

# Level of evidence of clinical orthopedic surgery research in Saudi Arabia

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## ABSTRACT

**الأهداف:** تقييم الأبحاث المنشورة في مجال جراحة العظام بالمملكة.

**الطريقة:** قمنا بجمع أسماء جراحين العظام السعوديين في الجامعات والمستشفيات الرئيسية بالمملكة في شهر يوليو 2012م. بعد ذلك أجرينا البحث في موقعي النشر (PubMed and Embase) عن أبحاثهم المنشورة خلال العقد الماضي، ثم قمنا بتصنيف هذه الأبحاث حسب النوعية استناداً لتصنيف (أكسفورد العالمي لمستويات طب البراهين) الذي يتكون من 5 مستويات. تم استثناء المستوى الخامس خلال عملية البحث. ثم قمنا بمقارنة هذه المستويات بين العقدين السابقين. أيضاً قمنا بمقارنة الأبحاث المنشورة من حيث النوعية مع دراسة مماثلة في أمريكا الشمالية.

**النتائج:** وجدنا عدد الأبحاث المنشورة 251 منها 159 بحث وافق شروط الدراسة لنصنّفه حسب مستويات طب البراهين. وجدنا أن 86% من الأبحاث المنشورة يحتل الدرجة الرابعة من التصنيف. وبعد عملية التحليل لم نلاحظ تقدم في مستوى التصنيف خلال آخر عقدين. وجدنا أيضاً أن الأبحاث المنشورة في أمريكا الشمالية عند المقارنة حازت على مستويات أعلى من حيث التصنيف.

**خاتمة:** أن الأبحاث المنشورة من حيث التصنيف النوعي بالمملكة تتطلب المزيد من الجهد ولذلك تضافر الجهود بين المؤسسات التعليمية وبرامج الزمالة وأعضاء هيئة التدريس بالجامعات مهم جداً لإنشاء آلية لتطوير عجلة البحث العلمي بمجال جراحة العظام بالمملكة العربية السعودية.

**Objectives:** To evaluate the level of evidence (LOE) of Saudi clinical orthopedic research.

**Methods:** In July 2012, a list of Saudi orthopedic surgeons (N=93) affiliated with all major universities and hospitals in Saudi Arabia were obtained. PubMed and Embase searches were performed for all eligible studies over the last 2 decades (August 1991 to

May 2012). The Oxford LOE scale was utilized to determine the LOE of these studies (Level V studies were excluded). The LOE trends were compared between the last 2 decades. In addition, the LOE of Saudi orthopedic studies was compared with North American studies.

**Results:** Of 251 articles, 159 met the inclusion criteria for the LOE evaluation. Most of the published studies are Level IV (86%). The average level of evidence was 3.75. There was no statistically significant difference when we compared the LOE trend between the last 2 decades. North American studies contained higher proportions of high-level studies when compared to Saudi studies ( $p<0.05$ ).

**Conclusion:** Most of the published studies are low LOE. Academic staff, institutions, and training programs are required to develop research strategies to improve orthopedic research quality in Saudi Arabia.

*Saudi Med J 2013; Vol. 34 (4): 395-400*

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Received 11th February 2013. Accepted 20th March 2013.

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**Disclosure.** Authors have no conflict of interests, and the work was not supported or funded by any drug company.

Recently, evidence-based medicine (EBM) has become a fundamental part of clinical research and practice. High-quality research and evidence have a positive impact on decision making and clinical practice.<sup>1</sup> Research quality is ranked according to the level of evidence (LOE), ranging from Level I (high quality, for example, meta-analysis of randomized control trials) to Level V (low quality, for example, expert opinion).<sup>1-3</sup> First described by David Sackett, the Oxford Centre for Evidence Based Medicine “Levels of Evidence” are widely used as the standard method to rank the LOE (Table 1).<sup>4</sup> In surgical medicine, there are many obstacles for conducting high level studies.<sup>5,6</sup> Nevertheless, orthopedic surgeons and scientists in North American and European countries have contributed in many effective and innovative research endeavors. In contrary, the orthopedic surgery research in Saudi Arabia is felt to have had a limited impact in the form of high-level surgical literature. No previous published study that indexed in PubMed, Midline, EmBase and Cochrane library databases to explore the levels of evidence in orthopedic surgery research in Saudi Arabia. The primary aim of this study was to analyze Saudi publications in orthopedic surgery literature and determine the LOE of clinical orthopedic surgery research in the kingdom. Secondary aims were: to determine the changes in the LOE trend over the last 2 decades in Saudi Arabia and to compare the LOE of Saudi clinical orthopedic surgery research with the LOE of clinical orthopedic surgery research in North America.

**Methods.** An online review was carried out on July 2012 to describe the LOE of clinical orthopedic surgery research in Saudi Arabia. A list of all Saudi orthopedic surgeons [those who work in established Universities in Saudi Arabia (King Saud University,

King Abdul-Aziz University, Dammam University, Um Al Qura University, King Khalid University, and Taibah University) and main hospitals (King Fahad and Abdulaziz medical cities, King Faisal Specialist Hospitals and Research centers in Jeddah, Riyadh and Dammam), (National guard hospitals in Jeddah, Riyadh and Al Hasa), and (King Fahad Armed force hospitals in Jeddah, Riyadh and Al Hasa)] were obtained. PubMed and Embase searches were then performed. The inclusion criteria were all studies published in English by Saudi orthopedic surgeons in a Saudi institution from August 1991 to May 2012. Four reviewers classified all the studies independently. Any disagreement between the reviewers was resolved by consensus. Studies were categorized according to the type of the study: (1) randomized control trial (RCT), (2) meta-analysis, (3) prospective cohort, (4) retrospective cohort, (5) cross-sectional studies, (6) epidemiological studies, (7) case series, and (8) case reports. We have excluded basic science, bench work, animal, cadaveric, instructional course lectures, correspondences, discussions, letters to the editor, and other non-human-related studies as these studies do not reflect clinical orthopedic research. The Oxford level of evidence scale was utilized to determine the LOE of these studies.<sup>4</sup> The articles were ranked according to their level; from Level I (highest evidence, for example, meta-analysis of randomized control trials) to Level IV (lowest evidence, for example, case reports). Level V studies were excluded from our review as the studies that fell under this category (for example, basic science) were excluded from our review. Furthermore, subspecialty analysis was performed to determine the frequency of the published articles in each orthopedic subspecialty. The LOE of Saudi orthopedic publications was compared to the level of evidence of studies in North America. Hanzlik et al<sup>7</sup> have utilized the oxford EBM scale to assess the LOE of orthopedic research over 30 years (1975, 1985, 1995, and 2005) for articles published in the Journal of Bone and Joint Surgery (American) using the same exclusion criteria. We used the articles in the year of 2005 and 1995 from their study for the comparison with Saudi orthopedic articles in last 2 decades. The weighted average evidence levels were calculated using the following formula: average of (percentage of articles per level of evidence) X (level of evidence)/(100).

**Statistical analysis.** The frequency of different study types and levels of evidence (Level I to Level IV) in various journals were determined. Chi-square analysis was used to compare categorical variables. The confidence intervals were used to detect the difference between proportions. Unpaired t-test was used to

**Table 1** - Oxford's level of evidence scale.<sup>4</sup>

Level	Description
I*	Randomized controlled clinical trials (RCTs) and meta-analysis of RCTs
II	Systematic review of Cohort studies, individual Cohort studies, outcomes research, ecological studies.
III	Systematic review of case-control studies, individual case-control studies.
IV	Case series, case-control studies and reviews, poor-quality cohort and case-control studies.
V†	Expert opinion(s) without explicit critical appraisal, experimental research, animal studies.

\*highest level "score", †lowest level "score"

compare between means. The confidence interval of 95% and  $p$ -value  $<0.05$  were considered statistically significant. The statistical package for the social sciences (Inc., Chicago, IL, USA) version 20.0 was utilized for the statistical work.

**Results.** Ninety-three Saudi orthopedic surgeons were included in our review. A total of 251 published articles were found and reviewed. Of these, 92 were excluded leaving 159 eligible studies that met the inclusion criteria for the LOE evaluation (Figure 1). Retrospective studies were the most common published type and comprised 40% of the total published articles included in our review (Table 2). Case series and case reports were the second most published articles and comprised 36% of the total published articles. One hundred and fifty nine articles were published in 44 different journals (Table 3). Interestingly, 59% of the studies were published in orthopedic journals, while 31% in non-orthopedic journals. Level IV studies accounted for 86% of all publications, followed by Level II (6%), Level III (5%), and Level I (3%). The average LOE was 3.75 for all studies included from

August 1991 to May 2012. The total number of studies from August 1991 to December 2001 was 46 and the total number of studies from January 2002 to May 2012 was 113. The average LOE for published studies from August 1991 to December 2001 was 3.81 and the average LOE from January 2002 to May 2012 was 3.77 (Figure 2). There was no statistically significant difference when comparing the average LOE in the last decade 2002 to May 2012 (3.77) with studies published before 2001 (3.81), ( $p=0.54$ ). Furthermore, there was no statistically significant difference in terms of LOE proportions between the last 2 decades (Table 4). Moreover, North American studies contained statistically significant higher proportions of Levels I, II, III and low proportion of Level IV studies when compared with the LOE of Saudi orthopedic studies (Table 5). Subspecialty analysis revealed that pediatric orthopedic surgery was the leading domain in terms of proportion of publications comprising 26% of the total publications, followed by trauma 14%, spine 12%, sports 10%, arthroplasty 5% and others comprising 33%. Two to three studies (251/93) were the average number of publications per an orthopedic Saudi surgeon.

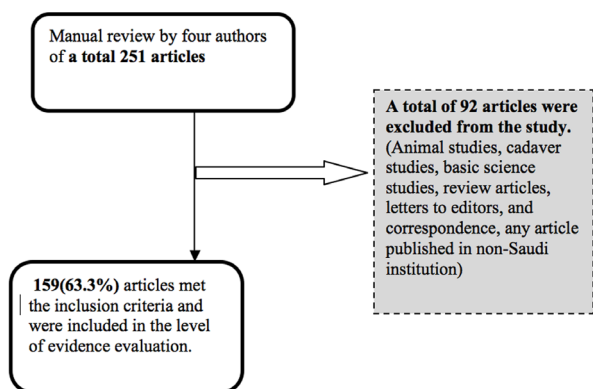


Figure 1 - Schematic of the articles' review process.

Table 2 - Classification of the articles according to the type of study.

Study type	Frequency (%)
Randomized control trials	4 (3)
Meta-analysis	0 (0)
Prospective studies	9 (5)
Retrospective studies	64 (40)
Cross-sectional studies	18 (11)
Epidemiological	5 (3)
Case series	39 (25)
Case reports	20 (13)
<b>Total</b>	<b>159 (100)</b>

Table 3 - Frequencies of publication in different journals in the field of orthopedic surgery.

Journal	Frequency of publication (%)
Saudi Medical Journal	39 (24.5)
Annals of Saudi Medicine	14 (8.8)
Injury	14 (8.8)
Journal of Pediatric orthopedics	9 (5.5)
International Surgery	8 (2.0)
Journal of Child Orthopedics	6 (3.7)
International Orthopedics	6 (3.7)
Indian Journal of Orthopedics	4 (2.5)
Others	59 (37.0)

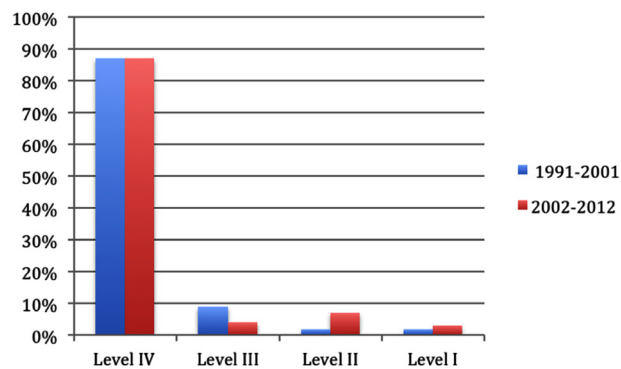


Figure 2 - Graph demonstrates the percentage of published studies ranked by level of evidence from August 1991 to December 2001 and from January 2002 to May 2012.

**Table 4 -** Comparison of the level of evidence of Saudi orthopedic studies over the last 2 decades.

Level of evidence	Studies from 1991 to 2001 n (%)	Studies from 2002 to 2012 n (%)	95% Confidence interval
Level I	1 (2.1)	3 (2.8)	-0.10 - 0.06
Level II	4 (8.8)	4 (3.5)	-0.031 - 0.18
Level III	1 (2.1)	8 (7.0)	-0.06 - 0.12
Level IV	40 (87.0)	98 (86.7)	-0.14 - 0.11
<b>Total</b>	<b>46 (100.0)</b>	<b>113 (100.0)</b>	

**Table 5 -** Level of evidence of orthopedic surgery studies in North America as compared with the level of evidence of Saudi orthopedic studies.

Level of evidence	Current study n (%)	Hanzlik et al <sup>7</sup> n (%)	95% Confidence interval	P-value
Level I	4 (3)	47 (16)	0.07 - 0.28	<0.001
Level II	9 (6)	38 (13)	0.005 - 0.12	<0.02
Level III	8 (5)	45 (15)	0.03 - 0.15	<0.001
Level IV	138 (86)	161 (56)	0.22 - 0.39	<0.001
<b>Total</b>	<b>159 (100)</b>	<b>291 (100)</b>		

**Discussion.** Since its introduction by Sackett, the LOE concept has been increasingly used to quantify the quality of surgical research.<sup>8-10</sup> This study was performed to assess the orthopedic clinical research in Saudi Arabia with particular attention to trends in LOE over the last 20 years.

There is a paucity of high-level evidence research in Saudi Arabia as seen by the low number of levels I (3%) and II (6%) studies. Level III and IV evidence studies compromise the majority (91%) of publications. In general, the orthopedic literature has a well-known weakness with a tendency to contain studies in the lower half of the evidence scale. Obermskey et al<sup>11</sup> have assessed the LOE of 382 articles published in 2003 in 9 major orthopedic journals in North America and found that the majority of the articles were Level IV (58.1%). Cashin et al<sup>12</sup> have also evaluated the LOE trends of 750 articles published in the Journal of Pediatric Orthopedics and the Journal of Child Orthopedics before and after the introduction of LOE; they found no significant change in the LOE with the majority being Level IV (58%). Wupperman et al<sup>13</sup> found similar results in terms of LOE scale when they compared 112 articles in the Spine (Phila Pa 1976) journal with 111 from 2 other orthopedic journals. Although Level IV studies can provide valuable information (especially for rare conditions), authors should be encouraged to conduct higher-level studies as bias and confounding factors can be decreased by using such methods.

Our results have shown that North American orthopedic studies contained higher proportions of

high-level studies when compared to Saudi orthopedic studies ( $p < 0.05$ ). We have also shown that the LOE trend of Saudi orthopedic studies did not improve over the last 2 decades. One factor that might contribute to such results is the lack of full-time research assistants/personnel in most academic institutions in Saudi Arabia as higher level studies often employ study coordinators to absorb the heavy task of enrolling, assessing and following patients. Thus, most academic orthopedic surgeons in Saudi may choose to conduct retrospective case-series studies that do not require additional manpower or time consequently skewing the evidence level towards lower level studies.

The average number of publication per surgeon (2-3) and the total number of publications (n=251) over 20 years are low considering that 41% of surgeons who were included in the study had university affiliations. Al Zahrani<sup>14</sup> has shown that academic staff across all Saudi universities from 2001 to 2005 typically published 1 to 3 studies over that time period. This highlights the fact that the research activity in Saudi Arabia is not progressing over the last decade.<sup>14</sup> Al Faleh et al<sup>4</sup> and Aziz et al<sup>5</sup> have discussed some barriers of research activities in the Kingdom and emphasized some points that might improve orthopedic research.<sup>15,16</sup> They discussed obstacles related to the academic staff personnel, training programs, and medical schools. The academic staff has a lack of interest in conducting research, and this might be secondary to lack of financial incentives and absence of prestigious research awards. Furthermore, due to the lack of financial incentives most academic

surgeons elect to be engaged in private practice, which is time consuming at the expense of research activities. In addition, since the majority of the current faculty and staff have no formal training in research,<sup>16</sup> establishing workshops in research methodology would have a significant impact on the quality and number of papers published. Orthopedic training programs in Saudi lack resident participation in research; there is an absence of research-related mandatory projects, competitions, and awards. Post-graduate program directors should promote such activities, and perhaps this needs to be implemented at an even earlier point in the medical career such as medical school. Interestingly in USA, prospective candidates must demonstrate their commitment through publication to increase the probability of matching to a residency position.<sup>7</sup> There are obstacles related to the institutions as well, the world bank statistics (2010 statistics) have shown that, in 2007 Japan spent 3.4% of its gross domestic product (GDP) on research and development, the United States of America spent 2.7%, and the United Kingdom spent 1.8%. While in 2007 Egypt spent only 0.2% of its GDP, Kuwait spent 0.1% and Saudi Arabia spent 0.1% in 2004 which decreased to 0.0% in 2007.<sup>14</sup> This highlights the lack of research funds, grants, and personnel, which will negatively influence research productivity.

We believe it is the time to establish a Saudi national registry; surgeons will be able to collect data quickly, which will definitely improve research outcomes. The Scandinavian experience in national registries has had a positive impact on their practice and the high level of data enabled researchers to ask important and relevant questions.<sup>17</sup>

**Study limitations.** The tracking of surgeon names and institutions is imperfect as misspelled names can result in a decreased capture rate of published studies. Misspelled names can result in a decreased capture rate of published studies. While this is a theoretical concern we do not feel that this affected our results significantly, primarily since most of the papers we evaluated had more than one Saudi author. To miss a relevant study would typically require multiple spelling errors. Secondly, our search was limited to PubMed and Embase and as such, certain publications not indexed by these databases were missed; since there are no dedicated orthopedic journals in Saudi Arabia, we did not feel that there was an efficient method to avoid this problem. Another limitation is that our comparison with the North American studies might be influenced by the fact that Hanzlik et al<sup>7</sup> have evaluated only one high impact journal over 30 years. This will increase the

probability of having higher LOE studies in their data when compared to the LOE in Saudi.

In conclusion, our study has shown that the majority of the orthopedic research publications in Saudi contained higher proportions of low-level studies when compared with North American studies. In addition, no change in the LOE trend over the last 2 decades was observed. Surgeons are encouraged to conduct further research as a low number of publications were noted in the 20-year period studied. Academic staff, institutions, medical schools and training programs are required to support, promote, and develop research strategies to improve orthopedic research in the kingdom. Moreover, we recommend further studies to objectively evaluate the reasons behind the slow improvement in the orthopedic publications in Saudi Arabia.

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