Orthopaedics & Traumatology: Surgery & Research 105 (2019) 791–793

Contents lists available at ScienceDirect

Orthopaedics & Traumatology: Surgery & Research

journal homepage: www.elsevier.com

Letter to the Editor

Reply to the letter set to the *OTSR* editorial board by Federico Solla, Antoine Tran, and Virginie Rampal. Level of evidence criteria: Distinguishing level 3 from level 4 therapeutic studies

Dear colleagues,

Your correspondence to the editorial board of *Orthopaedics and Traumatology: Surgery and Research* (*OTSR*) has received our careful attention. The criteria you apply to assess the level of evidence of three articles published in *OTSR* [1–3] differ from those applied by the editorial board. The arguments put forward in your letter indicate a need to describe the latter in detail, both to assist authors and to improve practice uniformity among editorial board members. Therefore, this reply describes the criteria applied by *OTSR*, which comply with the recommendations issued by the Centre for Evidence-Based Medicine [4] and are consistent with the table of criteria provided when *OTSR* was first published [5]. We will then discuss the classification of the articles mentioned in your letter [1–3,6–11].

1. Level of evidence criteria

One of the distinctions made by the criteria used by *OTSR* (Table 1) is between therapeutic and prognostic studies. Prognostic studies assess the course of a health condition. Studies of patient outcomes after a specific treatment do not fall within this category but belong instead to the therapeutic study category. The criteria for classifying therapeutic studies as level 3 or level 4 are detailed below.

Level 3 therapeutic studies include several study designs. A well-conducted case-control study provides level 3 evidence. These studies compare a group of patients having achieved a health-related endpoint (cases) to a group that has not achieved this endpoint (controls). Exposures potentially related to achieving versus not achieving the endpoint are then sought retrospectively. Level 3 therapeutic studies also include retrospective studies comparing patients with versus without an exposure: the cases are exposed to a factor (as part of their own circumstances, not experimentally) to which the controls are not exposed. The study compares the health outcomes between the cases and controls. The patient inclusion criterion must be assessed at a time when the health outcomes are unknown. Also in the level 3 category are retrospective cohort studies, in which patient inclusion does not depend on exposure status or health outcome. These two study designs fall into the 'retrospective study' category in the table. In addition, according to the accepted terminology, the term 'cohort studies' can include studies comparing exposed to unexposed patients. Finally, level 3 includes systematic literature reviews focussing on studies having any of the above-described designs.

Level 4 includes non-comparative studies. Studies in this category may be performed in patients who were all exposed to the same treatment, although exposures other than the treatment may be assessed also. Alternatively, the patient population may be composed of individuals who all have the same health outcome. In analogy with the criteria for levels 1 and 2, the *OTSR* editorial board classifies studies that would appear to meet level 3 criteria as level 4 studies because they have major sources of bias that challenge the validity of the comparison.

2. Analysis of the classification of thirteen articles

We will now detail the criteria used to classify the articles that caught your attention [1–3,6–11]. For one of these three articles [1], we suggest a different category.

Mercier et al. [1] conducted a retrospective therapeutic study comparing two groups of patients who received the same treatment but differed regarding another exposure (dysplasia, yes/no). We agree with you that this study did not use a case-control design, contrary to the statement by the authors. Although, by definition, no indication bias can have occurred, there is a risk of bias related to reporting non-significant differences, although the sample size was small. Furthermore, a large number of patients were lost to follow-up. We therefore consider that the stated level of evidence should have been 4 and not 3 for this study.

The study by Le Baron et al. [2] is a retrospective therapeutic study comparing exposed to unexposed patients. There is a risk of indication bias, since the decision to perform surgery (the exposure) was not random. However, this bias, in conjunction with the seemingly adequate sample size, would decrease the likelihood of obtaining the observed results. We therefore classified this study as providing level 3 evidence.

The study by Mehdi et al. [3] is a retrospective therapeutic comparison of exposed and unexposed patients. Undocumented selection bias may have occurred, as the manner in which the two groups, each composed of 25 patients, were obtained is unknown, despite the 69-month inclusion period. Furthermore, there is a major risk of indication bias, and we therefore considered that this study provided level 4 evidence.

El Batti et al. [6] performed a retrospective therapeutic study of exposed versus unexposed patients. Major indication bias occurred, resulting in a difference being found by bivariate analysis but not by multivariate analysis. The final non-significant result is difficult to interpret, particularly given the limited statistical power. These sources of bias warrant classification as a level 4 study.

Finally, the study by Sabah et al. [9] is also a retrospective therapeutic study of exposed versus unexposed patients. The small sample size resulted in limited statistical power for detecting a

DOIs of original articles:https://doi.org/10.1016/j.otsr.2019.03.013, https://doi.org/10.1016/j.otsr.2018.10.014, https://doi.org/10.1016/j.otsr.2018.10.011, https://doi.org/10.1016/j.otsr.2018.10.015

https://doi.org/10.1016/j.otsr.2019.04.002

Table 1
Levels of evidence for primary research question [a] according to guidelines issued by the Centre for Evidence-Based Medicine (http://www.cebm.net/index.aspx?o=5653).

Level	Therapeutic studies — Investigating the results of treatment	Prognostic studies — Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic studies—Investigating a diagnostic test	Economic and decision analyses — Developing an economic or decision model
I	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic review[b] of Level I RCTs (and study results were homogenous[c])	High quality prospective study[d] (all patients were enrolled at the same point in their disease with P80% of enrolled patients) Systematic review[b] of level I studies	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review[b] of level I studies	Sensible costs and alternatives; values obtained from many studies; with multi-way sensitivity analyses Systematic review[b] of level I studies
II	Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) Prospective[d] comparative study[e] Systematic review[b] of Level II studies or Level I studies with inconsistent results	Retrospective[f] study Untreated controls from an RCT Lesser quality prospective study (e.g. patients enrolled at different points in their disease or < 80% follow-up) Systematic review[b] of Level II studies	Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review[b] of Level II studies	Sensible costs and alternatives; values obtained from limited studies; with multi-way sensitivity analyses Systematic review[b] of Level II studies
III	Case-control study[g] Retrospective[f] comparative study[e] Systematic review[b] of Level III studies	Case-control study[g]	Study of non-consecutive patients; without consistently applied reference "gold" standard Systematic review[b] of Level III studies	Analyses based on limited alternatives and costs; and poor estimates Systematic review[b] of Level III studies
IV	Case series[h]	Case series	Case-control study Poor reference standard	Analyses with no sensitivity analyses
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

[a] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
[b] A combination of results from two or more prior studies.
[c] Studies provided consistent results.
[d] Study was started before the first patient enrolled.
[e] Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
[f] The study was started after the first patient enrolled.
[g] Patients identified for the study based on their outcome, called "cases" e.g. failed total arthroplasty, are compared with patients who did not have outcome, called "controls" e.g. successful total hip arthroplasty.
[h] Patients treated one way with no comparison group of patients treated in another way.

difference. The observed difference was not statistically significant. This bias warrants classification as a level 4 study. Finally, the last studies mentioned [7,8,10,11] included only patients exposed to a given treatment and are therefore level 4.

3. Conclusion

We are grateful for your query, which has allowed us to explain the classification criteria and to identify an inconsistency in the classification of one of the 13 cited articles. Increasing uniformity among practices of the *OTSR* editors is a key short-term priority, as further emphasised by your letter. Importantly, it is the responsibility of the authors to indicate a level of evidence, which is then confirmed or corrected by the reviewers and/or the editor assigned to the manuscript. To support the level of evidence claimed for their study, the authors must, when appropriate, highlight the comparative nature of the study design and absence of bias, in compliance with *OTSR* instructions for authors [5].

Disclosure of interest

H.M. is an associate editor of *Orthopaedics and Traumatology: Surgery and Research*; independently from this reply, H.M. is an education and research consultant for Zimmer-Biomet, Corin, SERF, and MSD.

P.B. is the editor-in-chief of *Orthopaedics and Traumatology: Surgery and Research*.

R.S. and E.C. declare that they have no competing interest.

Funding

None.

Contributions

E.C. and H.M. wrote the manuscript.

P.B. and R.S. revised the manuscript and approved the final submitted version.

References

[1] Mercier M, Dangin A, Ollier E, Bonin N. Does acetabular dysplasia affect outcome in arthroscopic treatment of cam femoroacetabular impingement? Case-control study with and without acetabular dysplasia. Orthop Traumatol Surg Res 2019;105:7–10.
[2] Le Baron M, Cermolacce M, Flecher X, Guillotin C, Bauer T, Ehlinger M. SoFCOT. Tibial plateau fracture management: ARIF versus ORIF–clinical and radiological comparison. Orthop Traumatol Surg Res 2019;105:101–6.
[3] Mehdi N, Bernasconi A, Laborde J, Lintz F. Comparison of 25 ankle arthrodeses and 25 replacements at 67 months' follow-up. Orthop Traumatol Surg Res 2019;105:139–44.
[4] Centre for Evidence-Based Medicine. Levels of Evidence. https://www.cebm.net/2016/05/ocebm-levels-of-evidence/. Access February 1, 2019.
[5] Note for authors of Orthopaedics and Traumatology: Surgery and Research. http://www.em-consulte.com/getInfoProduit/RCOT/instructionsAuteurs/RCOT.pdf. Access February 1, 2019.
[6] El Batti S, Solla F, Clément JL, Rosello O, Oborocianu I, Chau E, et al. Initial treatment of congenital idiopathic clubfoot: Prognostic factors. Orthop Traumatol Surg Res 2016;102:1081–5.
[7] Rosello O, Solla F, Oborocianu I, Chau E, Yagoubi F, Clément JL, et al. Too-long calcaneal process: Results of surgical treatment and prognostic factors. Orthop Traumatol Surg Res 2016;102:663–7.

[8] Clément JL, Solla F, Tran A, Morin C, Lakhal W, et al. Five-year outcomes of the First Distal Uninstrumented Vertebra after posterior fusion for Adolescent Idiopathic Scoliosis Lenke 1 or 2. Orthop Traumatol Surg Res 2017;103:727–31.
[9] Sabah Y, Clément JL, Solla F, Rosello O, Rampal V. Cobalt-chrome and titanium alloy rods provide similar coronal and sagittal correction in adolescent idiopathic scoliosis. Orthop Traumatol Surg Res 2018;104:1073–7.
[10] Muccioli C, ElBatti S, Oborocianu I, Rosello O, Solla F, Chau E, et al. Outcomes of Gartland type III supracondylar fractures treated using Blount's method. Orthop Traumatol Surg Res 2017;103:1121–5.
[11] Thomas J, Rosello O, Oborocianu I, Solla F, Clement JL, Rampal V. Can Gartland II and III supracondylar humerus fractures be treated using Blount's method in the emergency room? Orthop Traumatol Surg Res 2018;104:1079–81.

Henri Migaud [a,b,*]
Emmanuel Chazard [c]
Raphaël Seringe [b,d]
Philippe Beaufils [b]
[a] *PMOI EA4490, service d'orthopédie, université de Lille, hôpital Salengro, CHU de Lille, Place de Verdun, 59000 Lille, France*
[b] *Orthopaedics and traumatology: surgery and research editorial office, 56, rue Boissonade, 75014 Paris, France*
[c] *CERIM EA2694, université de Lille, Public Health Department, Place de Verdun, CHU de Lille, 59000 Lille, France*
[d] *Service d'orthopédie, hôpital Cochin-Saint-Vincent-de-Paul, 27, rue du Faubourg Saint-Jacques, 75674 Paris cedex 14, France*

* Corresponding author at: Département universitaire de chirurgie orthopédique et de traumatologie, hôpital Salengro, Place de Verdun, 59037 Lille, France.
E-mail address: hemigaud@nordnet.fr (H. Migaud)

Received 26 February 2019

Accepted 25 March 2019