Abstract

Background: Randomized controlled trials (RCTs) are an important foundation for evidence-based healthcare. Despite an increase in the number of RCTs in Japan, existing international databases fail to capture them, and detailed information on the quality of Japanese RCTs is lacking.

Objectives: This study assessed the number, characteristics, and quality of RCTs published from Japan in 2010, and analyzed factors related to quality of Japanese RCTs.

Methods: One Japanese database and four international databases were searched for all RCTs published from Japan in 2010. Among 2957 studies, 1013 were identified as RCTs. Characteristics of these RCTs were analyzed based on trial design. Sixty percent of the included RCTs were randomly sampled and the quality was assessed using the risk of bias tool. Quality was compared with a random sample of 50 Cochrane systematic reviews in the Cochrane Library. The quality of Japanese RCTs indexed in international databases was also compared with that of non-indexed RCTs. Lastly, factors relating to quality were analyzed using multi-level logistic regression.

Results: The most common characteristics were drug trials (505 trials), and trials of circulatory system treatments (161 trials). The proportion with sample size less than 50 was 54%. Eighty percent of RCTs had no information on the funding source and only 8% had registered their study protocol before their implementation. Japanese RCTs had a significantly higher odds of risk of bias ($p<0.05$) compared with relevant Cochrane

systematic reviews in the following domains: sequence generation, allocation concealment, blinding of the outcome assessor, and selective outcome reporting. Non-indexed RCTs in international databases were lower in quality than indexed RCTs in some domains, but overall quality was not significantly different.

Conclusion: More than 1000 Japanese RCTs were published in 2010 and 60% were drug trials. Most trials had a small sample size, were implemented without any trial registration and did not report the funding source. Their quality was insufficient to clarify the true effect of health interventions. Clinical trials need enhanced monitoring, especially drug trials funded by pharmaceutical company, and journals, funding bodies and drug safety agencies in Japan should enforce stricter rules about reporting both methods and funding sources. The CONSORT statement should be endorsed by Japanese researchers, funding bodies and organizations to promote and improve the quality of Japanese RCTs. In addition, since the overall quality of indexed and non-indexed Japanese RCTs was not significantly different, systematic reviewers should consider including Japanese databases.