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Original article

Methodological quality of articles on therapeutic procedures published in *Cirugía Española*. Evaluation of the period 2005–2008

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A B S T R A C T

Aim: To determine methodological quality of therapy articles published in Cirugía Española and to study its association with the publication year, the centre of origin and subjects.
Material and methods: A literature study which included all therapy articles published between 2005 and 2008. All kinds of clinical designs were considered, excluding editorials, review articles, letters to editor and experimental studies. Variables analysed included: year of publication, centre of origin, design, and methodological quality of articles. A valid and reliable scale was applied to determine methodological quality.
Results: A total of 243 articles (206 series of cases [84.8%], 27 cohort studies [11.1%], 9 clinical trials [3.7%] and 1 case control study [0.4%]) were found. Studies came preferentially from Catalonia and Valencia (22.3% and 12.3% respectively). Thematic areas most frequently found were hepato-bilio-pancreatic and colorectal surgery (20.0% and 16.6%, respectively). Average and median of the methodological quality score calculated for the entire series were 9.5 ± 4.3 points and 8 points, respectively. Association between methodological quality and geographical area (P=.0101), subject area (P=.0267), and university origin (P=.0369) was found. A significant increase of methodological quality by publication year was observed (P=.0004).
Conclusions: Methodological quality of therapy articles published in Cirugía Española between 2005 and 2008 is low; but an increase tendency with statistical significance was observed.

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Calidad metodológica de los artículos publicados en *Cirugía Española* referentes a procedimientos terapéuticos. Evaluación del período 2005–2008

Palabras clave:
Bibliometría
Metodología
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RESUMEN

Objetivo: Evaluar la calidad metodológica de los artículos relativos a procedimientos terapéuticos publicados en la revista *Cirugía Española* y su asociación con el año de publicación, su procedencia y el área temática estudiada.

Material y método: Estudio bibliométrico que analiza todos los artículos publicados entre los años 2005 y 2008 relacionados con procedimientos terapéuticos. Se analizó cualquier tipo de diseño, excluyendo editoriales, artículos de revisión, cartas al director y estudios experimentales. Las variables consideradas fueron año de publicación, procedencia, área temática, diseño y calidad metodológica. Se aplicó un análisis de calidad metodológica empleando una escala válida y confiable.

Resultados: Se estudiaron 243 artículos (206 series de casos [84,8%], 27 estudios de cohortes [11,1%], 9 ensayos clínicos [3,7%] y un estudio de casos y controles [0,4%]). Los estudios provenían preferentemente de Cataluña y Valencia, con un 22,3 y un 12,3%, respectivamente. Las áreas temáticas con mayor número de publicaciones fueron la cirugía hepatobiliopancreática y la cirugía colorrectal con el 20,0 y el 16,6%, respectivamente. El promedio y la mediana de la calidad metodológica de la totalidad de la serie fueron de 9,5 ± 4,3 puntos y de 8 puntos, respectivamente. Se verificó un incremento significativo de la calidad metodológica por año de publicación (p = 0,0004). Se observó una asociación entre calidad metodológica y procedencia geográfica (p = 0,0101), área temática (p = 0,0267) y carácter universitario del centro generador de las publicaciones (p = 0,0369).

Conclusiones: La calidad metodológica de los estudios relacionados con los procedimientos terapéuticos publicados en *Cirugía Española* entre los años 2005 y 2008 es baja. Se constató una tendencia significativa a la mejoría en el año 2008.

Introduction

In 2005, a bibliometric study was performed evaluating the methodological quality of the articles published in the journal *Cirugía Española* with regard to therapeutic procedures. At the time, all articles regarding treatment from the period of 2001 to 2004 were included (including both years), and of the 244 articles analysed, 81% corresponded to case series, 12% were cohort studies, and 7% were clinical studies. Using a point system for evaluating the methodological quality of the articles, the mean quality was 10.2 ± 3.9 points. This was on a scale that went from 6 to 36 points; in which the score of 18 points was used as a cut-off point between high and low quality. In spite of the medical value, which was below the desired level, a significant increase was observed in the methodological quality of publications in progressive years, and a strong correlation existed between article quality and subject area. In contrast, no correlation was shown with the medical centre where the study took place, nor the university capacity of the centres that generated the articles.[1]

Although the methodology used in bibliometric analyses can generate controversy, it is an element of evaluation at the scientific level for working groups, institutions, and journals.[2] As such, it is important to perform a periodic analysis of the academic reality of a journal.

The objective of this study was to determine the level of evidence and the methodological quality of the articles published on therapeutic procedures in the *Cirugía Española* journal in the period between 2005 and 2008. We wanted, at the same time, to study the possible associations between article quality and year of publication, article source, and subject area in the articles analysed.

Materials and methods

Design: bibliometric study.

Population: initially, all articles related to therapeutic procedures from the *Cirugía Española* journal between January 2005 and December 2008 were considered. In the second stage of selection, clinical research studies were included that were performed with the following designs: report and case series (retrospective and prospective), cross-sectional studies, historical and concurrent cohorts, and individual and multicentric clinical studies with and without randomised treatments and with and without blinds. Editorials, review articles, general reviews, systematic reviews, clinical practice pathways and guides, letters to the editor, and experimental studies were excluded.

Article analysis: all articles that were initially considered were classified according to the Oxford levels of evidence

for treatment articles.[6] Subsequently, all of the articles that satisfied the inclusion criteria were analysed for methodological quality. A point system designed ad hoc was applied to these articles following validation tests (facade validity, content and concepts for outliers) and reliability (interobserver reliability).[7-11] This is composed of 3 domains: the first is related to the type of study design; the second is related to the size of the adjusted study population whether or not justification of the sample size exists, and the third is related to the description of the methodology used in the study (including objectives, justification of the study design, criteria for eligibility of the sample and justification). In this manner, a final point score is awarded that can fluctuate between 6 and 36 points, with 6 points assigned to the articles with the lowest methodological quality, and 36 points corresponding to the highest methodological quality. The cut-off point that dichotomised high or low quality was 18 points.[1]

Two researchers (CM and LG), who came to a consensus to resolve those situations in which distinct results were generated, developed the mechanism for determining levels of evidence and the analysis of methodological quality for each article.

Variable studies: in addition to the level of evidence and methodological quality of the studies, other variables were also considered, such as year of publication, location of the study, subject area, and whether or not the centre that generated the article was university-affiliated.

All of the variables, with exception of "methodological quality", were nominal variables, and were therefore divided into categories: publication year (2005, 2006, 2007, 2008), place of origin (by autonomous communities), university affiliation of the centre that generated the article (yes/no), study design according to the level of evidence criteria (1, 2, 3, 4, and 5),[6] and subject area in 7 subgroups (endocrine surgery and surgeries of the head and neck, thoracic and cardiovascular surgeries, abdominal wall surgeries, breast and soft tissue surgeries, oesophagogastroduodenal surgeries and surgeries of the small intestine, hepatobiliopancreatic surgeries, colorectal and proctologic surgeries, and miscellaneous).

Analysis plan: following an exploratory analysis of the data, descriptive statistics were applied to discover the means, standard deviations, medians, and outliers for the datasets. Analytical statistics were then applied to establish possible

Table 1 – Distribution of all articles on therapeutic procedures published during the period studied, arranged by year of publication

Year of publication	Articles, n	%
2005	106	22.2
2006	109	22.9
2007	137	28.8
2008	124	26.1
Total	476	100.0

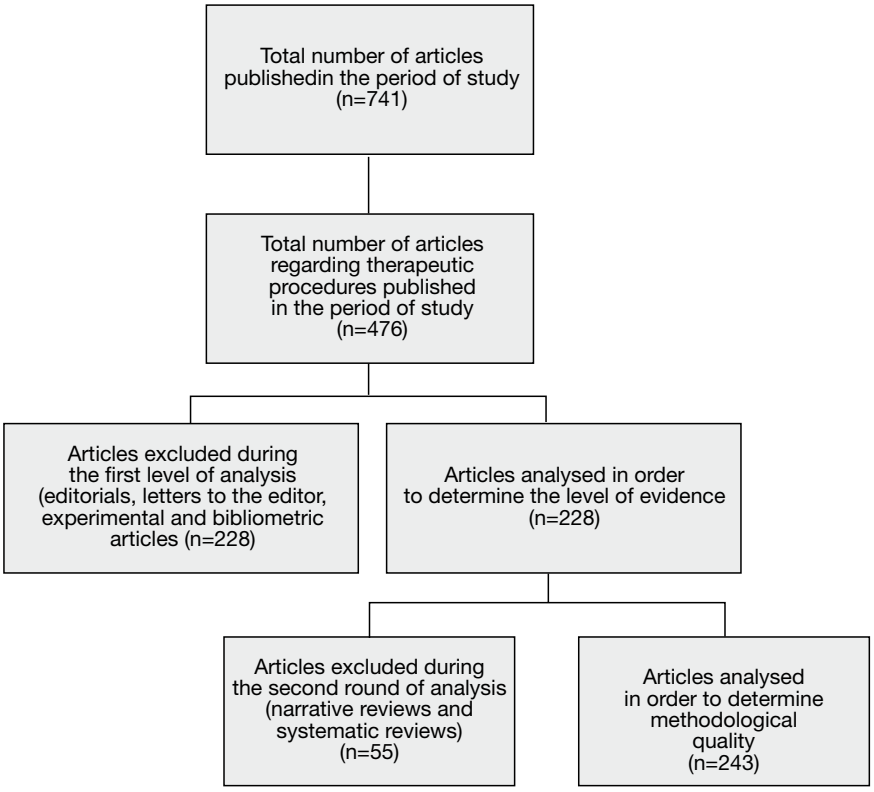

Figure 1 – Flowchart of the studied articles.

Table 2 – Total distribution of the articles on therapeutic procedures published during the period studied arranged by place of origin of the studies

Origin	Studies, n	%
Catalonia	106	22.3
Andalusia	66	13.9
Valencia	58	12.2
Madrid	53	11.1
Foreign	41	8.6
The Basque Country	32	6.7
Murcia	31	6.5
Galicia	19	4.0
Castile-Leon	11	2.3
Castile-La Mancha	11	2.3
Aragon	10	2.1
Navarra	9	1.9
Asturias	8	1.7
Canaries	8	1.7
Cantabria	6	1.3
Balearic Islands	3	0.6
Extremadura	3	0.6
Ceuta-Melilla	1	0.2
Total	476	100.0

Table 3 – Total distribution of the articles on therapeutic procedures published during the period studied arranged by subject area

Subject area	Articles, n	%
Liver, biliary ducts, and pancreas	95	20.0
Colorectal and proctologic	79	16.6
Oesophagus, stomach, duodenum, and small intestine[a]	73	15.4
Breast, abdominal wall, and soft tissues	53	11.1
Thorax and cardiovascular	49	10.3
Endocrine and the head and neck	32	6.7
Miscellaneous[b]	95	19.9
Total	476	100.0

[a]Includes bariatric surgery.
[b]Includes anaesthesia, spleen, medications, gynecology, infections, general laparoscopies, melanomas, nutrition, general oncology, pelvis, peritoneum, retroperitoneum, robotic, sutures, transfusions, traumas, traumatology, and urology. Furthermore, it includes experimental and bibliometric studies.

correlations between the methodological quality and other variables; here we used the Chi,[2] Pearsons, and Fisher exact tests for the comparison of categorical variables, t-tests, non-parametric tests, ANOVAs, and Scheffe tests for comparisons of continuous variables, and 95% confidence intervals.

Ethical considerations: the data obtained were coded in order to ensure the confidentiality of the authors and centres that generated the articles under study.

Results

From the total of 741 published articles, 476 were dedicated to therapeutic procedures and the rest to diagnostic procedures, prognostics, and other scenarios (Figure 1). These were distributed homogenously throughout the time period under study (Table 1), while place of origin was heavily weighted (60%) towards the autonomous communities of Catalonia, Andalusia, Valencia and Madrid (Table 2). The most frequently observed subject areas were hepatobiliopancreatic and colorectal surgeries (20.0% and 16.6%, respectively) (Table 3). Furthermore, a greater proportion of studies came from universities (313 articles [65.8%]) as opposed to non-university health centres (163 articles [34.2%]).

The Oxford levels of evidence classification system for treatment studies[12] was applied to 298 articles after letters to the editor (n=148), editorials (n=19), experimental studies (n=10), and one bibliometric study related to treatment were excluded (Figure 1). Seven point eight percent of the studies were scored 1 or 2 for levels of evidence, and 91.9% obtained a level of evidence of 4 or 5 (Table 4).

Subsequently, in order to apply a point system for methodological quality, 51 narrative review articles were excluded (special articles and general reviews) along with 4 systematic reviews, yielding a subgroup of 243 articles for assessment under this analysis. The mean and median point scores for methodological quality of all articles were 9.5 ± 4.3 points and 8 points, respectively (95% confidence interval: 8.9–10.1). Surprisingly, 95.5% of published articles were below the 18 point cut-off. Only 11 studies surpassed this level (2 from 2005, 3 from 2006, 3 from 2007, and 3 from 2008). Upon comparing the methodological quality score by year of publication of the articles, a statistically significant increase in points was seen in 2008 with respect to the other years, with a *P* value =.0004 (Figure 2).

On the other hand, there was a tendency of higher methodological quality scores for articles from other countries, the Canaries, and Valencia (13.2 ± 3.9; 10.8 ± 3.8 and 10.4 ± 4.2, respectively) and lower methodological quality in articles from Extremadura, Castile-La Mancha, and the Balearic Islands (6.0 ± 0.0 for each); with a *P* value =.0101 (Figure 3).

There was also a tendency for higher scores of methodological quality in articles related to colorectal and proctologic surgeries, surgeries of the abdominal wall, breasts, and soft tissues (11.0 ± 5.4 and 10.5 ± 5.5, respectively); and lower scores of methodological quality in articles related to thorax and cardiovascular surgery, oesophagogastroduodenal surgery and surgery of the small intestine (7.6 ± 2.6 and 8.0 ± 2.8, respectively); statistically significant differences were also found between articles on colorectal and proctologic surgeries vs articles on oesophagogastroduodenal surgeries and surgeries of the small intestine (P=.0267) (Figure 4).

Finally, it is worth noting the association between the university affiliation of the study centre or not for the articles and their respective methodological quality (9.9 ± 4.5 and 8.7 ± 3.8, respectively, with a *P* value = .0369).

Discussion

This study demonstrates that the mean methodological quality of therapeutic treatment articles published in the Cirugía Española journal is low, although it has increased yearly since 2005. However, this improvement is only

Table 4 – Total distribution of articles on therapeutic procedures published during the period studied arranged by study design type[6]

Study design[a]	Evidence level	Articles, n	%
Clinical study with randomised design and double blind[b]	1[b]	2	0.7
Systematic revision of the medical literature	2[a]	4	1.3
Clinical study[c]	2[b]	7	2.4
Concurrent or prospective cohort study	2[b]	10	3.4
Case studies and controls	3[b]	1	0.3
Historical and retrospective cohort studies	4	17	5.7
Case series[d]	4	206	69.1
Narrative reviews	5	51	17.1
Total		298	100.0

Note: For this description, we excluded letters to the editor, editorials, and experimental and bibliometric studies.
[a]For this description, we excluded letters to the editor, editorials, and experimental and bibliometric studies.
[b]Includes individual and multicentric studies.
[c]clinical study without randomised design, blinds (or simple blinds), sample size estimation, etc.
[d]Includes case reports (n=117), retrospective case series (n=60), prospective series (n=27), and cross-sectional studies (n=2).

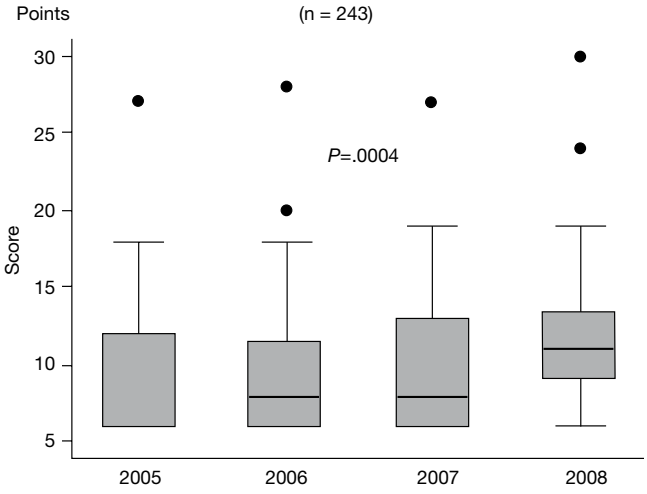

Figure 2 – Comparison of the median and 25% and 75% confidence intervals of the methodological quality of the articles studied according to publication year. Seventy-six articles in 2005, 60 in 2006, 49 in 2007, and 59 in 2008. *P* value =.0004.

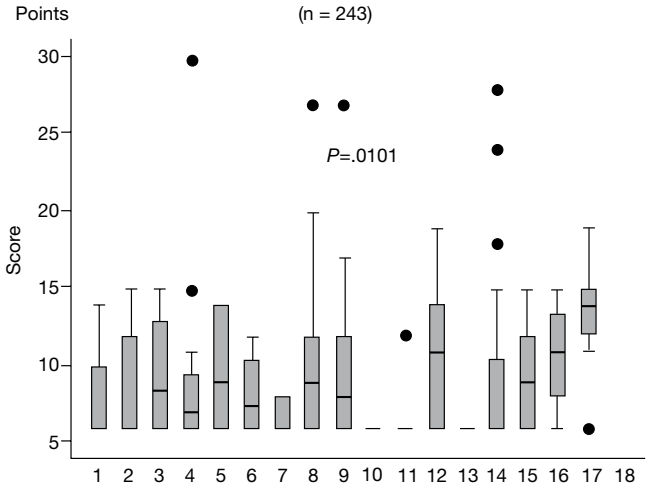

Figure 3 – Comparison of the median and 25% and 75% confidence intervals of the methodological quality of the articles studies according to the autonomous community of origin.
1: Galicia (19 articles [4.1%]); 2: Asturias (8 articles [1.7%]); 3: Cantabria (6 articles [1.3%]); 4: Basque Country (32 articles [6.9%]); 5: Navarra (9 articles [1.9%]); 6: Castile-León (11 articles [2.4%]); 7: Aragon (12 articles [2.6%]); 8: Catalonia (103 articles [22.2%]); 9: Madrid (48 articles [10.3%]); 1 0: Extremadura (3 articles [0.7%]); 11: Castile-La Mancha 11 articles [2.4%]); 12: Valencia (57 articles [12.3%]); 13: Balearic Islands (3 articles [0.7%]); 14: Andalusia (63 articles [13.6%]); 15: Murcia (31 articles [6.7%]); 16: Canaries (8 articles [1.7%]); 17: Foreign (40 articles [8.6%]), and 18: Ceuta and Melilla (one article [0.2%]). *P* value =.0101.

apparent, since comparison of this study with the previous four years shows that the starting point in 2005 is clearly under the levels for 2004 and that the levels reached in the year 2008 are still below those from 2004 (Figure 5). Furthermore, the median scores from the 8 years analysed do not achieve the minimum score in order to consider the overall production of articles as being high in methodological quality.

The evaluation of methodological quality of a scientific work is not an easy task. The concept of quality is multidimensional and can include many different variables. Currently, in spite of the efforts directed at this issue, we still lack a standard methodology. In the Surgery Department of the University of La Frontera (Temuco, Chile), an instrument has been developed whose validity and utility have already stood out in other studies and has been used in this journal. It emphasizes 3 fundamental aspects: the design of the study, the population under study, and the description of the methodology employed. This last point shows the detailed statement of objectives, a mention of the justification of the design employed, the description of the inclusion/exclusion criteria, and justification of the sample size.

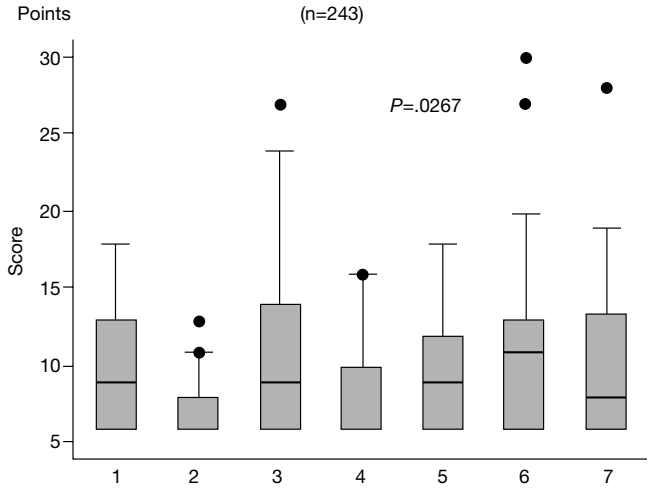

Figure 4 – Comparison of the median and 25% and 75% confidence intervals of the methodological quality of the articles studied according to subject area.
1: head, neck, and endocrine surgeries; 2: thoracic and cardiovascular surgeries; 3: abdominal wall, breasts, and soft tissue surgeries; 4: oesophogogastroduodenal and small intestine surgeries; 5: hepatobiliopancreatic surgeries; 6: colorectal and proctologic surgeries, and 7: miscellaneous. *P* value =.0267.

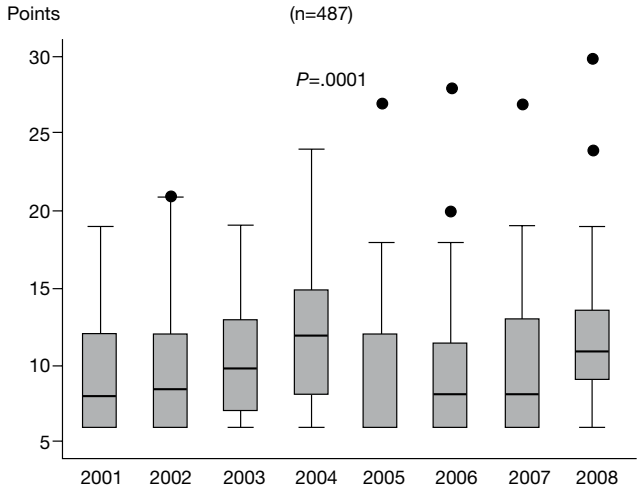

Figure 5 – Comparison of the median and 25 and 75% confidence intervals of the methodological quality of the articles studied according to year of publication (2001 to 2008). *P* value <.0001.

It goes without saying that methodological quality does not necessarily imply an association with innovation, technological input, development of ideas, modifications of technical aspects, etc. It is well understood that the most novel aspects often are published in studies with a low level of evidence and limited numbers of patients in the study. But even in these circumstances, the highest possible level of methodological quality would be desirable in the articles we write and publish. The most frequent methodological defects in the analysed articles were vague statement of objectives, the use of study designs with low levels of evidence, lack of selection criteria and the absence of justification in the sample size used, a trend that is even more noticeable in clinical studies. The most important point is that all of these faults can be easily remedied through the implementation of a verification system (checklist) that would be useful not just for the author, but also for the reviewer. The score for methodological quality could increase with an improved explanation of the objectives, design, and selection criteria for the article. This would increase the point totals for a study of 25 patients and a level of evidence of 4 from 6 to 11 points, a study of 250 patients from 11 to 16 points, and a clinical study of 150 patients from 14 to 29 points.

In a similar fashion to the previous study, almost 60% of the analysed publications came from 4 autonomous communities, but the role in methodological quality of these 4 populations is very disparate. One example of the disparity is the Andalusian community, that although it is the second biggest producer of publications, the mean quality of these articles does not surpass 6 points. That is, the composition of their portfolio consists of a few high-quality studies with a large litany of cases and retrospective case series that increase the production level but negatively affect their final score. The extreme opposite is the Canary community, with few articles, but the highest median methodological quality in the entire country, along with Valencia, which could be considered as the example to follow: the third largest producer and third highest scorer. It is true that, sensu stricto, the example to follow should be the production coming from outside the country, which achieves the highest score in methodological quality with a low rate of dispersion. However, although this point is valid, it is difficult to maintain due to the characteristics of our journal. These are the works signed by foreign authors, papers from Spanish authors that perform scientific research while working out of foreign health and research centres that cannot be considered representative of the methodological quality of the country, a scientific community, or a determined area.

We insist in this manuscript that the concept of "methodological quality" must be understood as a multidimensional concept, in which it is possible to evaluate multiple facets or domains, in which for the moment, no consensus exists; although a series of recommendations has been reported for the publication of results, such as CONSORT (for clinical studies),[3] STARD (for diagnostic test studies),[4] STROBE (for observational studies),[5] Moose (for meta-analysis of observational studies),[12] TREND (for non-randomised studies),[13] and others. However, it is important to mention that these initiatives only constitute checklists, and none of them is designed or validated for the evaluation of methodological quality in this type of study; however, they do contribute to the normalization and homogenization of report quality, a highly relevant facet/domain in the concept of methodological quality.

As opposed to the previous report, in this evaluation, studies from the field of hepatobiliopancreatic surgeries surpassed the rest of the fields in number of articles, but

those regarding colorectal and proctologic surgeries had the highest methodological quality scores.

Other aspects require some additional comments. The Cirugía Española journal was indexed online on MEDLINE in November 2005, and on ISI a few months ago. It is obvious that during this period, a good part of the contributing national authors, those who are the main contributors to the journal, have preferred to send their higher quality papers to other journals to the detriment of Cirugía Española. Our hope is that indexation with ISI will elevate the methodological quality and level of reports and signify a new era for Cirugía Española. Indeed, this trend is what seems to stand out from this study and the previous one,[1] in which a progressive increase in methodological quality and reports can be observed through the years, and although we cannot ignore that the starting point for this evaluation was below the levels achieved in 2004, we hope that, under the current conditions and upon taking the necessary steps, another inflection point like the one currently seen will be avoided.

One final aspect for discussion is that the problem of insufficient quality in the reporting of articles and methodological quality are not exclusive issues of Spanish Surgery. Indeed, this situation has also been evidenced in other studies that have analysed these variable in several journals of our field, such as Annals of Surgery, British Journal of Surgery, Archives of Surgery, World Journal of Surgery, American Surgeon, European Journal of Surgery, Journal American College of Surgeons and the Revista Chilena de Cirugía journal.[7-14]

In summary, this study demonstrates that the methodological quality of the studies related to the therapeutic procedures published in Spanish Surgery has not improved during the period of 2005 to 2008 with respect to the previously studied period. The defects observed are obvious and easily remedied with the application of a verification system during the elaboration phase of the manuscript and the peer revision process.

Conflict of interest

The authors affirm that they have no conflicts of interest.

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