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ΠΜΣ «Μεθοδολογία Βιοϊατρικής Έρευνας, Βιοστατιστική και Κλινική Βιοπληροφορική

Assessment of reporting quality of RCTs for interlaminar epidural injections in chronic low back pain published from 2000 to 2019, based on CONSORT checklist

Αξιολόγηση τυχαιοποιημένων ελεγχόμενων μελετών που αφορούν τη διαπεταλιακή, επισκληρίδια έγχυση φαρμάκων για την αντιμετώπιση της χρόνιας οσφυαλγίας, που δημοσιεύθηκαν από το 2000 έως το 2019, βάσει του CONSORT checklist

Τριμελής Συμβουλευτική Επιτροπή

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Ακαδημαϊκό έτος: 2018-2019

Contents:

1. Abstract

Introduction: The prevalence of chronic low back pain and its related disability has been a medical challenge for years. As a result, more and more studies are published every year investigating the varying effects of different treatments. Some of these are Randomized Control Trials, the ‘‘gold standard’’ within the hierarchy of clinical studies. The CONSORT (CONsolidated Standards of Reporting Trials) 2010 guideline represents a tool, that intent to improve the reporting of parallel-group randomized controlled trials (RCTs) and to make feasible the assessment of the validity of their results.

Purpose: The aim of this particular study is to evaluate the reporting quality of RCTs regarding to interlaminar epidural injections in chronic low back pain based on CONSORT checklist.

Methods: PubMed and Cochrane Library databases were searched from July 15, 2000 through July 15, 2019. Studies were considered eligible if they had randomly assigned participants to at least two treatment arms and included patients with chronic low back pain. The obtained data were processed with descriptive and analytical statistics, in terms of assessing the reporting quality of RCTs.

Results: The search identified twenty RCTs eligible for analysis. About 32,43 % (12/37) of CONSORT items were referred to 75% of the studies or more. The mean CONSORT compliance proved to be low through the whole time period, since it was 57% for the total of articles, 58% in the first time period and 56% in the second time period.

Conclusion: Randomized controlled trials (RCTs) associated with interlaminar epidural injections showed a low quality of reporting. It seems that there has been no improvement from 2000 till today, despite the existence of the CONSORT statement. Since accuracy of RCT reporting is indissolubly connected with evidence-based information and assist to the assessment of the validity of RCT results, it is mandatory to further improve the reporting quality of RCTs on interlaminar epidural injections in chronic low back pain in order to assist health care providers to their clinical decisions.

Περίληψη

Εισαγωγή: Ο επιπολασμός της χρόνιας οσφυαλγίας και η αναπηρία που σχετίζεται με αυτόν, αποτελεί εδώ και χρόνια ιατρική πρόκληση. Ως αποτέλεσμα, όλο και περισσότερες μελέτες δημοσιεύονται κάθε χρόνο διερευνώντας τις ποικίλες επιδράσεις των διαφορετικών θεραπειών που εφαρμόζονται. Ορισμένες από αυτές είναι τυχαιοποιημένες δοκιμές ελέγχου, το «gold standard» στην ιεραρχία των κλινικών μελετών. Οι κατευθυντήριες οδηγίες του CONSORT 2010 αποτελούν ένα εργαλείο που αποσκοπεί στη βελτίωση της ποιότητας συγγραφής των τυχαιοποιημένων ελεγχόμενων δοκιμών παράλληλων ομάδων (RCT) και στο να καταστεί εφικτή η αξιολόγηση της εγκυρότητας των αποτελεσμάτων τους.

Σκοπός: Στόχος της παρούσας μελέτης είναι να αξιολογηθεί η ποιότητα συγγραφής των RCTs σχετικά με την διαπεταλιακή, επισκληρίδια έγχυση φαρμάκων για χρόνιο οσφυϊκό άλγος με βάση το κατάλογο CONSORT checklist.

Μέθοδοι: Πραγματοποιήθηκε αναζήτηση στις βάσεις δεδομένων PubMed και Cochrane Library από τις 15 Ιουλίου 2000 έως τις 15 Ιουλίου 2019. Οι μελέτες θεωρήθηκαν κατάλληλες εφόσον είχαν τοποθετήσει τους συμμετέχοντες τυχαία σε τουλάχιστον δύο γκρουπ θεραπείας και εφόσον συμπεριελάμβαναν ασθενείς με χρόνια οσφυαλγία. Για την ανάλυση των δεδομένων σχετικά με την εκτίμηση της ποιότητας συγγραφής των RCTs, χρησιμοποιήθηκε περιγραφική και αναλυτική στατιστική.

Αποτελέσματα: Από την αναζήτηση προέκυψαν είκοσι RCTs κατάλληλες για ανάλυση. Από τα αντικείμενα του CONSOSRT περίπου το 32,43% (12/37) αναφερόταν στο >75% των μελετών. Η μέση τιμή του CONSORT score αποδείχθηκε χαμηλή καθ 'όλη τη διάρκεια της καθορισμένης χρονικής περιόδου, καθώς ήταν 57% για το σύνολο των μελετών, 58% για την πρώτη χρονική περίοδο και 56% για τη δεύτερη περίοδο.

Συμπέρασμα: Οι τυχαιοποιημένες ελεγχόμενες μελέτες (RCTs) που σχετίζονται με τη διαπεταλιακή, επισκληρίδια έγχυση φαρμάκων για χρόνια οσφυαλγία, παρουσίασαν χαμηλή ποιότητα συγγραφής. Όπως φαίνεται, δεν υπήρξε καμία βελτίωση από το 2000 έως σήμερα, παρά την ύπαρξη του CONSOR statement. Δεδομένου ότι η ακρίβεια κατά την συγγραφή των RCTs είναι αφενός άρρηκτα συνδεδεμένη με τη βασιζόμενη σε τεκμήρια πληροφόρηση και αφετέρου βοηθά στην αξιολόγηση της εγκυρότητας των αποτελεσμάτων των RCTs, καθίσταται υποχρεωτική η περαιτέρω βελτίωση της συγγραφικής ποιότητας των RCTs σχετικά με τη διαπεταλιακή, επισκληρίδια έγχυση φαρμάκων για χρόνια οσφυαλγία προκειμένου να βοηθηθούν οι επαγγελματίες στη λήψη κλινικών αποφάσεων.

2. Introduction

By the late 20th century, RCT is recognized as the ‘‘gold standard’’ within the hierarchy of clinical studies. The first reported clinical trial was conducted by James Lind in 1747, while the first published RCT in medicine appeared in the 1948. Despite the fact that an RCT can be expensive or that special ethic considerations may revile when an RCT is conducted, RCTs are considered to be the most reliable form of scientific evidence that influences healthcare policy and practice because RCTs reduce spurious causality and bias (1-2). Results of RCTs may be combined in systematic reviews which are increasingly being used in the conduct of evidence-based practice (3).

In an RCT subjects are randomly allocated to two or more groups. The experimental group has the intervention being assessed, while the other (usually called the control group) has an alternative intervention, such as a placebo or no intervention. Each trial has its own careful defined design. A randomized controlled trial aims to reduce certain sources of bias when testing the effectiveness of new treatments. Both randomization and blinding, the corn stones of RCTs are necessary in order to accomplish this goal. Good blinding may reduce or eliminate some sources of experimental and subject bias. On the other hand, the randomness in the assignment of subjects to groups reduces selection and allocation bias, balancing both known and unknown prognostic factors, in the assignment of treatments. It is of paramount importance to mention that not all randomized clinical trials are randomized controlled trials. Although, the terms "RCT" and "randomized trial" are sometimes used synonymously they do differ since the latter term omits mention of controls and can therefore describe studies that compare multiple treatment groups with each other in the absence of a control group.

Unfortunately, not all RCTs are completely and comprehensibly conducted and reported, so that important information is missing decreasing their liability and making it impossible to have applicable results. In most times the problem generates at the design of the RCT. Other times it is the low reporting quality and improper interpretation of information that counts for gaps in many RCTs found in the literature (3). In order to improve the reporting of RCTs in the medical literature, an international group of scientists and editors published Consolidated Standards of Reporting Trials (CONSORT) Statements in 1996, 2001 and 2010, and these have become widely accepted (4-6).

The CONSORT 2010 guideline through its primary goal, to improve the reporting of RCTs, is intended to enable readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results. This can only be achieved through complete adherence and transparency by authors. CONSORT 2010 was developed through collaboration and consensus between clinical trial methodologists, guideline developers, knowledge translation specialists, and journal editors. It comprises the current version of the guideline and supersedes the 2001 and 1996 versions. It contains a 25-item checklist (many with sub-items) and flow diagram, freely available for viewing and downloading through this website. For other RCT study designs, "CONSORT extensions" have been published (4-6).

The purpose of this study is to assess the reporting quality of RCTs regarding to interlaminar epidural injections in chronic low back pain based on CONSORT checklist. This treatment was chosen for assessment since epidural injections are one of the most commonly performed interventions for managing chronic low back pain. However, there is no consensus on how epidural injection therapy should be done with respect to the method used for epidural injections. Lumbar epidural steroid injections can be accomplished by one of three methods: caudal (C), interlaminar (IL), or transforaminal (TF). While TF approach is considered more efficacious than the midline IL approach, concerns regarding the safety of this approach led to search for a technically better route with lesser complications (7).

3. Materials and methods

3.1 Selection of RCTs

In this study, we searched PubMed and Cochrane library databases for reports on RCTs regarding interlaminar epidural injections in chronic low back pain from July 15, 2000 through July 15, 2019. We used "((((((((((((((chronic low back pain) OR (chronic mild back OR upper back pain)) OR chronic lumbar pain) OR discogenic pain) OR herniated lumbar discs) OR lumbosciatic pain) OR radicular pain) OR radiculitis) OR sciatica) OR spinal stenosis) OR sciatic pain) OR lumbar herniation) AND (((((((interlaminar epidural injection) OR interlaminar epidural steroid) OR epidural perineural injection) OR interlaminar epidural) OR nerve root blocks) OR periradicular infiltration) OR interlaminar epidural corticosteroid) OR interlaminar epidural local anesthetics))" as search term. All references cited in the retrieved articles were also reviewed to identify additional published work not indexed by PubMed or Cochrane. We used as filters the ''Randomized Controlled Trial'' for type of article, the "Human" for species and the ''English'' for language. References were also screened for eligibility in the study.

3.2 Eligibility criteria

Studies were considered eligible if:

• they had randomly assigned participants to at least two treatment arms and included patients with chronic low back pain

• they were in English language

Studies were excluded if:

•they were trials which used animals

•they were subgroups analysis, observational studies nested within RCTs and trials without the outcomes

• they were trials referred to management of persistent post-operative lumbar pain or acute/sub acute lumbar pain

3.3 Data extraction and quality assessment

The evaluation of methodological quality was performed according to 25-items with sub-items (total 37 items) described in the 2010 CONSORT statement (4-6). We used the CONSORT explanation and elaboration document (available at the CONSORT web page) as guidelines (8). Out of the total of 20 eligible trials 2 articles were published before 2010 and 18 after 2010. We used the revised CONSORT version for all extracted articles either or not published before 2010 when the revised CONSORT version was published. All items were investigated in terms of whether they were reported in articles, not whether they were actually carried out during the trial. Each item was assigned a yes or no response depending on whether the item was included in this study report. Alternatives responses (apart from yes or no) and unclear responses to each question were coded as negative responses. When an item was reported in a different section of the trial (title, abstract, methods, results, discussion) it was considered as a negative response, except for the "other information" section, which was considered as positive regardless of where it was mentioned. Finally, the quality assessment of each article was performed comprehensively. We separated articles in two time periods from 2000 to 2014 (period before the revision of CONSORT and the first five years after its revision) and from 2015 to 2019 (period five years after CONSORT revision).

3.4 Statistical analysis

Descriptive statistics (mean, median, standard deviation) were used to describe important issues raised from the evaluation of the assessed studies. Firstly, we calculated the mean CONSORT compliance of all the articles and the mean CONSORT compliance of the two different periods. Then, we calculated the greater than 75% compliance with the CONSORT statement items, i.e. the percentage of the articles (overall and by time period) that addressed at least 75% of the 37 checklist items. Compliance with the CONSORT items more than 75% was regarded as an adequate cut-off in a number of studies (9-10). Comparison between >75% compliance among different time periods was made using the Pearson chi-square statistic. We calculated the percentage of reporting of each item for the two different periods and for the total period (2000-2019). We also calculated the percentage of the items that was reported in at least 75% of the articles for the 15-year period and in each one of the two time periods. We calculated the median CONSORT compliance of the articles published in journals with current Impact Factor greater than three and lower than three and we performed a Kruskal-Wallis non parametric test to compare the two groups. We also performed linear regration analysis to assess the correlation of CONSORT score with the Journal Impact Factor. A p-value of less than 0.05 was considered significant. All statistical analyses were performed using Statistical Program for Social Sciences (SPSS v. 25.0) for Windows.

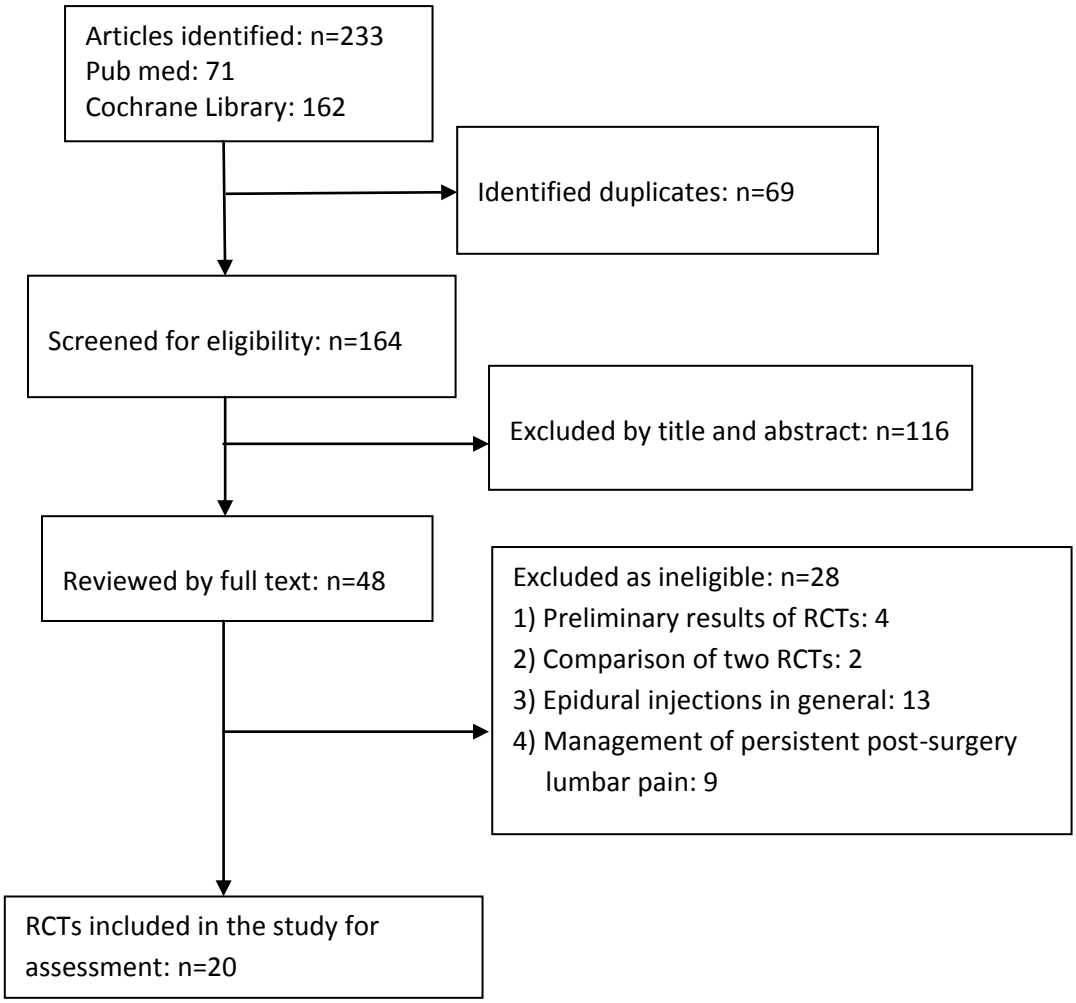
4. Results

4.1 Eligible Studies

The initial search in PubMed and Cochrane library databases yielded 233 studies of which 69 were excluded because of duplicate records. After the title and abstract review, 116 studies were excluded (they were not relevant or not randomized trials), leaving 48 for full-text review. Of those remaining

studies were excluded since they were preliminary results of RCTs that have already been completed. Thus, we decided to include only the final studies in our assessment because both the article of preliminary results and that of the final study had been written from the same author and in the same manner. Moreover, 2 studies were excluded as they were comparison studies of two RCTs and 13 studies were excluded because they were referred to epidural injections in general and not to the interlaminar technique. Other 9 studies were excluded since they had to do with the management of persistent post-surgery lumbar pain. Ultimately, 20 RCTs that met the inclusion criteria were included for assessment (11-30). A flowchart of the literature search strategy is shown in **Figure 1**.

Figure 1. Flowchart



4.2 Main Results

Out of the total of 20 eligible trials, 12 were published the period 2000-2014, that is, the period before the revision of CONSORT and the first five years after its revision and 8 were published the period 2015

to 2019, that is, five years after the revision of CONSORT statement. The articles were published in 11 different scientific journals. Assessed RCTs along with their publication date, their CONSORT score and the journal where they were published are shown in **Table 1.** The mean CONSORT compliance of the articles in the first time period was 57, 87% compared with the second time period that it was 56, 38%. The mean CONSORT compliance of the total articles was 57, 25%. Moreover, RCTs that covered more than 75% of the CONSORT items where overall 5 (25%), in the time period 2000-2014 were 3 (25%) and in the time period 2015-2019 were 2 (25%), showing no alteration in compliance with CONSORT among the different periods. Pearson chi-square analysis: (p-value 1>0,05, Odds Ratio: 1, CI: 0.127, 7.893). There were 4 articles with a CONSORT compliance of 86%, all of them written by the same author, Laxmaiah Manchikanti, who had stated explicitly in each of these articles that the CONSORT statement was used to guide the reporting of them.

Table 1. RCTs with information regarding publication year, CONSORT score, journal where they were published and impact factor of each journal.

RCT	PUBLICATION YEAR	JOURNAL	IF	CONSORT SCORE
William E. Ackerman et al.	2007	Anaesthesia and analgesia	3,489	17/37 (46%)
Kenneth D. Candido et al.	2008	Anaesthesia and analgesia	3,489	16/37 (43%)
Irina Evansa et al.	2014	EJA	4,140	21/37 (57%)
Babita Ghai et al.	2013	Anaesthesia and analgesia	3,489	25/37 (68%)
James Milburn et al.	2014	Ochsner	0,70	14/37 (38%)
Ruchi Gupta et al.	2014	KJP	1,563	20/37 (54%)
Laxmaiah Manchikanti et al.	2012	Pain practice	2,486	32/37 (86%)
Laxmaiah Manchikanti et al.	2013	Pain physician	2,942	32/37 (86%)
Laxmaiah Manchikanti et al.	2014	Pain physician	2,942	32/37 (86%)
Ivan Rados et al.	2011	Pain medicine	2,782	15/37 (41%)
Fαtima Aparecida Emm Faleiros Sousa et al.	2011	Rev Bras Anestesiol	0,968	12/37 (32%)
Kenneth D. Candido et al.	2013	Pain physician	2,942	21/37 (57%)
Amr Atteya Soliman et al.	2018	Curent Orthopedics practice	0,16	14/37 (38%)

Seyed Masoud Hashemi et al.	2015	Pain physician	2,942	26/37 (43%)
Jeetinder Kaur Makkar et al.	2015	Pain physician	2,942	24/37 (65%)
Babita Ghai et al.	2015	Pain physician	2,942	30/37 (81%)
Eung Don Kim et al.	2016	Pain medicine	2,782	21/37 (57%)
Laxmaiah Manchikanti et al.	2015	Pain physician	2,942	32/37 (86%)
Korgün Ökmen et al.	2016	The spine journal	3,024	16/37 (43%)
Seyed Masoud Hashemi et al.	2015	Anaesthesia and pain medicine	0,49	14/37 (38%)

Percentages of CONSORT items reported by time period and by the total of RCTs are presented in **Table 2**. We did not find statistical significant difference between the two time periods regarding the reporting of the 37 items included in CONSORT except for item 19 (All important harms or unintended effects in each group), (percentage of reporting in first time period 83%, percentage of reporting in the second time period 38%, Odds Ratio: 8,333, CI:1.034, 67.142, P-value: 0,035) and item 22 (Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence), (percentage of reporting in first time period 92%, percentage of reporting in the second time period 100%, Odds Ratio: 11, CI:1.137, 106,430, P-value: 0,019). 12 items (32,43%) were reported in >75% of the articles in the whole period 2000-2019, while the respective number in both periods 2000-2014 and 2015-2019 was 14 (37,83%) showing a steadiness in reporting of CONSORT items among the two time periods.

Table 2. CONSORT items reported by time period and by the total of RCTs.

CONSORT ITEMS	2000-2014 (n=12)	2015-2019 (n=8)	COMPINED 2000-2019 (n=20)	p-value
ABSTRACT / TITLE				
1a	6/12 (50%)	4/8 (50%)	10/20 (50%)	1
1b	REPORTED IN ALL RCTs			
INTRODUCTION				
2a	REPORTED IN ALL RCTs			
2b	REPORTED IN ALL RCTs			
METHODS				
3a	5/12 (42%)	7/8 (86%)	12/20 (60%)	0,4
3b	REPORTED IN NO RCT			
4a	REPORTED IN ALL RCTs			
4b	6/12 (50%)	3/8 (38%)	9/20 (45%)	0,582
5	REPORTED IN ALL RCTs			

6a	6/12 (50%)	6/8 (75%)	12/20 (60%)	0,264
6b	REPORTED IN NO RCT			
7a	9/12 (75%)	3/8 (38%)	12/20 (60%)	0,094
7b	REPORTED IN NO RCT			
8a	8/12 (67%)	7/8 (86%)	15/20 (75%)	0,292
8b	6/12 (50%)	6/8 (75%)	12/20 (60%)	0,264
9	5/12 (42%)	4/8 (50%)	9/20 (45%)	0,714
10	3/12 (25%)	2/8 (25%)	5/20 (25%)	1
11a	8/12 (67%)	6/8 (75%)	14/20 (70%)	0,690
11b	5/12 (42%)	5/8 (63%)	10/20 (50%)	0,361
12a	11/12 (92%)	5/8 (63%)	16/20 (80%)	0,110
12b	6/12 (50%)	3/8 (38%)	9/20 (45%)	0,582
RESULTS				
13a	9/12 (75%)	5/8 (63%)	14/20 (70%)	0,550
13b	REPORTED IN ALL RCTs			
14a	3/12 (25%)	2/8 (25%)	5/20 (25%)	1
14b	REPORTED IN NO RCT			
15	REPORTED IN ALL RCTs			
16	REPORTED IN ALL RCTs			
17a	8/12 (67%)	4/8 (50%)	12/20 (60%)	0,456
17b	6/12 (50%)	4/8 (50%)	10/20 (50%)	1
18	6/12 (50%)	3/8 (38%)	9/20 (45%)	0,582
19	10/12 (83%)	3/8 (38%)	13/20 (65%)	0,035
DISCUSSION				
20	10/12 (83%)	5/8 (63%)	15/20 (75%)	0,292
21	3/12 (25%)	2/8 (25%)	5/20 (25%)	1
22	11/12 (92%)	8/8 (100%)	19/20 (95%)	0,019
OTHER INFORMATION				
23	3/12 (25%)	2/8 (25%)	5/20 (25%)	1
24	3/12 (25%)	3/8 (38%)	6/20 (30%)	0,550
25	6/12 (50%)	3/8 (38%)	9/20 (45%)	0,582

The median compliance of the articles published in journals with IF<3, was 54% while it was 46% for articles published in journals with IF>3, and the difference between the two groups found not statistically significant (KW test, p-value=0.826). Furthermore, we found that there was no linear regression between CONSORT score and journal's Impact Factor (Pearson correlation 0,385, p-value: 0,094).

5. Discussion

This appears to be the first study investigating the quality of reporting of RCTs for interlaminar epidural injections in chronic lumbar pain relative to the CONSORT checklist. This study suggests, that the quality

of reporting of RCTs relative to that specific issue is still not optimal and no improvement has been made on reporting from 2000 till today, despite the existence and revision of CONSORT statement. Out of 37 items of the CONSORT checklist only 12 (32%) were addressed in 75% or more of the studies published in the period between 2000 and 2019, while there were many items that were generally underreported. On this stage we have to mention that some of the items included in CONSORT checklist were not applicable in our trials like the item 3b (Important changes to methods after trial commencement, with reasons), 6b (Any changes to trial outcomes after the trial commenced, with reasons), 7b (Explanation of any interim analyses and stopping guidelines) and 14b (Why the trial ended or was stopped).

As we have already mentioned, 10 items were reported in less than the half of the studies. These items along with their percentages of reporting for the whole period (2000-2019) and for each period (2000-2014 and 2015-2019) were 4b (Settings and locations where the data were collected, 45%, 50%, 38%), 9 (Mechanism used to implement the random allocation sequence describing any steps taken to conceal the sequence until interventions were assigned, 45%, 42%, 50%), 10 (Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions, 25%, 25%, 25%), 12b (Methods for additional analyses, 45%, 50%, 38%), 14a (Dates defining the periods of recruitment and follow-up, 25%, 25%, 25%), 18 (Results of any other analyses performed, 45%, 50%, 38%), 21(Generalisability of the trial findings, 25%, 25%, 25%), 23 (Registration number and name of trial registry, 25%, 25%, 25%), 24 (Where the full trial protocol can be accessed, 30%, 25%, 38%) and 25 (Sources of funding and other support, role of funders, 45%, 50%, 38%). It is obvious that important methodological information (items 9 and 10) and information regarding dates of recruitment and follow-up (item 14a) was underreported. Significant underreporting was also observed in the whole part of “Other Information”. In addition, item 7a (How sample size was determined) was reported in less than 50%, (38%), of RCTs in the period 2015-2019 and item 11b (If relevant, description of the similarity of interventions) was reported in less than 50%, (42%) of RCTs in the period 2000-2014. However, not statistical significant difference was observed in reporting for either of these items between the two time periods (p-value>0, 05).

On the other hand, 32,43% (12/37) of the items were reported to 75% or more of RCTs. These items were for the whole period (2000-2019) and for each period (2000-2014 and 2015-2019) along with their percentage of reporting, item 1b (Structured summary of trial design, methods, results, and conclusions, reported in all RCTs), 2a (Scientific background and explanation of rationale, reported in all RCTs), 2b (Specific objectives or hypotheses, reported in all RCTs), 4a (Eligibility criteria for participants, reported in all RCTs), 5 (The interventions for each group with sufficient details to allow replication, including how and when they were actually administered, reported in all RCTs), 8a (Method used to generate the random allocation sequence, 75%, 67%, 86%), 12a (Statistical methods used to compare groups for primary and secondary outcomes, 80%, 92%, 63%), 13b (For each group, losses and exclusions after randomisation, together with reasons, reported in all RCTs), 15 (A table showing baseline demographic and clinical characteristics for each group, reported in all RCTs), 16 (For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups, reported in all RCTs), 20 (Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses, 75%, 83%, 63%) and 22 (Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence, 95%, 92%, 100%). Moreover, items 7a (How sample size was determined), 12a (Statistical methods used to compare groups for primary and secondary outcomes) and 19 (All important harms or unintended effects in each group)

were reported with percentages 75%, 75% and 83% respectively in RCTs during the period 2000-2014, while items 3a (Description of trial design including allocation ratio), 6a (Completely defined pre-specified primary and secondary outcome measures), 8b (Type of randomization) and 11a (If done, who was blinded after assignment to interventions) were reported in percentages 86%, 75%, 75% and 75% respectively in the RCTs during the period 2015-2019. Statistical significant different between the two time periods was found only for item 19, (p-value<0,05), with the RCTs between 2000-0014 reporting the item more frequently.

Furthermore, we performed statistical analysis in order to investigate any relation between CONSORT compliance and the different journals where RCTs were published. We did not find statistical significant difference regarding CONSORT compliance between RCTs reported in journals with Impact Factor<3 and RCTs reported in journals with Impact Factor>3. Neither the linear regression analysis showed any association between CONSORT compliance and Journal's Impact Factor. Thus, we can support that the Impact Factor of the journal did not influence the reporting quality of RCTs.

We observed that 4 out of 5 RCTs that had a CONSORT compliance greater than 75% (86%) had been written by the same author, Laxmaiah Manchikanti (23-26). Three of them were published during 2000-2014 and one during 2015-2019. In addition, 3 of them were published in Pain Physician Journal (IF: 2,942) and one was published in Pain Practice Journal (IF: 2, 486). In our study we included also RCTs that had been published in the same Journals (Pain Physician) but had CONSORT compliance less than 75%. Thus, we can claim that in our study the reporting quality of RCTs was more closely related to the author than to the journal where they had been published or to the time period that they had been written. However, all of the RCTs that had a high quality of reporting (>75%) had been written after 2010 when the CONSORT checklist was revised.

It has been known for some time that the quality of reporting has significantly improved in the medical literature with the adoption of the CONSORT guidelines (31). Transparency and accuracy of RCT reporting contributes to the evidence-based information for the profession and will make assessing the validity of RCT results easier. Improving quality of reporting of RCTs related to interlaminar epidural injections can help pain-medicine professionals to improve their clinical decision making, leading to better outcomes for patients. The result gained from this study should be viewed as an opportunity for improvement in reporting of RCTs and enhancement in awareness regarding to the importance of using the CONSORT statement amongst pain-physicians. To enhance the practice of evidence-based medicine, researchers are encouraged to implement the CONSORT guidelines with greater rigor, especially in reporting of key methodological items. In addition, journal editors and authors should certify that each RCT that is to be published comply with the CONSORT checklist.

This study has its weaknesses. Firstly, we used the revised CONSORT 2010 checklist for all the trials despite they were published before or after its publication. Moreover, since there had been a few RCTs published by the time we performed our study, the number of RCTs included in the assessment was small (only 20). In addition, 4 out of 5 RCTs that showed >75% adherence to CONSORT checklist had been written by one author who followed the same manner in writing. Finally, some of the items included in CONSORT checklist were not applicable in our trials, thus we had to assign them as NO during the assessment and so the final CONSORT score was underestimated in all of the RCTs.

In conclusion, our attempt to assess the quality of RCTs, centering on Interlaminar Epidural Injections on

chronic low back pain, indicated no improvement on reporting of RCTs by time period. The Impact Factor of journals dealing with management of chronic lumbar pain seems to have no association with the reporting quality of RCTs published on them. In the area of management of chronic lumbar pain which is still searching for an effective treatment, further improving the quality of RCTs and their reporting could assist health care providers to their clinical decisions, increase the clinical significance of RCTs and direct more specifically future medical research.

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