of Helicobacter pylori related randomized controlled trials: a focus on highly ranked gastroenterology journals', International Journal of Clinical Trials, vol. 5, no. 1, pp. 21-29. https://doi.org/10.18203/2349-3259.ijct20180127

Link to publication on Research at Birmingham portal

Publisher Rights Statement:
Checked for eligibility: 12/11/2018

General rights
Unless a licence is specified above, all rights (including copyright and moral rights) in this document are retained by the authors and/or the copyright holders. The express permission of the copyright holder must be obtained for any use of this material other than for purposes permitted by law.

• Users may freely distribute the URL that is used to identify this publication.
• Users may download and/or print one copy of the publication from the University of Birmingham research portal for the purpose of private study or non-commercial research.
• Users may use extracts from the document in line with the concept of 'fair dealing' under the Copyright, Designs and Patents Act 1988 (?).
• Users may not further distribute the material nor use it for the purposes of commercial gain.

Where a licence is displayed above, please note the terms and conditions of the licence govern your use of this document.
When citing, please reference the published version.

Take down policy
While the University of Birmingham exercises care and attention in making items available there are rare occasions when an item has been uploaded in error or has been deemed to be commercially or otherwise sensitive.

If you believe that this is the case for this document, please contact UBIRA@lists.bham.ac.uk providing details and we will remove access to the work immediately and investigate.
Original Research Article

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

Mahmood E. Elraggal, Morooj Al-Muwallad, Areej Al-Otaibi, Jomanah Alsiddik, Alaa Shahbar, Ejaz Cheema*

Department of Clinical Pharmacy, College of Pharmacy, Umm-ul-Qura University, Makkah, Saudi Arabia

Received: 02 December 2017  
Accepted: 05 January 2018

*Correspondence:* Dr. Ejaz Cheema,  
E-mail: E.cheema.1@warwick.ac.uk

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

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. It is a major cause of majority of gastroduodenal diseases. The prevalence of *H. pylori* associated infections is extremely variable and mostly depends on various factors including geographical location, socioeconomic factors, and personal hygiene.

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.1 However, inappropriate or poor reporting of RCTs can produce biased estimates of treatment effects.5-8

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 hepatogastroenterology 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.
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. 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. 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.

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.

ACKNOWLEDGEMENTS

The authors would like to thank Dr. Muhammad Abdul Hadi for his support in designing the research question.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

REFERENCES

1. Dunn BE, Cohen H, Blaser MJ. Helicobacter pylori. Clin Microbiol Rev 1997;10:720-41.
2. Megraud F. H. pylori antibiotic resistance: prevalence, importance, and advances in testing. Gut. 2004;53:1374-84.
3. Blaser MJ. Epidemiology and pathophysiology of Campylobacter pylori infections. Rev Infect Dis 1990; 12:99-106.
4. Megraud F. Epidemiology and mechanism of antibiotic resistance in Helicobacter pylori. Gastroenterology 1998;115:1278-82.
5. Conato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000;342:1887-92.
6. Juni P, Altman DG, Egger M. Systematic reviews in health care: Assessing the quality of controlled clinical trials. BMJ. 2001;323:42-6.
7. Moher D, Schulz KF, Altman; CONSORT Group (Consolidated Standards of Reporting Trials). The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Ann Intern Med. 2001;134:657-62.
8. The EQUATOR Network. EQUATOR: enhancing the quality and transparency of health research, 2012. Available at: http://www.equator-network.org. Accessed on 11 November 2017.
9. Schulz KF, Altman DG, Moher D. Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. PLoS Med. 2010;7(3):e1000251.
10. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche P, Devereaux PJ. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869.
11. The CONSORT Group. The CONSORT statement. Available at http://www.consort-statement.org. Accessed on 6 November 2017.
12. Wang JL, Sun TT, Lin YW, Lu R, Fang JU. Methodological reporting of randomized controlled trials in major hepato-gastroenterology journals in 2008 and 1998: a comparative study. BMC Med Res Methodol. 2011;11:110.
13. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman G, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5:e20.
14. Nojomi M, Ramezani M, Ghafari-Anvar A. Quality of reports on randomized controlled trials published in Iranian journals: application of the new version of
15. Wang P, Xu Q, Sun Q, Fan FF, Guo XR, Guo F. Assessment of the reporting quality of randomized controlled trials on the treatment of diabetes mellitus with traditional Chinese medicine: a systematic review. PLoS One 2013;8:e70586.

16. Liu KS, Hung IF, Seto WK, Tong T, Hsu AS, Lam FY, et al. Ten day sequential versus 10 day modified bismuth quadruple therapy as empirical first line and second line treatment for Helicobacter pylori in Chinese patients: an open label, randomised, crossover trial. Gut 2014;63(9):1410-5.

17. McNicholl AG, Marin AC, Molina-Infante J, Castro M, Barrio J, Ducons J, et al. Randomised clinical trial comparing sequential and concomitant therapies for Helicobacter pylori eradication in routine clinical practice. Gut. 2014;63(2):244-9.

18. Wong BC, Zhang L, Ma JL, Pan KF, Li JY, Shen L, et al. Effects of selective COX-2 inhibitor and Helicobacter pylori eradication on precancerous gastric lesions. Gut. 2012;61(6):812-8.

19. Park CS, Lee SM, Park CH, Koh HR, Jun CH, Park SY, et al. Pre-treatment antimicrobial susceptibility-guided vs. clarithromycin-based triple therapy for Helicobacter pylori eradication in a region with high rates of multiple drug resistance. Am J Gastroenterol. 2014;109(10):1595-602.

20. Zhou L, Zhang J, Chen M, Hou X, Li Z, Song Z, et al. A comparative study of sequential therapy and standard triple therapy for Helicobacter pylori infection: a randomized multicenter trial. Am J Gastroenterol. 2014;109(4):535-41.

21. Basu PP, Rayapudi K, Pacana T, Shah NJ, Krishnaswamy N, Flynn M. A randomized study comparing levofloxacin, omeprazole, nitazoxamide, and doxycycline versus triple therapy for the eradication of Helicobacter pylori. Am J Gastroenterol. 2011;106:1970-5.

22. Liang X, Xu X, Zheng Q, Zhang W, Sun Q, Liu W, et al. Efficacy of bismuth-containing quadruple therapies for clarithromycin-, metronidazole-, and fluoroquinolone-resistant Helicobacter pylori infections in a prospective study. Clin Gastroenterol Hepatol. 2013;11(7):802-7.

23. Cho SJ, Choi IJ, Kook MC, Yoon H, Park S, Kim C, et al. Randomised clinical trial: the effects of Helicobacter pylori eradication on glandular atrophy and intestinal metaplasia after subtotal gastrectomy for gastric cancer. Aliment Pharmacol Ther. 2013;38:477-89.

24. Huang J, Zhou L, Geng L, Yang M, Xu XW, Ding ZL, et al. Randomised controlled trial: sequential vs. standard triple therapy for Helicobacter pylori infection in Chinese children—a multicentre, open-labelled study. Aliment Pharmacol Ther. 2013;38:1230-5.

25. Lane JA, Murray LJ, Harvey IM, Donovan JL, Nair P, Harvey RF. Randomised clinical trial: Helicobacter pylori eradication is associated with a significantly increased body mass index in a placebo-controlled study. Alimentary Pharmacol Therap 2011;33:922-9.

26. Kim YS, Kim SJ, Yoon JH, Suk KT, Kim JB, Kim DJ, et al. Randomised clinical trial: the efficacy of a 10-day sequential therapy vs. a 14-day standard proton pump inhibitor-based triple therapy for Helicobacter pylori in Korea. Alimentary Pharmacol Therap. 2011;34:1098-105.

27. Park HG, Jung MK, Jung JT, Kwon JG, Kim EY, et al. Randomised clinical trial: comparative study of 10-day sequential therapy with 7-day standard triple therapy for Helicobacter pylori infection in naive patients. Alimentary Pharmacol Therap. 2012;35:56-65.

28. Nseir W, Diab H, Mahamid M, Abu-Elheja O, Samara M, Abid A, et al. Randomised clinical trial: simvastatin as adjuvant therapy improves significantly the Helicobacter pylori eradication rate - a placebo-controlled study. Aliment Pharmacol Ther. 2012;36:231-8.

29. Murakami K, Furuta T, Ando T, Nakajima T, Inui Y, Oshima T, et al. Multi-centre randomized controlled study to establish the standard third-line regimen for Helicobacter pylori eradication in Japan. J Gastroenterol. 2013;48(10):1128-35.

30. Sugano K, Kontani T, Katsuo S, Takei Y, Sakaki N, Ashida K, et al. Lansoprazole for secondary prevention of gastric or duodenal ulcers associated with long-term non-steroidal anti-inflammatory drug (NSAID) therapy: results of a prospective, multicenter, double-blind, randomized, double-dummy, active-controlled J Gastroenterol. 2012;47(5):540-52.

31. Sanuki T, Fujita T, Kutsumi H, Hayakumo T, Yoshida S, Inokuchi H, et al. Rabeprazole reduces the recurrence risk of peptic ulcers associated with low-dose aspirin in patients with cardiovascular or cerebrovascular disease: a prospective randomized active-controlled trial. J Gastroenterol. 2012;47(11):1186-97.

32. Sugano K, Kontani T, Katsuo S, Takei Y, Sakaki N, Ashida K, et al. Lansoprazole for secondary prevention of gastric or duodenal ulcers associated with long-term low-dose aspirin therapy: results of a prospective, multicenter, double-blind, randomized, double-dummy, active-controlled trial. J Gastroenterol. 2011;46:724.

33. Fujiwara S, Morita Y, Toyonaga T, Kawakami F, Sugano K, Kontani T, Katsuo S, Takei Y, Sakaki N, Ashida K, et al. Rabeprazole for secondary prevention of gastric or duodenal ulcers associated with long-term low-dose aspirin therapy: results of a prospective, multicenter, double-blind, randomized, double-dummy, active-controlled trial. J Gastroenterol. 2011;46:724.
35. Tan VP, Wong WM, Cheung TK, Lai K, Hung I, Chan P, et al. Treatment of non-erosive reflux disease with a proton pump inhibitor in Chinese patients: a randomized controlled trial. J Gastroenterol. 2011;46(7):906-12.

36. Nagahara A, Suzuki T, Nagata N, Sugai N, Takeuchi Y, Sakuri K, et al. A multicentre randomised trial to compare the efficacy of omeprazole versus rabeprazole in early symptom relief in patients with reflux esophagitis. J Gastroenterol. 2014;49(12):1536-47.

37. Kjaergard LL, Frederiksen SL, Gluud C. Validity of randomized clinical trials in gastroenterology from 1964-2000. Gastroenterology. 2002;122:1157-60.

38. Godwin OP, Dyson B, Lee PS, Lee E. Compliance with the CONSORT Statement on Participant Flow Diagrams in Infectious Disease Randomized Clinical Trials. J Pharma Care Health Sys. 2015;2:129.

39. Ziogas DC, Zintzaras E. Analysis of the quality of reporting of randomized controlled trials in acute and chronic myeloid leukemia, and myelodysplastic syndromes as governed by the CONSORT statement. Ann Epidemiol. 2009;19:494-500.

40. Halpern SH, Darani R, Douglas MJ, Wight W, Yee J. Compliance with the CONSORT checklist in obstetric anaesthesia randomised controlled trials. Int J Obstet Anesth. 2004;13:207-14.

Cite this article as: Elraggal ME, Al-Muwallad M, Al-Otaibi A, Alsiddik J, Shahbar A, Cheema E. Assessment of quality of reporting of Helicobacter pylori related randomized controlled trials: a focus on highly ranked gastroenterology journals. Int J Clin Trials 2018;5(1):21-9.
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       | 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 |
| mechanism                    |         |                                                                                                |
| 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             | 15      | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |
| (a diagram is strongly      | 16      | For each group, losses and exclusions after randomisation, together with reasons                    |
| recommended)                 |         |                                                                                                |
| 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.