Aesth Plast Surg (2019) 43:866–873
https://doi.org/10.1007/s00266-019-01335-3

ORIGINAL ARTICLE SPECIAL TOPICS

Quality of Randomized Controlled Trials Published By Plastic Surgeons: Long-Term Follow-Up

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Received: 11 November 2018 / Accepted: 15 February 2019 / Published online: 9 April 2019

Abstract

Introduction In two previous studies, the quality of randomized controlled trials (RCTs) with the participation of at least one plastic surgeon was evaluated in two periods: 1966–2003 and 2004–2008.

Objective To evaluate the evolution of the quality of RCT publications by plastic surgeons in the subsequent 5-year period, from 2009 to 2013.

Methods RCTs published from 2009 to 2013 in English with the participation of at least one plastic surgeon were identified by electronic search and classified for concealment of allocation by two independent evaluators. The studies with adequate allocation concealment had their quality evaluated by two evaluators using the Delphi List and the Jadad Quality Scale.

Results Of the 6997 identified studies, 261 were classified as to concealment of allocation. Of these, 43 (16.47%) had adequate allocation concealment. According to the evaluation in the Delphi List, there was an improvement, in relation to 1966–2003, in the items "most important characteristics of the prognosis" ($p < 0.001$), "use of independent evaluator" ($p = 0.0029$), and "measures of variability and point estimate for the primary variable" ($p = 0.0057$); there was no difference in relation to 2004–2008. Regarding the Jadad Quality Scale, there was an increase in scores in relation to 1966–2003 ($p < 0.0004$) but not in relation to the 2004–2008 period.

Conclusion There was no difference in the quality of publications of RCTs by plastic surgeons in the period 2009–2013 compared to the previous 5 years (2004–2008), but both periods presented higher quality than the period 1966–2003.

Level of Evidence III This journal requires that authors assign a level of evidence to each article. For a full description of these evidence-based medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Randomized controlled trials · Plastic surgery · Quality · Evaluation

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Introduction

The randomized controlled trial (RCT) is a prospective study design that compares the effect of interventions on humans in one or more groups against a control group. RCTs are the best source of evidence on health interventions. Evidence-based medicine (EBM) is defined as the use of the best existing scientific evidence provided by the results of appropriately designed and conducted RCTs combined with individual clinical expertise and the patient's preferences and values for decision making about the individual care of the patient [1–4].

EBM was popularized in the 1980s and impacted all fields of medicine, including plastic surgery [5]. The application of the EBM principles can determine the best treatment for the patient and can also reduce the costs of health systems [2]. However, particularly in the surgical areas, there are challenges to be overcome, including the belief that the application of EBM could reduce the autonomy of surgeons, and the best scientific evidence is not always better than the best practice.

This concern is even greater in plastic surgery, in which the results are measured not only by the occurrence of complications and the need for reintervention but mainly by the patients' satisfaction with aesthetic results [6]. Despite this, the practice of EBM in plastic surgery is no longer a trend but a well-established reality [6].

Information obtained from research using scientific rigor in the methods employed has become the key point of EBM and the translation of knowledge [7]. Well-conducted RCTs, therefore, can have a significant impact on medical care by contributing to the establishment of a sound scientific evidence base that will underpin care protocols and clinical interventions [8]. Research in plastic surgery will have a much greater influence on clinical practice if studies with greater impact are published [4, 9]. Thus, the systematic identification and evaluation of RCTs performed by plastic surgeons, and their impact on the specialty, allow for the implementation of evidence-based practice with direct benefit to patients [10], [11]

Several studies have shown that plastic surgeons recognize the need to improve the level of evidence in plastic surgery research, and this recognition is reflected by the continued increase in clinical trial publications in the specialty [2, 8, 11–16]. A previous study identified RCTs with adequately described allocation concealment published by plastic surgeons between 1966 and 2003 and assessed their quality [17]. In a later study, the evolution of RCTs in 2004–2008 was evaluated, and an increase in the quantity and quality of the RCTs published by plastic surgeons was observed [8]. The present study aimed to test the hypothesis that there was a quantitative and qualitative improvement in the RCTs in plastic surgery in the 5-year period after that (2009–2013) in relation to the periods previously studied.

Methods

The study project was approved by the institutional research ethics committee.

Sampling was by convenience, consisting of all RCTs retrieved that met the eligibility criteria for the study, published over a 5-year period (January 2009–December 2013). Electronic searches were conducted to identify the largest number of RCTs published by plastic surgeons in English. Specific search strategies were developed for each database, Cochrane Central Register of Controlled Trials (CCTR), Latin American and Caribbean Literature in Health Sciences (LILACS) and MEDLARS—Medical Literature Retrieval System—online (MEDLINE) (Tables 1, 2).

Abstracts of all papers retrieved were read by an evaluator, and those meeting the eligibility criteria (possible RCTs involving at least one plastic surgeon, published in English between 2009 and 2013) were selected for reading the full text. Studies that were not conducted by plastic surgeons, that did not involve at least one plastic surgeon, or that were published in a language other than English were excluded. At this stage, whenever there was any doubt, the study was selected for reading in its entirety.

The full texts of articles were read by an evaluator to confirm the eligibility criteria. Then, two independent evaluators classified the selected articles according to the confidentiality of allocation [18], and the disagreements were resolved at a consensus meeting. The RCTs published by plastic surgeons, with adequately described allocation concealment were selected and constituted the sample of this study.

The selected RCTs were then evaluated for their quality. The evaluation was performed independently by two evaluators, followed by a consensus meeting. Two validated instruments were used for the quality evaluation: the Delphi List [19] and the Jadad Quality Scale [20]. The evaluators held a prior meeting to discuss and standardize the criteria that would be used in their evaluations.

The Delphi List is a list of generic criteria for quality assessment of clinical trials, which should be used in association with other instruments. A punctuation calculation is not described, and all items have two response options: yes or no (Table 3) [19].

The Jadad Quality Scale is based on scores: one point is given for each "yes" answer and zero points for each "no" answer. Points accounted for the first two items (randomization and double blindness) depend not only on how they are described but also on the use of appropriate methods for this purpose. If the methods are described and appropriate, an additional point is given for each item. If the methods used to generate the randomization sequence or create the blinding conditions are described, but they are not appropriate, the entire item will receive zero points. Therefore, the scale produces scores from 0 to 5. The study is considered of poor quality if it receives two or fewer points (Table 4) [20].

The results were compared with those obtained in the two previous studies, which used the same method to evaluate the quality of RCTs published by plastic surgeons in the 1966–2003 and 2004–2008 periods [8, 17].

Table 1 Electronic search strategies for the CCTR database

Strategy	Terms or combinations used
#1	"Surgery Plastic" or "Plastic Surgery" or surg$ or procedure$ or method$ or tecnic$ or technique$
#2	Reconstru$ or cosmetic$ or plastic$ or esthetic$ or aesthetic$ or cosmiatr$ or correc$
	("Surgery Plastic" or "Plastic Surgery" or surg$ or procedure$ or method$ or tecnic$ or technique$) and (reconstru$ or cosmetic$ or plastic$ or esthetic$ or aesthetic$ or cosmiatr$ or correc$)

Table 2 Electronic search strategies for LILACS and MEDLINE databases

Strategy	Terms or combinations used
#1	Pt randomized controlled trial
#2	Pt randomized controlled clinical trial
#3	Pt controlled clinical trial
#4	Mh randomized controlled trials as a topic
#5	Mh clinical trials
#6	Randomized or Mh controlled clinical trials
#7	Randomized or Mh random allocation
#8	Mh randomization
#9	Mh double-blind method
#10	Mh double-masked study
#11	Mh single-blind method
#12	Mh single-masked study
#13	Tw randomi$ AND Tw control$ AND Tw trial$
#14	Tw control$ AND Tw clinic$ AND Tw trial$
#15	Tw randomi$ AND Tw allocation$
#16	Tw randomi$
#17	Tw double-$ AND Tw method$
#18	[Tw single-$ AND (Tw masked OR Tw study$)] AND Ct humans AND not [Ct animals OR (Ct animals AND Ct humans)]
#19	Ex E04 680$ OR Mh surgery
#20	Plastic OR (Tw surgery AND Tw plastic) OR Tw cirurg$ OR Tw cirug$ OR Tw surg$ OR Tw procedure$ OR Tw procedim$ OR Tw metodo$ OR Tw method$ OR Tw tecnic$ OR Tw technique$ AND (Tw reconstru$ OR Tw cosmeti$ OR Tw plastic$ OR Tw esthetic$ OR Tw estetic$ OR Tw aesthetic$ OR Tw correc$) AND (pd 2009 OR pd 2010 OR pd 2011 OR pd 2012 OR pd 2013)

Tw text words, *Mh* medical headings, *Ct* limits, *Ex* explode; *Pt* publication type, *$* truncates the root of a word, allowing the electronic search of all words derived from the root

Table 3 Delphi List items [19]

1.a. Was the allocation of patients random?
1.b. If individuals were randomly allocated to the treatment groups, was the allocation concealed?
2. Were the groups comparable in relation to the most important characteristics of the prognosis?
3. Were the inclusion and exclusion criteria specified?
4. Was an independent evaluator used to evaluate the results?
5. Was the caregiver blinded?
6. Was the patient blinded?
7. Were measures of variability and point estimates presented for the primary variable?
8. Did the study include an intention-to-treat analysis (all patients allocated)?

Table 4 Items of the Jadad Quality Scale [20]

1.a. Was the study described as random (use of words such as "random," "randomization")?
1.b. Was the method adequate?
2.a. Was the study described as double-blind?
2.b. Was the method adequate?
3. Was there a description of the losses and exclusions?

Statistical Analysis

The Kappa and McNemar tests were used to study the concordances and disagreements among the evaluators. The Chi-square test was applied to compare the three periods (1966–2003, 2004–2008, and 2009–2013) in the categorical variables evaluated. Kruskal–Wallis analysis of variance was used to compare the same three periods for the scores of the Jadad Quality Scale. The Kolmogorov–Smirnov test was applied to compare, two by two, the periods studied in the score of the Jadad Quality Scale [21].

The statistical analysis was performed with the program BioEstat 5.3 (Mamirauá Institute, Pará and Amazonas, Brazil). In all tests, the level of significance was set at 0.05 or 5%.

Results

The electronic search identified 6997 references in the databases consulted. One evaluator selected 616 references, excluding 6381 that clearly were not RCTs, were repeated in different databases, or were not related to studies performed by or with the participation of at least one plastic surgeon.

After the full texts of the 616 publications were read by an evaluator, 336 references were excluded for the following reasons: One was published in a language other than English (Russian); 219 did not involve the participation of at least one plastic surgeon; and 116 were not RCTs. Of the 280 remaining references, 19 were repeats, which is why the final selection comprised 261 studies.

Two evaluators independently classified the 261 selected studies according to the concealment of allocation [18]. The coefficient of agreement (k_w) between the two evaluators was 0.94 ($p = 0.000$). After a consensus meeting, 43 RCTs were chosen, all published in English, with the participation of at least one plastic surgeon, and with appropriately described allocation concealment.

Table 5 shows the distribution of these RCTs over a 5-year period, comparing the results of the present study with the data from the 1966–2003 [17] and 2004–2008 periods [8].

The comparison between the period from 2009 to 2013 and the previous studies (1966–2003 and 2004–2008) regarding the items in the Delphi List is shown in Table 6. A significant improvement compared to 1966–2003 and 2004–2008 was observed for the items "The groups were comparable regarding the most important characteristics of prognosis" ($p < 0.001$), "Inclusion and exclusion criteria were specified" ($p = 0.0029$), and "Measures of variability and the estimated points were presented for the primary variable" ($p = 0.0057$).

Table 5 Distribution of RCTs with allocation concealment adequately described in periods of 5 years

Year	RCTs	
	n	%
1966–1983	0	0
1984–1988	6	5.7
1989–1993	8	7.6
1994–1998	8	7.6
1999–2003	12	11.4
2004–2008	28	26.7
2009–2013	43	41.0
Total	105	100

The coefficient of agreement (k_w) between the evaluators in the evaluation of the 43 RCTs regarding the score of the Jadad Quality Scale [20] was 0.67 ($p = 0.0000$). Table 7 shows the distribution of RCTs according to the Jadad score.

Discussion

The present study evaluated the evolution of the quality of RCTs published by plastic surgeons since 1966. The long-term follow-up of 47 years using the same method allowed a clear analysis of the evolution of the studies over the years. Considering the growing demand for specialized treatments and the limitation of resources for health care, there has been an increasing interest in the practice of EBM [11, 13, 22, 23], and the qualitative and quantitative increase in RCT publications by plastic surgeons in the evaluated 47-year period confirms this interest.

The performance of RCTs in surgical areas brings many difficulties and challenges, which include ethical issues that make it impossible to use placebo procedures or even no procedure as controls, the inability to blind the surgeon, learning curves, and technical differences between

Table 6 Quality evaluation by the Delphi List [19], after the consensus meeting, and comparison with the 1966–2003 and 2004–2008 periods

	1966–2003		2004–2008		2009–2013		Chi-square test
	Yes *n* (%)	No *n* (%)	Yes *n* (%)	No *n* (%)	Yes *n* (%)	No *n* (%)	
1.a. Was patient allocation random?	34 (100.0)	0	28 (100.0)	0	43 (100.0)	0	–
1.b. If individuals were randomly assigned to the treatment groups, was allocation concealed?	34 (100.0)	0	28 (100.0)	0	43 (100.0)	0	–
2. Were the groups comparable to the most important characteristics of the prognosis?	14 (41.2)	20 (58.0)	27 (96.4)	1 (3.6)	30 (69.8)	13 (30.2)	**$\chi^2 = 21.6$ $p < 0.0001$**
3. Were the inclusion and exclusion criteria specified?	17 (50.0)	17 (50.0)	19 (67.9)	9 (32.1)	37 (86.0)	6 (14.0)	**$\chi^2 = 11.7$ $p = 0.0029$**
4. Was an independent evaluator used to evaluate the results?	17 (50.0)	17 (50.0)	18 (64.3)	10 (35.7)	21 (48.9)	22 (51.1)	$\chi^2 = 1.85$ $p = 0.3964$
5. Was the patient's caretaker blinded?	11 (32.4)	23 (67.6)	9 (32.1)	19 (67.9)	16 (37.2)	27 (62.8)	$\chi^2 = 0.28$ $p = 0.8709$
6. Was the patient blinded?	20 (58.8)	14 (41.2)	14 (50.0)	14 (50.0)	24 (55.8)	19 (44.2)	$\chi^2 = 0.49$ $p = 0.7814$
7. Were variability measures and point estimates presented for the primary variable?	15 (44.1)	19 (55.9)	19 (67.9)	9 (32.1)	34 (79.0)	9 (21.0)	**$\chi^2 = 10.32$ $p = 0.0057$**
8. Did the study include an intention-to-treat analysis (all patients allocated)?	13 (38.2)	21 (61.8)	9 (32.1)	19 (67.9)	18 (41.8)	25 (58.2)	$\chi^2 = 0.68$ $p = 0.7120$

Table 7 Scores of the Jadad Quality Scale [20] after the consensus meeting

Scores	Studies					
	1966–2003		2004–2008		2009–2013	
	n	%	*n*	%	*n*	%
0	4	11.8	0	0	0	0
1	1	2.9	0	0	0	0
2	15	44.1	4	14.2	4	9.3
3	7	20.6	11	39.3	17	39.5
4	4	11.8	2	7.1	6	13.9
5	3	8.8	11	39.3	16	37.2
Total	34	100	28	100	43	100
Kruskal–Wallis analysis of variance:						
$p = 0.0001$						
1966–2003 versus 2004–2008 and versus 2009–2013						
Kolmogorov–Smirnov test:						
Maximum differences between accumulated ratios:						
1966–2003 versus 2004–2008: $\chi^2 = 12.18$; $p = 0.0023$						
1966–2003 versus 2009–2013: $\chi^2 = 18.63$; $p < 0.0001$						
2004–2008 versus 2009–2013: $\chi^2 = 0.16$; $p = 0.9192$						

surgeons [24, 25]. Thus, the production of RCTs in the area has been slower than in other medical specialties [23, 26–30]. Despite the difficulties in conducting a RCT in plastic surgery, EBM is the key to the progress of the specialty [15, 31]. Thus, clinical trials that are effectively performed must follow strict quality standards and methodological rigor, so that they have more impact on clinical practice [10, 11, 31].

There has been a progressive increase in the number of RCTs published by plastic surgeons over time. No RCT with adequately described allocation concealment was published by plastic surgeons from 1966 to 1983. The first RCT with these characteristics was published in 1984, comparing the occurrence of capsular contracture after the use of saline or silicone gel implants for breast reconstruction [32]. Thereafter, a progressive increase was observed, corroborating the popularization of EBM from the 1980s but with a substantial increase from the 2000s [6]. To improve the quality of articles related to RCTs, a group of researchers and editors developed the Consolidated Standards of Reporting Trials (CONSORT) Statement, first published in 1996 and updated in 2001 [33, 34]. However, it was from its review, published in 2010, that the use of the CONSORT Statement, which includes a checklist and a flow diagram, became popular, being adopted by most medical journals as a standard for describing RCTs [35]. The use of the CONSORT Statement has contributed to a change in the quality level of RCT publications [36]. Currently, in addition to

CONSORT, there are available in the literature many statements for different types of studies, such as SPIRIT, STROBE, PRISMA-P, PRISMA, SCARE, PROCESS, among others [37–42].

We hypothesized that the increasing adoption by medical journals, as of 2010, of a policy of mandatory adherence to the CONSORT statement in the description of RCTs would lead to an improvement in the quality of RCTs published by plastic surgeons from 2009 to 2013, in contrast with the previous period of 5 years. However, despite the progressive increase in the number of RCTs, we did not observe an improvement on quality, when compared to the previous 5-year period.

An important limitation of the present study was that it did not use the CONSORT checklist to evaluate the quality of the RCT publications. The main reason for this is that the checklist in its current form was not available when the two previous studies were designed and conducted, and the present study intended to use the same method of the two previous studies, thus allowing us to evaluate the long-term evolution. Another limitation is that only RCTs with adequate allocation concealment were eligible for quality assessment. This criterion could have led to the exclusion of high quality RCTs that failed to describe this item.

The Delphi List [19] evaluates three dimensions of the quality of an RCT: internal validity (degree of validity of the study for the sample evaluated), external validity (degree of validity of the study when extrapolating its results to the population), and statistical analysis. The comparison between the present study period (2009–2013) and the first study period (1966–2003) regarding items in the Delphi List indicated a larger number of responses with statistical significance for the items "The groups were comparable in relation to the most important characteristics of the prognosis," "Inclusion and exclusion criteria were specified," and "Measures of variability and estimation of points were presented for the primary variable." This demonstrates an increase in the quality of the publications of RCTs in the current period in terms of these items. However, there was no change in the quality of the studies when the 2009–2013 period was compared to the previous 5 years (2004–2008).

The Jadad Quality Scale is a short, simple, reliable, valid, and widely used instrument [20, 43]. Originally designed to evaluate RCTs on pain, it can be applied to other areas of medicine because the items are not specific [20]. Olivo et al., in a systematic review, analyzed the scales used to assess the methodological quality of RCTs in the health area. They found that most of the scales did not have a rigorous control in their development, nor were they tested for their validity and applicability. They also observed that the Jadad Quality Scale has been one of the most cited and used in the academic community of the health area, in addition to presenting the best evidence of validity and applicability [43]. However, this scale is less specific than the Delphi List. To minimize this potential source of bias, two evaluators assessed the RCTs, independently. Prior to the independent evaluation, the evaluators held a meeting to discuss and standardize the criteria to be used in their evaluation. In addition, a consensus meeting followed the independent evaluation.

The evaluation of the scores of the Jadad Quality Scale showed that there was an increase in quality, with statistical significance, when comparing the period 1966–2003 with the periods 2004–2008 and 2009–2013. However, an improvement in quality was not observed when comparing 2009–2013 with the previous 5 years (2004–2008), indicating a stabilization in the quality of RCTs.

Conversely, Yu et al. [44] carried out a cross-sectional study with the objective of evaluating the quality of the publications of the RCTs in surgery published between 2003 and 2013. They used the application of the CONSORT 2010 checklist items as a criterion of quality [35, 44]. They observed that the studies published in 2013 obtained significantly higher scores than those published in 2003, suggesting an improvement in the quality of the publications. They concluded that there was an increase in the quality of the publications of RCTs in surgery in the last decade; however, this quality still remains at suboptimal levels, especially with regard to surgical interventions [44]. Agha et al. [45] also used the CONSORT checklist to assess the methodological quality of RCTs in plastic surgery published between January 2009 and June 2011, and concluded that the reporting quality of RCTs in plastic surgery needs improvement.

In the present study, the studies were stable in quality from the 2004–2008 period to 2009–2013 period, according to the methodological criteria evaluated in both the Delphi List and the Jadad Quality Scale. This could indicate that plastic surgeons, after a significant improvement, may have reached a basic level of quality regarding the criteria adopted for the publications of RCTs. However, a number of other items would need to be incorporated to increase their quality. This is because of the constant improvement of the CONSORT 2010 checklist [36] and the requirement by an increasing number of journals that a RCT comply with the checklist items to be published.

Plastic surgery is characterized by a long history of innovation, which continues to this day and has many contributions to share with other medical, clinical, or surgical specialties [30]. Existing barriers should not be obstacles to the scientific growth of the specialty but rather challenges to be overcome.

Conclusion

There was no difference in the quality of RCTs, especially regarding adequately described allocation concealment, published by plastic surgeons in the period 2009–2013 compared to the previous 5 years (2004–2008), but both periods presented better quality than the period 1966–2003.

Compliance with Ethical Standards

Conflicts of interest The authors declare that they have no conflict of interest to disclosure.

Ethical Approval The institutional research ethics committee approved the study (Approval #842388).

Informed Consent For this type of study informed consent is not required.

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