



Quality Assessment of Published Randomized, Controlled Trials in Trauma Monthly Journal

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Abstract

Context: Randomized controlled trials (RCTs) have a major role in making the evidence-based decisions on healthcare. Therefore, the assessment of the quality of RCTs is important to properly apply the evidence-based healthcare. The current study aimed at assessing the quality of RCT reports published in Trauma Monthly Journal.

Evidence Acquisition: The quality assessment of each report was performed using a checklist based on the CONSORT (consolidated standards of reporting trials) Statement and Jadad criteria.

Results: Fifteen RCTs were published from 2011 to 2015 in Trauma Monthly journal out of which 5 (33.3%) reported the pain outcomes, 7 (46.6%) reports included surgical interventions, and 3 (33.3%) reports included patients with different types of fractures. According to the CONSORT checklist, the best report belonged to the definition of interventions for each group with sufficient details. The mean score of Jadad was 2.27 (45.4% of maximum possible total score). According to both scales, there was an increase in the periods of time in the quality of reporting.

Conclusions: The results showed a moderate quality score in RCTs and an improvement over the years. Training courses for researchers, managing reporting standard tools presented by editors (CONSORT checklist) and employing methodologists and statistical experts can improve the quality of published RCTs.

Keywords: Quality Assessment, Randomized Controlled Trial, Checklist, Trauma

1. Context

1.1. Quality Assessment of Randomized Controlled Trials

RCTs are often performed to assess the effect of new treatments and are considered evidence-based for clinical trials (1). Therefore, it is of paramount importance to design and report high-quality RCTs. Also, for proper use and exploration of the evidence-based approach, it is important and necessary to assess the quality of RCTs.

The quality of a trial was explained by the validity and accuracy of analysis and design. But, the quality of reporting was explained as reporting characteristics about the analysis and design of the RCT (2).

There are various approaches to assess the quality of RCTs. It is usually performed using 3 tools of the component, checklist, and scale.

Also, the quality of RCTs was evaluated in the meta-analysis studies. The CONSORT (consolidated standards

of reporting trials) guidelines and Jadad criteria are often used in meta-analysis studies. Recently, to integrate the results of RCTs, meta-analyses are conducted increasingly (3, 4). Therefore, there is a great interest to evaluate the quality of RCTs to include them in the meta-analyses (5-7). Therefore, since the quality of trials affect the results of meta-analyses, results may be less valuable if the quality of RCTs is not assessed (2). To achieve the valuable results of a trial, the quality of RCT is very important.

It is recommended that journals implement more CONSORT guidelines (8). The works should be complete and clear before publishing.

However, RCTs are increasingly published in journals (9). It is important for the promotion of journals to pay more attention to quality assessment of trials.

1.2. Trauma Monthly Journal

Trauma Monthly is an open access Iranian Journal indexed in Thomson Reuters, PubMed, Scopus, etc. with 40 published papers per year. The aim and scope of the journal are in the fields of trauma and emergency medicine. The main focus is on the efficacy in improving clinical outcomes such as quality of life (QOL), morbidity, and mortality. Trauma Monthly receives submissions in the form of research articles, reviews, case reports, short communications, technical reports, iatrogenic trauma, surgical pathology, and letters to editor. The rejection rate of this journal is 34%.

2. Objectives

The current study aimed at assessing the quality of the RCTs published in Trauma Monthly Journal.

3. Evidence Acquisition

The current study was conducted in Baqiyatallah University of Medical Sciences, Tehran, Iran, from January to March 2016. Inclusion criteria were RCTs on the human subjects with the control group published from 2011 to 2015 in Trauma Monthly Journal.

Information regarding the year of publication, region of publication (country), gender, the study characteristics, the type of outcomes, intervention, and comparison groups as well as the ethical approval was pertained.

The current study conducted a quality assessment of each included RCT using the CONSORT checklist and Jadad scale. The CONSORT checklist included the title, abstract, introduction, discussion, randomization, allocation concealment, sample size, statistical analysis, blinding, and primary and secondary outcomes (under 37 sub-items) (10). Each item was marked yes if the author had reported it. The CONSORT 2010 Statement and additional information are available on the website (www.consort-statement.org) that can be helpful to describe the quality of RCTs. In this evaluation, only 7 essential items of CONSORT 37 sub-items were applied. These items included 1a: title and abstract; recognition as a randomized study in the title, 4a: participants; inclusion and exclusion criteria, 4b: participants; locations where the data were obtained, 5: interventions; the interventions for each group with enough features to permit replication, including how and when they were really applied, 6a: outcomes; fully explained pre-specified primary and secondary outcome measures, including how and when they were evaluated, 17a: results; for each primary and secondary outcome, results for each group, and the assessed effect size and its accuracy (such

as 95% confidence interval), 23: registration number and name of trial registry.

The Jadad scale (11) includes 5 questions, and each question is answered with either yes = 1 point or no = 0 point. Questions are about randomization, the method of randomization, blinding, the method of blinding, and failures and withdrawals. Allocating trials a score ranging from 0 (very poor) to 5 (high quality).

Each included RCT was assessed independently by 2 reviewers (HRR and JM). A 3rd reviewer (MS) solved conflicts between the 2 reviewers.

The mean number of CONSORT checklist reported items and that of mean jaded score were compared over time.

4. Results

Search in the web of Trauma Monthly Journal extracted 178 papers published from 2011 to 2015 of which 163 were the trials without a control group, non-trial, or non-human trials. Overall, 15 eligible RCTs were identified and included in the study (Figure 1). Descriptive information and details of quality assessment of the 15 RCTs are shown in Tables 1 and 2.

The mean score of Jadad scale was 2.27 (45.4% of the maximum possible total score). The items of randomized, method of randomization, blinding, method of blinding, and dropouts/withdrawal of Jadad scale were reported in 80%, 33.3%, 33.3%, 20%, and 60% of RCTs, respectively. This score was 2, 2, and 2.66 in 2011 to 2012, 2013 to 2014 and 2015, respectively. It seems that the number of studies increased after 2015; somewhere it was said that the studies in other universities had higher qualities, compared with those affiliated to Baqiyatallah University of Medical Sciences (Table 3).

All RCTs were submitted from Iran and the authors of Baqiyatallah University of Medical Sciences, in more than half of the reports (53.3%), were the first or corresponding authors (Table 4). Twelve (80%) reports involved both male and female subjects; 5 (33.3%) reports included pain outcomes, 7 (46.6%) reports included surgical interventions, and 5 (33.3%) reports included patients with different types of fractures (Table 4).

The items of 1a, 4a, 4b, 5, 6a, 17a, and 23 of the CONSORT 2010 checklist were reported in 40%, 93.3%, 53.3%, 100%, 93.3%, 46.6%, and 26.6% of RCTs, respectively (Table 4). The best report belonged to the definition of interventions for each group with sufficient details. The current study explained some appropriate reported items as a whole score for this checklist. Just 2 studies received full points (7 items). The quality of reporting was 3.75, 4, and 5.5

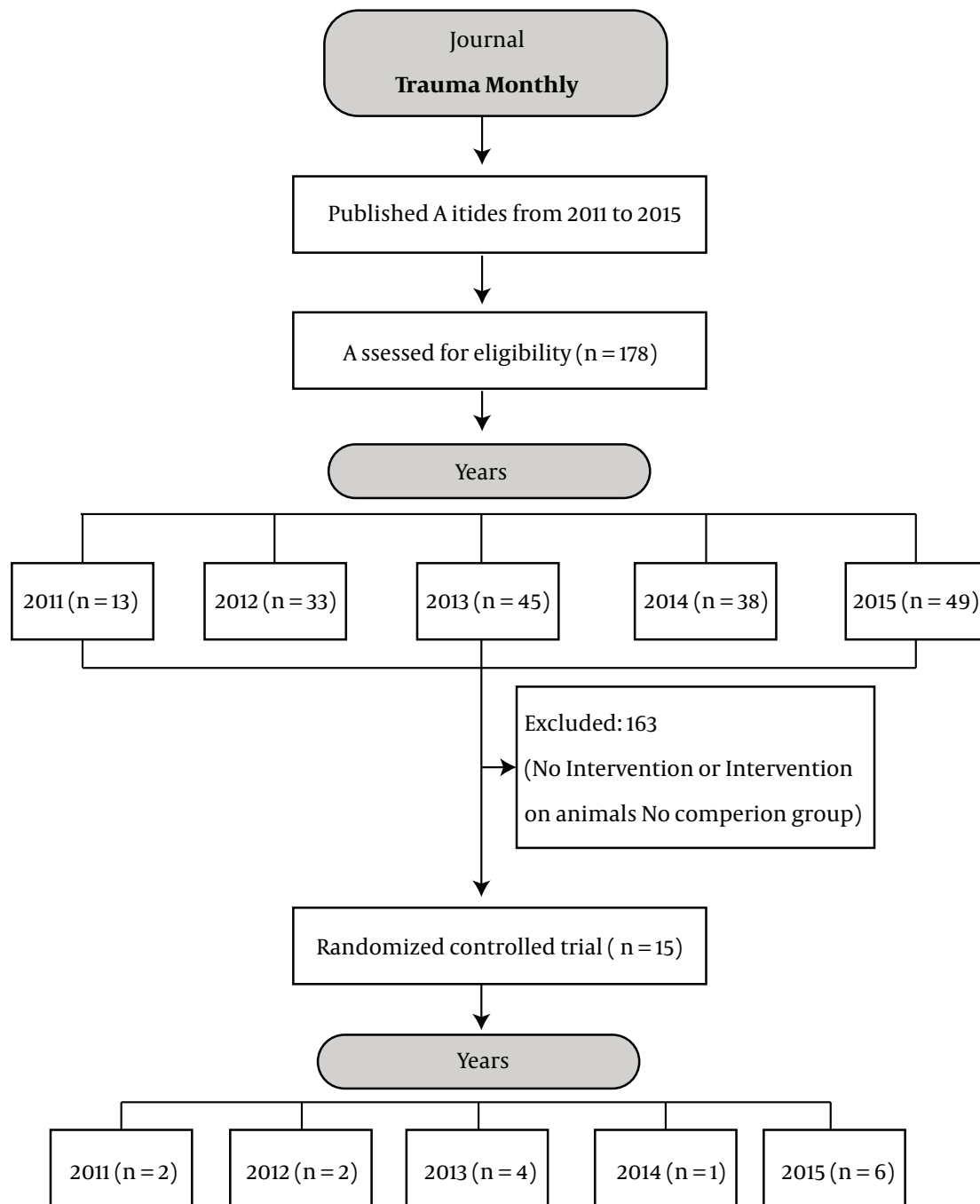


Figure 1. Tracking and Enrollment of RCTs

in 2011 to 2012, 2013 to 2014, and 2015, respectively. Therefore, there was an improvement in the quality of reporting (the number of checklist items included in the reports) over time. According to this checklist, the reports not af-

filiated to Baqiyatallah University of Medical Sciences had higher quality (Table 3).

Table 1. The Quality Assessment by Jadad Score for the RCTs Publishes in Trauma Monthly Journal From 2011 to 2015

Reference	Randomization		Blinding		Dropouts/Withdrawal	Total Score
	Randomized	Method of Randomization	Blinding	Method of Blinding		
Khoshmohabat et al. (12)B	1	1	1	0 NR	0 NR	3
Lak et al. (13) B	1	0 NR	1	1	0 NA	3
Towliat Kashani et al. (14) B	0 NR	0 NR	0 NR	0 NR	1	1
Mohebbi et al. (15) B	0 NR	0 NR	0 NR	0 NR	1	1
KarimiMobarakeh et al. (16)	1	0 NR	0 NR	0 NR	1	2
Bahari-Kashani et al. (17)	1	0 NR	0 NR	0 NR	0 NR	1
Yazdani et al. (18) B	0 NR	0 NR	0 NR	0 NR	1	1
Bakhshi et al. (19)	1	0 NR	1	0 NR	1	3
Vahedian et al. (21) B	1	1	0 NR	0 NR	1	3
Hatamabadi et al. (20)	1	1	0 NR	0 NR	1	3
Hatamabadi et al.(20)	1	1	1	1	0 NR	4
Marzieh Lak et al.(20)	1	1	1	1	0 NR	4
Forootan et al. (20)	1	0 NR	0 NR	0 NR	1	2
Fakoor et al. (20)	1	0 NR	0 NR	0 NR	1	2
Ebadi et al. (20) B	1	0 NR	0 NR	0 NR	0 NR	1

Abbreviations: B, Baqiyatallah University of Medical Sciences as the first or corresponding author; NA, not appropriate; NR, not reported.

Table 3. Randomized Controlled Trials Published in Trauma Monthly Journal Based on the Publication Year

	N	Year			Country		
		2011 - 2012	2013 - 2014	2015	Total	Iran B	Iran
Jadad scale	Mean of score	2	2	2.66	2.27	2.4	2.1
Consort statement	Mean number of the appropriate reported items	3.75	4	5.5	4.53	4.3	4.7

5. Discussion

The current study assessed the reporting quality of RCTs in the Trauma Monthly Journal using the CONSORT checklist and the Jadad scale.

The current study reported the method of randomization, introduction as a randomized trial in the title, inclusion and exclusion criteria, and settings and locations where the data were collected.

Amanollahi et al. evaluated 314 RCTs indexed in PubMed database with the affiliations of Tehran and Iran universities of medical science using CONSORT checklist. They showed that among the items considered in the consort checklist, only the intervention used in the 2 groups were thoroughly presented (100%) in the summaries. In the current study, the best report was associated with the definition of interventions for each group with sufficient

details that confirmed it. Another item in their research about the method of randomization, blinding, introduction as a randomized trial in the title (item 1a), inclusion and exclusion criteria (item 4a), and settings and type of information (item 4b) were recorded weakly and observed in 5.4%, 50.3%, 37.6%, 66.4%, and 19.4% of the reports, respectively (8). These results were comparable to those of the current study.

Faizi et al. (21) in a quality evaluation of RCTs used psychotherapy for chronic pains in Iran and determined that the mean score of Jadad was 1.53 ± 1.37 , while in the current assessment this score had a greater average. They reported that the items (5 items) of jaded score were appropriately reported in 41.2%, 64.7%, 11.8%, 5.9%, and 29.4% of RCTs respectively, but these percentages in the current study were 80%, 33.3%, 33.3%, 20%, and 60% of RCTs, respectively that indicate, except for the method of randomization, a higher

Table 4. Published Randomized Controlled Trials in Trauma Monthly Journal

	Status	No. (%)
Country	IranB	8 (53.3)
	Iran	7 (46.6)
Outcome	Pain	5 (33.3)
Gender	Male and female	12 (80)
Interventions	Surgery	7 (46.6)
Disease	Fracture	5 (33.3)
Consort statement yes items	1a	6 (40)
	4a	14 (93.3)
	4b	8 (53.3)
	5	15 (100)
	6a	14 (93.3)
	17a	7 (46.6)
	23	4 (26.6)
Jadad score	Randomized	12 (80)
	Method of randomization	5 (33.3)
	Blinding	5 (33.3)
	Method of blinding	3 (20)
	Dropouts/withdrawal	9 (60)

quality of reports in the current study.

In study by Moher et al. (2) on evaluating reporting quality of RCTs in pediatric alternative medicine showed that the quality of reporting obtained approximately 40% of their maximum possible total Jadad score. This result was lower than that of the current study.

RCTs published in the Nephrology Urology Monthly Journal

In the current study, the quality of each report was assessed using the CONSORT Statement checklist and Jadad scale, which concluded the low quality score of the reports (9). The results of the current study showed that the average quality score in RCTs and the improvement over the years were minor.

According to SCImago journal rank (SJR) indicator (<http://www.scimagojr.com/>), rank of Trauma Monthly in 2013 and 2014 were higher than 2012 (SJR2012 = 0.102 vs. SJR2013 = 0.144 and SJR2014 = 0.138), which confirms the results of this assessment and shows that reporting quality score can be considered as a supplement to the ranking index.

The quality of RCTs reported in Persian and English languages in Iran has weaknesses. Some of the studies showed that the quality of trials in the English language was similar to those of the RCTs reported in non-English languages

(10).

Although all quality score scales have inherent limitations; eg, in an RCT with surgical intervention, sometimes blinding is impossible (9). Therefore, the quality of reports should be assessed cautiously since the overall score indicates that there is a gap that should be narrowed.

But in the current assessment, similar to the quality assessment of other Iranian researchers, in some of the items, low or moderate quality of reporting was observed in reports. The reason may be that the Iranian investigators in this field conduct fewer RCTs and are, therefore, less experienced.

Journals that use the CONSORT guideline have higher quality of RCTs, compared with journals that do not (4).

Training courses for authors, necessary reporting standard tools provided by editors of medical journals (eg, CONSORT checklist), and using methodologists and statistical experts can improve the quality of published RCTs.

The current study had some limitations. First, there was not information about all sections of the articles. Second, not all types of articles were considered and only RCTs were included in the current study.

Implication for health policy/ practice/ research/ medical education: In order to guide editors, reviewers and authors to assess and improve the quality of their publication reporting.

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Footnotes

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Table 2. RCTs Published in Trauma Monthly Journal From 2011 to 2015

Reference	Year	Country	Area	Gender	Sample Size	Interventions	Comparison Group	Outcome	Ethical Approval	Quality Score (Jadad)	CONSORT ^a							
											1a	4a	4b	5	6a	17a	23	No Yes Item
(12)B	2012	Iran	Unilateral inguinal hernia	Male	66+74	Excised nerve surgery	Preserved-nerve surgery	Pain severity (VAS), numbness	y	3	y	y	NA	y	NA	N	N	4
(13)B	2011	Iran	Elective inguinal hernia repair (caudal anesthesia) (children)	Both	20+20	Bupivacaine plus clonidine	Bupivacaine drug	Pain, sedation objective pain scale, the Ramsay sedation scale	N	3	y	NA	NA	y	y	N	N	4
(14)B	2011	Iran	Proximal hemorrhoids	Both	40+40	Scapled hemorrhoidectomy	Miligan Morgan hemorrhoidectomy	Pain (VAS), duration of surgery, hospital stay, recurrence	y	1	N	y	NA	y	y	N	N	3
(15)B	2012	Iran	Primary hyperhidrosis	Both	30+30	Sympathectomy surgery	Sympathectomy	Early and late satisfaction	y	1	N	y	y	y	y	NA	N	4
(16)	2013	Iran	Distal forearm torus fractures	Both	65+77	Removable wrist splint	Short arm cast	Pain, satisfaction (Verhaar scale)	y	2	N	NA	y	y	NA	N	N	3
(17)	2013	Iran	Distal radius intraarticular fractures	Both	57+57	Pin and plaster fixation	Volar locking plate	SF56, MAYO, DASH, pain	N	1	N	y	y	y	NA	N	N	4
(18)B	2013	Iran	Mandibular angle fractures	Both	45+42	Single miniplate	Double miniplates	Malocclusion, infection, sensory disturbances	y	1	N	y	N	y	y	NA	N	3
(19)	2013	Iran	Tibiofibular fracture	Both	30+30	Erythropoietin drug	Placebo	Period of fracture union, incidence of nonunion	N	3	N	y	NA	y	y	NA	N	3
(20)B	2014	Iran	Intensive care unit	Both	45+45	Massage therapy	Routine care of the unit	Vital signs, Glasgow coma scale score	y	3	y	y	y	y	y	y	y	7
(20)	2015	Iran	Civilian stab-wound trauma	Both	80+80	Celox-coated gauze	Simple pressure dressing	Time for achievement of hemostasis, the amount of bleeding	y	3	y	y	y	y	y	N	N	6
(20)	2015	Iran	Anterior shoulder dislocation	Male	29+19	Midazolam	Propofol	Time interval between injection and induction of sedation (T1), duration of time from sedation to awakening (T2), the duration of time between sedation and full awareness to time, location and individuals (T3)	N	4	y	y	y	y	y	y	y	7
(20)B	2015	Iran	ASA class I or II	Male	50	Bupivacaine plus clonidine	Bupivacaine	Systolic and diastolic blood pressure, VAS, SpO2, Ramsay score, Bromage scale, pulse rate per minute	y	4	y	y	N	y	y	y	y	6
(20)	2015	Iran	Laser therapy after repair of the distal half of the median nerve	Both	14+13	Low power laser therapy	Standard methods	Nerve conduction velocity, (Electromyography)	N	2	N	y	y	y	y	N	N	5
(20)	2015	Iran	Distal radius fractures	Both	55+39	CR+EF	ORIF	MHOQ questionnaire, ROM of the wrist, duration of rehabilitation, complication, patient satisfaction	N	2	N	y	y	y	y	y	N	5
(20)B	2015	Iran	Competency of nurses in biological incidents	Both	30+30+30	Lecture presentation	Multimedia, control	Knowledge, VAS for attitude, competency	y	1	N	y	N	y	y	y	N	4

Abbreviations: B, Baqiyatallah University of Medical Sciences as the first or corresponding author; NA, not appropriate.
^a 2010 Checklist Important Items No.