ORIGINAL ARTICLE

Quality and reproducibility of French publications on total hip arthroplasty

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Prosthetic implants; Total hip arthroplasty; Scientific; Medical publication

Summary

Introduction: The goal of the Quality of Literature in Arthroplasty (QoLA) project launched in 2009 was to compare the implant results from clinical studies published in indexed scientific journals with those found in reference national registers. The potential biases in the chosen articles (country of origin, inventor involved in study, methodological quality) were systematically analyzed and the revisions per 100 observed component years (Revp100OCY) index was calculated. For a given implant, a differential factor greater than 3 between the Revp100OCY index for published series and the one from registers was considered indicative of a potential selection bias. Although initially performed on English publications, this methodology was subsequently applied to French publications in the field of total hip arthroplasty (THA).

Material and methods: French publications indexed in Medline (Rev Chir Orthop and Orthop Trauma Surg Res since 2009) were analyzed. These studies involved implants designed in France (ABG\textsuperscript{TM}, Corail\textsuperscript{TM} stem, Cerafit\textsuperscript{TM}/Osteal\textsuperscript{TM}, Bousquet) or that were used worldwide (Omnifit\textsuperscript{TM} stem, Alloclassic\textsuperscript{TM} and Charnley-type or Müller-type implants). The articles or abstracts selected had to contain sufficient information (number of revisions, number of cases and/or revisions, average follow-up) to allow the Revp100OCY index to be calculated.

Results: Overall, the average Revp100OCY index for THA series published in French was 0.76, which is consistent with the worldwide average of 1.29. For the ABG\textsuperscript{TM} System, the Revp100OCY

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Introduction

There are two major datasets available for the assessment of implants or surgical techniques: clinical studies that have been published in peer-reviewed, scientific journals and national, regional or multicenter arthroplasty registers.

Clinical studies are observational and based on a limited number of cases (cohort). They tend to extrapolate the results from a small group of studied patients/implants to the entire patient population. It is well known that certain biases occurring during the conduct of a clinical trial can significantly impact the conclusions: patient selection, study design (retrospective, prospective), concentration of interested parties (designers and manufacturers). Consequently, the ability to reproduce the results in the general population has been questioned. This problem is clearly found within the scientific selection of various top arthroplasty journals. The European Arthroplasty Register (EAR) group has already recognized the accumulation of non-reproducible results in studies published in two North American journals (Clinical Orthopaedics and Related Research and Journal of Arthroplasty) that publish most of the arthroplasty-related studies.

Thus, 76% (CORR) and 63% (JOA) of all published cases in these two journals were from the inventors of the implants in question (unpublished EAR data).

Conversely, epidemiological registers tend to collate most cases of primary arthroplasty with the primary failure criterion being the revision of part or all of the components. To encourage participation while trying to be as complete as possible, the documentation burden must not be too heavy and must focus on the essential points: surgical approach, implant type and fixation method, bearings used, comparative survival analysis, etc. Registers reflect on the current practice in the country or region in which the data are collected. Because of the sheer mass of data included, they drown out the results from series involving implant inventors.

The Quality of Literature in Arthroplasty (QoLA) project was launched by the EAR group in 2009 [1]. The goal was to compare implant results between clinical studies published in indexed journals and data provided by high-level national registers. Although survival analysis is the gold standard to express and compare implant-related results, as in all Scandinavian registers, they require the implant data to be matched with vital records data for the death of an implanted patient to be automatically detected [2]. This prerequisite to establishing survival curves is not legally feasible in a large number of developed countries. Thus another criterion was needed to compare the implant results from one register to another, and between clinical studies and registers. The EAR group decided to use the ‘‘revision per 100 observed component years’’ (Revp100OCY) index. Initially, this index was developed in Great Britain in the 1950s for epidemiological studies on smoking [3] and was introduced in orthopedics by the Australian Joint Replacement Registry [4]. The formula for the calculation is:

\[
\text{Revp100OCY index} = \frac{\text{Number of revisions} \times 100}{\text{Number of primary THA reviewed} \times \text{average follow-up}}
\]

One of the first steps of the QoLA project was to apply this formula to as many published hip arthroplasty clinical studies as possible. Articles written in English were identified in Medline-indexed journals and through a manual search. The selected publications had to contain the information needed to calculate the revision index and analyze potential biases: country of origin, inventor involved in study and methodological quality.

Also, in registers comparing results from various teams and/or facilities (Sweden, Denmark), the best differ by a factor of 3 among each other. Based on this observation, the EAR group chose to use a differential factor greater than 3 as the threshold level to indicate a potential bias between clinical study results and register results. In other words, when the Revp100COA index for a well-defined implant is at least 3 times lower in a clinical study than the index calculated from registers where this same implant is present, the clinical study results are considered as non-reproducible by all standard orthopedic surgeons. This can either be the result of the inventor’s facility having special expertise, or a methodological bias or conflict of interest being present. This method was applied on a very large scale to data available in the most recent reports of the six largest registers (Sweden, Denmark, Norway, Finland, Australia and New Zealand). In terms of total hip arthroplasty (THA), 79,231 revisions were identified from a total of 689,608 THA collected at an average follow-up of 8.9 years. The average Revp100COA index was calculated to be 1.29 (range 1.28–1.30), which serves as the worldwide reference index [5].

Material and methods

The aforementioned methodology for international publications was applied to French publications in the field of total hip arthroplasty through a search for studies published in the only French, Medline-indexed journal, Revue de Chirurgie Orthopédique et Traumatologique. Surgery & Research (2013), http://dx.doi.org/10.1016/j.jotr.2013.02.001
French hip arthroplasty publications

Orthopédique (RCO), which became Orthopaedics & Traumatology Surgery and Research (OTSR) in 2009. Only articles published since 2000 were included, as were peer-reviewed conference abstracts (mostly for the annual meeting of the French Orthopedics and Trauma Surgery Society [SoFCOT]) that had the information needed to calculate the Revp100O CY index (number of cases actually followed at the average follow-up and number of revisions) and had an average follow-up of at least eight years. The selection was focused on hip implants designed in France (ABG\textsuperscript{TM} system, Corail\textsuperscript{TM} femoral stem, Cerafit\textsuperscript{TM} cup-Osteal\textsuperscript{TM} stem, Bousquet dual mobility cup), along with implants used worldwide such as Omnifit\textsuperscript{TM} stems, Zweymüller-Alloclassic\textsuperscript{TM} or Müller and Charnley-Low Friction Arthroplasty (LFA) implants. In the end, eight articles and six abstracts were retained.

The Revp100O CY index was calculated for each implant and compared to the information available in the reference national registers. Since many of the implants used in France were not present in the historical Swedish, Finnish or British registers, most of the comparative data came from the Australian, Norwegian and New Zealand registers. When the clinical and register data could be compared for a given implant, the differential factor was calculated (ratio between the highest and lowest index). A differential greater than 3 was considered as an indicator of a potentially worrisome discordance between the two types of evaluations.

**Results**

The comparison between the data from articles and abstracts published in RCO-OTSR and those found in the reference registers is summarized in Table 1.

For the ABG\textsuperscript{TM} implant system, the French studies consisted of small series for the entire system, with no clear selection of the revised implant(s). The Revp100O CY index was 0.77 in the Australian and New Zealand registers [4,6]. This is better than in the French series, [1,5] despite the fact that one of series was published by an inventor [7,8].

For the Corail\textsuperscript{TM} system, the Revp100O CY index was excellent (0.25 with 6.8 years average follow-up) in the Norwegian register [9]. It was even better (0.1) in the French publications, with one involving an inventor, despite the fact that the average follow-up was longer (12 years) [10,11].

The results with cemented Charnley stems (0.64) were better in the Danish register [12], than the series (1.68) published in RCO-OTSR that came from a Norwegian group [13]. As for the Charnley-Kerboul or Charnley-type cemented THA, the results were comparable: 0.33 in the New Zealand

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**Table 1** Comparison of the revision per 100 observed component years index between international registers and French studies.

<table>
<thead>
<tr>
<th>Implant</th>
<th>Average follow-up</th>
<th>Number of primary</th>
<th>Number of revisions</th>
<th>Observed component years (O CY)</th>
<th>Revp100O CY index (differential)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABG\textsuperscript{TM} I and II system</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australian and New Zealand registers [4,6]</td>
<td>6.9</td>
<td>3787</td>
<td>201</td>
<td>26,107</td>
<td>0.77</td>
</tr>
<tr>
<td>RCO/OTSR [7,8]</td>
<td>10</td>
<td>165</td>
<td>25</td>
<td>1665</td>
<td>1.5 (1.9)</td>
</tr>
<tr>
<td>Corail\textsuperscript{TM} stem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norwegian register [9]</td>
<td>6.8</td>
<td>5130</td>
<td>83</td>
<td>34,884</td>
<td>0.24</td>
</tr>
<tr>
<td>RCO/OTSR [10,11]</td>
<td>12</td>
<td>183</td>
<td>2</td>
<td>2196</td>
<td>0.1 (2.4)</td>
</tr>
<tr>
<td>Charnley stem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Danish register [12]</td>
<td>5.8</td>
<td>3856</td>
<td>976</td>
<td>26,221</td>
<td>0.64</td>
</tr>
<tr>
<td>RCO/OTSR [13]</td>
<td>10</td>
<td>185</td>
<td>31</td>
<td>1850</td>
<td>1.68 (2.6)</td>
</tr>
<tr>
<td>Charnley-type THA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>New Zealand register [6]</td>
<td>8</td>
<td>456</td>
<td>12</td>
<td>3667</td>
<td>0.33</td>
</tr>
<tr>
<td>RCO/OTSR [14]</td>
<td>14.2</td>
<td>215</td>
<td>18</td>
<td>3053</td>
<td>0.59 (1.8)</td>
</tr>
<tr>
<td>Omnifit\textsuperscript{TM} stem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norwegian register [9]</td>
<td>4.5</td>
<td>299</td>
<td>5</td>
<td>1345</td>
<td>0.37</td>
</tr>
<tr>
<td>RCO/OTSR [15]</td>
<td>8.2</td>
<td>424</td>
<td>9</td>
<td>3490</td>
<td>0.26 (1.4)</td>
</tr>
<tr>
<td>Alloclassic-SL\textsuperscript{TM} stem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norwegian register [9]</td>
<td>8.3</td>
<td>512</td>
<td>21</td>
<td>4249</td>
<td>0.49</td>
</tr>
<tr>
<td>RCO/OTSR [16,17]</td>
<td>8.8</td>
<td>432</td>
<td>8</td>
<td>3796</td>
<td>0.21 (2.3)</td>
</tr>
<tr>
<td>Cemented Müller THA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Zealand register [6]</td>
<td>7</td>
<td>1353</td>
<td>32</td>
<td>9570</td>
<td>0.33</td>
</tr>
<tr>
<td>RCO/OTSR [18]</td>
<td>10</td>
<td>90</td>
<td>2</td>
<td>900</td>
<td>0.22 (1.5)</td>
</tr>
<tr>
<td>Cerafit\textsuperscript{TM} -Osteal\textsuperscript{TM} RCO [19–21]</td>
<td>9.1</td>
<td>299</td>
<td>37</td>
<td>2735</td>
<td>1.35</td>
</tr>
<tr>
<td>Bousquet cup RCO [22]</td>
<td>10.7</td>
<td>364</td>
<td>47</td>
<td>3895</td>
<td>1.2</td>
</tr>
</tbody>
</table>

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register [6] and 0.59 in a series published by an inventor [14].

With the Omnifit™ and Alloclassic-SL™ stems, the indexes were good overall in the Norwegian register [9] and even better in the French studies, despite none of the inventors having been involved [15–17]. This was similar to the cemented Müller implant system with a low index (0.31) in the New Zealand register [6] and one published study in RCO-OTSR (0.22) [18]. The differential factor between the Revp1000CY clinical and register indexes varied from 1.4 for the Omnifit™ stem to 2.6 for the Charnley stem and never attained the threshold value of 3.

For other implants invented in France but with no comparable register data, the cohorts were relatively small for a follow-up of more than nine years. The Revp1000CY index was at the higher end: 1.35 for the Ceraver-Osteal™ implant with an alumina-alumina bearing and a study involving the inventors [19–21] and 1.2 for the original Bousquet dual mobility cup [22].

Table 2 summarizes the results from all the French studies selected [23]. The global revision index was 0.76, which is consistent but slightly lower than the worldwide average of 1.29 for THA. Six of the clinical studies evaluated had cohorts of patients below 50 years of age [8,10,14,15,20,21].

Other clinical studies involving specific hip implants were published in RCO-OTSR, but the follow-up was too short to be included in this evaluation. For example, the Revp1000CY index was low (0.35) for the Evora™ cup (no conflict of interest declared) and quite low (0.16) for the SPS™ stem in a single-surgeon series where two of the authors were affiliated with the manufacturer [24,25]. There is currently no data available in the reference registers for the two implants.

Discussion

In his thesis, Havelin determined that a prospective study would have to include 13,474 cases to show a 1% difference in revisions between two implants with the usual statistical standards (95% confidence interval and 80% power) [26]. It is readily apparent that clinical studies with generally smaller cohorts are regularly at fault in terms of statistical power. Hence the importance of registers. Because of the large numbers, sufficient statistical power exists to show significant differences in the performance of various implants.

Following the efforts initiated in Sweden in the early 1970s, a few developed countries now have national arthroplasty registers that are effective because they are compulsory (Scandinavian countries, Australia, England and Wales, New Zealand). These registers provide a good view of the practices and comparative results for the implants used in the corresponding region. Given the variations in the market from one country or continent to another, the current trend is to group the register results within international organizations such as EAR in Europe and the International Consortium of Orthopaedic Registries (ICOR) in the United States [27]. But several large developed countries only have either regional (Italy, Spain) or multicenter (France, United States) registers with participation that is voluntary and not required by health authorities; others is still being launched (Germany, Austria).

The lack of a national register is even more harmful in the United States because the arthroplasty surgery activity is intense and the sheer number of publications resulting from this activity has a significant influence throughout the world. The impact of the work of American inventors was revealed by the EAR team [28]. Overall, for implants developed in the USA, 48.2% of primary implantations and 47.1% of observed component years were reported by authors affiliated with the inventor(s). If we compare this with implants developed in continental Europe, only 10.2% of implantations and 15.9% of observed component years were reported by teams comprising the inventor(s).

The methodology developed by the QoLA group can also be used with a specific implant when data from clinical studies is or becomes conflicting. A multiregister analysis was conducted on the SL-Plus™ stem based on a request from its manufacturer (Smith & Nephew, Memphis, TN) to improve the worldwide evaluation of the product and get away from potential publication biases [29]. This study showed that the quality of the implant was good in the registers and that the poor published results were in fact related to the bearings used (Sikomet™).

Calculating the annual revision index per 100 observed component years allows a comparison to be made (bench marking) between various implants without needing to be informed about patient deaths. This index was chosen to quantify and compare arthroplasty results in the registers of most of the countries grouped within the EAR, including the SoFCOT multicenter THA register. In 2012, the overall Revp1000CY index was 0.34 with an average follow-up of 3.4 years (Table 2). This was less than half the average index (0.76) calculated from studies published in RCO-OTSR, which had a longer follow-up (10 years).

One of the weak points of the current study is that part of the data was taken from abstracts presented at the annual SoFCOT meeting; these do not have the same scientific value as published studies that have met the requirements of an editorial board. However, all the included abstracts had

<table>
<thead>
<tr>
<th>Implant</th>
<th>Average follow-up</th>
<th>Number of primary</th>
<th>Number of revisions</th>
<th>Observed component years (OCY)</th>
<th>Average Revp1000CY index</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCO/OTSR articles</td>
<td>10</td>
<td>2357</td>
<td>179</td>
<td>23,580</td>
<td>0.76</td>
</tr>
<tr>
<td>Worldwide THA registers</td>
<td>8.9</td>
<td>689,608</td>
<td>79,231</td>
<td>6,137,511</td>
<td>1.29</td>
</tr>
<tr>
<td>SoFCOT THA register (2012)</td>
<td>3.42</td>
<td>11,116</td>
<td>130</td>
<td>38,017</td>
<td>0.34</td>
</tr>
</tbody>
</table>

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been selected after peer-review, all the implants in question have been the subject of numerous published scientific studies internationally and the three data elements used (number of THA actually analyzed at the average follow-up, follow-up of more than 8 years, and number of revisions) are in themselves not scientifically open to criticism.

In fact, the French inventors and users of several implants available in France have not only published their results in their native language, but also quite often in international English-language journals while seeking a broader audience. These English publications have probably contributed to some French implants breaking into foreign markets and appearing in the national registers of certain countries. This is especially the case for the ABG™ implants and Corail™ stem, which are found in the reference Danish, Norwegian, Australian and New Zealand registers.

Nevertheless, since the English indexed version of RCO was created in 2009 (OTSR), the impact factor has greatly increased (from 0.3 in 2008 to 0.943 in 2012), including an 81% increase in the past two years. We can speculate that this success may lead French groups to publish in their native language more often, while still enjoying the benefits of reaching an international audience when their study reports are translated into English for publication in OTSR.

Conclusions

There are very few hip arthroplasty studies published in French literature. They have small cohorts but a longer follow-up than those collected in the reference registers. The Revp1000CY index values were either higher or lower (but never more than 3 times) than those found in registers, including studies involving the French implant inventors. The finding that the French revision indexes were often higher than those in registers is more likely an indicator of quality, probably related to the longer follow-up in the French studies. In light of this work, these are no indications of any recurring bias in French scientific publications that would lead one to question the reproducibility of results of total hip arthroplasty and the quality of the average standard service provided to patients.

Disclosure of interest

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