Because of specific methodological difficulties in conducting Randomized controlled trials, surgical research remains dependent predominantly on observational or non-randomized studies. Few validated instruments are available to determine the methodological quality of such studies either from the reader's perspective or for the purpose of meta-analysis. The aim of a study was to develop and validate such an instrument.

After an initial conceptualization phase of a methodological index for non-randomized studies (MINORS), a list of 12 potential items was sent to 100 experts from different surgical specialties for evaluation and was also assessed by 10 clinical methodologists. Subsequent testing involved the assessment of inter-reviewer agreement, test-retest reliability at 2 months, internal consistency reliability and external validity.

The final version of MINORS contained 12 items, the first eight being specifically for non-comparative studies. Reliability was established on the basis of good inter-reviewer agreement, high test-retest reliability by the kappa-coefficient and good internal consistency by a high Cronbach's alpha-coefficient. External validity was established in terms of the ability of MINORS to identify excellent trials.

MINORS is a valid instrument designed to assess the methodological quality of non-randomized surgical studies, whether comparative or non-comparative. The next step will be to determine its external validity when used in a large number of studies and to compare it with other existing instruments [1)].

Methodological items for non-randomized studies	Score†
1. **A clearly stated aim:** the question addressed should be precise and relevant in the light of available literature	
2. **Inclusion of consecutive patients**: all patients potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion)	
3. **Prospective collection of data**: data were collected according to a protocol established before the beginning of the study	
4. **Endpoints appropriate to the aim of the study**: unambiguous explanation of the criteria used to evaluate the main outcome which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an intention-to-treat basis.	
5. **Unbiased assessment of the study endpoint**: blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise the reasons for not blinding should be stated	
6. **Follow-up period appropriate to the aim of the study**: the follow-up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events	
7. **Loss to follow up less than 5%**: all patients should be included in the follow up. Otherwise, the proportion lost to follow up should not exceed the proportion experiencing the major endpoint	
8. **Prospective calculation of the study size**: information of the size of detectable difference of interest with a calculation of 95% confidence interval, according to the expected incidence of the outcome event, and information about the level for statistical significance and estimates of power when comparing the outcomes	
Additional criteria in the case of comparative study	
9. **An adequate control group**: having a gold standard diagnostic test or therapeutic intervention recognized as the optimal intervention according to the available published data	
10. **Contemporary groups**: control and studied group should be managed during the same time period (no historical comparison)	
11. **Baseline equivalence of groups**: the groups should be similar regarding the criteria other than the studied endpoints. Absence of confounding factors that could bias the interpretation of the results	
12. **Adequate statistical analyses**: whether the statistics were in accordance with the type of study with calculation of confidence intervals or relative risk	

†The items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The global ideal score being 16 for non-comparative studies and 24 for comparative studies.

1)

Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological index for non-randomized studies (minors): development and validation of a new instrument. ANZ J Surg. 2003 Sep;73(9):712-6. PubMed PMID: 12956787.