

Evidence-Based Medicine's Role of Levels of Evidence

Kevin C. Chung, M.D, M.S

Section of Plastic Surgery, Department of Surgery, University of Michigan Health System, 2130 Taubman Center, SPC 5340, 1500 East Medical Center Drive, Ann Arbor,

Corresponding Author:

Kevin C. Chung, M.D, M.S., Section of Plastic Surgery, Department of Surgery, University of Michigan Health System, 2130 Taubman Center, SPC 5340, 1500 East Medical Center Drive, Ann Arbor, Mich. 48109-5340,

Received Date: 01 April 2024

Accepted Date: 16 April 2024

Published Date: 22 April 2024

Citation:

Kevin C. Chung. Evidence-Based Medicine's Role of Levels of Evidence. New American Journal of Medicine 2024.

1. Introduction

Evidence-based medicine, as its name implies, focuses on locating evidence and applying it to clinical decision-making. The hierarchical system of evidence classification is a fundamental component of evidence-based medicine. The degrees of evidence are the names given to this system. Finding the strongest degree of evidence to address clinical concerns is advocated for doctors. This topic has been mentioned in a number of publications about evidence-based medicine that have been published in plastic surgery journals.¹⁻⁶ In particular, earlier papers have addressed the deficiency of higher level evidence in the field of plastic and reconstructive surgery as well as the necessity of enhancing the evidence that is published in the Journal. It is necessary to comprehend the background of the levels. The origins of evidence levels, their applicability to the evidence-based medicine movement, and their consequences for the practice of plastic surgery as a whole are the main topics of this article.

2. The Levels of Evidence's History

The Canadian Task Force on the Periodic Health Examination first detailed the levels of evidence in a study published in 1979.⁽⁷⁾ The objective of the report was to formulate suggestions for the routine physical examination and support those suggestions with data from the medical literature. In order to assess the efficacy of a given intervention, the authors created a system for assessing the evidence. When grading recommendations, the evidence was taken into consideration. For instance, if a condition was recommended to be included in the periodic health assessment and there was strong evidence to back the advice, the recommendation was given

a grade of A. In an essay published in 1989 on the levels of evidence for antithrombotic drugs, Sackett⁽⁸⁾ went into additional detail and expanded on the degrees of evidence. In both approaches, case series or expert opinions are ranked lowest and randomized controlled trials are ranked highest. Studies are ranked in hierarchies based on the likelihood of bias. Since randomized controlled trials are less likely to have systematic flaws and are intended to be impartial, they receive the highest ranking. These studies randomize confounding variables that could skew results, for instance, by assigning participants at random to two or more treatment groups. A case series or expert opinion lacks control over confounding factors and is frequently skewed by the author's beliefs or experience.

3. Alterations to Levels

Numerous additional organizations and periodicals have implemented variants of the classification system since the inception of levels of evidence. It was acknowledged that different specialties frequently have distinct questions, and that the kind and degree of evidence required to change accordingly. The following categories are utilized to group research questions: The levels of evidence developed by the American Society of Plastic Surgeons for prognosis⁽⁹⁾ are displayed alongside the levels developed by the Centre for Evidence-Based Medicine for treatment, prognosis, diagnosis, and economic/decision analysis.¹⁰ The two tables illustrate the kinds of research that fit the topic (prognosis versus treatment) and how the leveling process considers data quality. For example, when examining a disease's prognosis, randomized controlled trials are inappropriate. In this case, the issue is, "What will happen if we do nothing at all?" The best evidence would come from a cohort study or a comprehensive review of cohort studies because a prognosis question does not entail comparing treatments. The quality of the data is another factor considered in the evidence levels. The Centre for Evidence-Based Medicine's graphic, for instance, shows that a poorly planned randomized controlled trial has the same level of evidence as a cohort study. The grading scheme that indicates how strongly suggestions are supported by the evidence has likewise evolved throughout time. The grading system aids in clinical decision making and is a crucial part of evidence-based medicine. When level I evidence and consistent evidence from level II, III, and IV studies are provided, for instance, a strong recommendation is made. If the results are consistent, the grading system does not devalue lower level evidence when making recommendations.

4. Level Interpretation

In addition to writers assigning a level when submitting an abstract to conference proceedings, several journals assign a level to the papers they publish. This enables the reader to understand the research's level of evidence, albeit the level of evidence assigned does not always imply the research's caliber. It's critical that readers understand that level I evidence

isn't always the greatest option or most appropriate for answering the study question. Understanding this idea will be crucial for all of us as we advance into the area of evidence-based medicine in plastic surgery. Since publications pertaining to innovation and techniques are necessary to advance our surgical specialty, it is inevitable that some of the most significant articles will have a lesser degree of proof than others.

Even though they are frequently given the highest level of evidence, not all randomized controlled trials are carried out correctly, and the findings need to be closely examined. Sackett [8] emphasized that when interpreting data from randomized controlled trials, it is crucial to estimate the types of mistakes and the power of research. For instance, low power in a badly executed randomized controlled trial may lead to the publication of a negative result even while there is actually a difference between the treatment groups. To assess the quality of randomized controlled trials, scales like the Jadad scale were created.[11] Despite the fact that doctors might not have the time or want to rate quality using a scale, there are a few fundamental factors that need to be considered. Randomization, blinding, an explanation of the randomization and blinding procedure, the number of subjects who withdrawn or left the study, the confidence intervals surrounding study estimates, and a description of the power analysis are among the items used to evaluate randomized controlled trials. For instance, a paper evaluating the caliber of surgical randomized controlled trials was released by Bhandari et al.¹² The quality of randomized controlled trials published in the *Journal of Bone and Joint Surgery* between 1988 and 2000 was assessed by the authors. Sixty percent of the articles had a score below seventy-five percent, and stories scoring more than seventy-five percent were considered excellent quality. During this time, the authors found 72 randomized controlled studies, with a mean score of 68 percent. The absence of suitable blinding, randomization, and a description of the patient exclusion criteria was the primary cause of the low-quality score.

5. Evidence-based medicine and plastic surgery

Evidence-based medicine has not been widely accepted in the field of plastic surgery. An article analyzing the degree of evidence in papers published in *Plastic and Reconstructive Surgery* provided evidence for this.¹⁹ Over a 20-year period, the authors rated the quality of evidence in articles that were published in *Plastic and Reconstructive Surgery*. Level IV or V studies, which indicate case series and case reports, accounted for 93% of all research in 1983. Despite the unsatisfactory outcomes, there was gradual progress. Level I studies accounted for 1.5 percent of all research by 2003, while level IV and V studies made for 87% of all studies. A recent analysis examined the quantity of level I studies published between 1978 and 2009 in five distinct publications related to plastic surgery. The authors limited their search to level I studies, which they characterized as randomized controlled trials and meta-analyses. By 2009, there were 32 level I studies, up from just one in 1978.²⁰ These findings demonstrate that although the field of plastic surgery is gathering more evidence, there is still much work to be done, particularly with regard to raising the caliber of published studies. About one-third

of the studies, for instance, used double blinding; nevertheless, most did not randomize patients, explain the randomization procedure, or carry out a power analysis. Another area of interest in plastic surgery is power analysis. The bulk of published studies had insufficient power to identify moderate to significant differences between treatment groups, according to an assessment of the literature on plastic surgery. No matter how strong the evidence is in support of a study, if it lacks sufficient power, the data's interpretation is dubious.

6. Conclusions

Evidence-based medicine relies heavily on the degrees of evidence. The reader can more easily prioritize material if they comprehend the levels and the rationale for their assignment to articles and abstracts. This is not to imply that all evidence at level IV should be disregarded and all evidence at level I should be taken at face value. The reader should exercise caution when interpreting these results because the evidence levels serve as a guide.

References:

1. McCarthy CM, Collins ED, Pusic AL. Where do we find the best evidence? *Plast Reconstr Surg*. 2008;122:1942–1947; discussion 1948–1951.
2. Chung KC, Swanson JA, Schmitz D, Sullivan D, Rohrich RJ. Introducing evidence-based medicine to plastic and reconstructive surgery. *Plast Reconstr Surg*. 2009;123:1385–1389.
3. Chung KC, Ram AN. Evidence-based medicine: The fourth revolution in American medicine? *Plast Reconstr Surg*. 2009;123:389–398.
4. Rohrich RJ. So you want to be better: The role of evidence-based medicine in plastic surgery. *Plast Reconstr Surg*. 2010;126:1395–1398.
5. Burns PB, Chung KC. Developing good clinical questions and finding the best evidence to answer those questions. *Plast Reconstr Surg*. 2010;126:613–618.
6. Sprague S, McKay P, Thoma A. Study design and hierarchy of evidence for surgical decision making. *Clin Plast Surg*. 2008;35:195–205.
7. The periodic health examination. Canadian Task Force on the Periodic Health Examination. *Can Med Assoc J*. 1979;121:1193–1254.
8. Sackett DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. *Chest* 1989;95(2 Suppl):2S–4S.
9. American Society of Plastic Surgeons. Scales for rating levels of evidence. Available at: http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence-based_Practice_Guidelines/ASPS_Evidence_Rating_Scales.html. Accessed December 17, 2010.
10. Centre for Evidence Based Medicine (Web site). Available at: <http://www.cebm.net>. Accessed December 17, 2010.

11. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: Is blinding necessary? *Control Clin Trials* 1996;17:1–12.
12. Bhandari M, Richards RR, Sprague S, Schemitsch EH. The quality of reporting of randomized trials in the *Journal of Bone and Joint Surgery* from 1988 through 2000. *J Bone Joint Surg Am.* 2002;84:388–396.
13. Poolman RW, Struijs PA, Krips R, Sierevelt IN, Lutz KH, Bhandari M. Does a “Level I Evidence” rating imply high quality of reporting in orthopaedic randomised controlled trials? *BMC Med Res Methodol.* 2006;6:44.
14. Urschel JD, Goldsmith CH, Tandan VR, Miller JD. Users’ guide to evidence-based surgery: How to use an article evaluating surgical interventions. Evidence-Based Surgery Working Group. *Can J Surg.* 2001;44:95–100.
15. Thoma A, Farrokhyar F, Bhandari M, Tandan V; Evidence-Based Surgery Working Group. Users’ guide to the surgical literature: How to assess a randomized controlled trial in surgery. *Can J Surg.* 2004;47:200–208.
16. Bhandari M, Guyatt GH, Swiontkowski MF. User’s guide to the orthopaedic literature: How to use an article about prognosis. *J Bone Joint Surg Am.* 2001;83:1555–1564.
17. Guyatt GH, Sackett DL, Cook DJ. Users’ guides to the medical literature: II. How to use an article about therapy or prevention. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA* 1993;270:2598–2601.
18. Guyatt GH, Haynes RB, Jaeschke RZ, et al. Users’ Guides to the Medical Literature: XXV. Evidence-based medicine: Principles for applying the Users’ Guides to patient care. Evidence-Based Medicine Working Group. *JAMA* 2000;284:1290–1296.
19. Loiselle F, Mahabir RC, Harrop AR. Levels of evidence in plastic surgery research over 20 years. *Plast Reconstr Surg.* 2008;121:207e–211e.
20. McCarthy JE, Chatterjee A, McKelvey TG, Jantzen EM, Kerrigan CL. A detailed analysis of level I evidence (randomized controlled trials and meta-analyses) in five plastic surgery journals to date: 1978 to 2009. *Plast Reconstr Surg.* 2010;126:1774–1778.
21. Chung KC, Kalliainen LK, Spilson SV, Walters MR, Kim HM. The prevalence of negative studies with inadequate statistical power: An analysis of the plastic surgery literature. *Plast Reconstr Surg.* 2002;109:1–6; discussion 7–8.
22. Newman MK, Zimmel NJ, Bandak AZ, Kaplan BJ. Primary breast lymphoma in a patient with silicone breast implants: A case report and review of the literature. *J Plast Reconstr Aesthet Surg.* 2008;61:822–825.
23. Gaudet G, Friedberg JW, Weng A, Pinkus GS, Freedman AS. Breast lymphoma associated with breast implants: Two case-reports and a review of the literature. *Leuk Lymphoma* 2002;43:115–119.
24. Sahoo S, Rosen PP, Feddersen RM, Viswanatha DS, Clark DA, Chadburn A. Anaplastic large cell lymphoma arising in a silicone breast implant capsule: A case report and review of the literature. *Arch Pathol Lab Med.* 2003;127:e115–e118.
25. Keech JA Jr, Creech BJ. Anaplastic T-cell lymphoma in proximity to a saline-filled breast implant. *Plast Reconstr Surg.* 1997;100:554–555.
26. Duvic M, Moore D, Menter A, Vonderheid EC. Cutaneous T-cell lymphoma in association with silicone breast implants. *J Am Acad Dermatol.* 1995;32:939–942.
27. Lipworth L, Tarone RE, McLaughlin JK. Breast implants and lymphoma risk: A review of the epidemiologic evidence through 2008. *Plast Reconstr Surg.* 2009;123:790–793.
28. Lipworth L, Tarone RE, Friis S, et al. Cancer among Scandinavian women with cosmetic breast implants: A pooled long-term follow-up study. *Int J Cancer* 2009;124:490–493.
29. Deapen DM, Hirsch EM, Brody GS. Cancer risk among Los Angeles women with cosmetic breast implants. *Plast Reconstr Surg.* 2007;119:1987–1992.
30. Brisson J, Holowaty EJ, Villeneuve PJ, et al. Cancer incidence in a cohort of Ontario and Quebec women having bilateral breast augmentation. *Int J Cancer* 2006;118:2854–2862.
31. Pukkala E, Boice JD Jr, Hovi SL, et al. Incidence of breast and other cancers among Finnish women with cosmetic breast implants, 1970–1999. *J Long Term Eff Med Implants* 2002;12:271–279.
32. Brinton LA, Lubin JH, Burich MC, Colton T, Brown SL, Hoover RN. Cancer risk at sites other than the breast following augmentation mammoplasty. *Ann Epidemiol.* 2001;11:248–256.
33. Denkler K. A comprehensive review of epinephrine in the finger: To do or not to do. *Plast Reconstr Surg.* 2001;108:114–124.
34. Thomson CJ, Lalonde DH, Denkler KA, Feicht AJ. A critical look at the evidence for and against elective epinephrine use in the finger. *Plast Reconstr Surg.* 2007;119:260–266.
35. Lalonde D, Bell M, Benoit P, Sparkes G, Denkler K, Chang P. A multicenter prospective study of 3,110 consecutive cases of elective epinephrine use in the fingers and hand: The Dalhousie Project clinical phase. *J Hand Surg Am.* 2005;30:1061–1067.
36. Chowdhry S, Seidenstricker L, Cooney DS, Hazani R, Wilhelmi BJ. Do not use epinephrine in digital blocks: Myth or truth? Part II: A retrospective review of 1111 cases. *Plast Reconstr Surg.* 2010;126:2031–2034.
37. Wilhelmi BJ, Blackwell SJ, Miller JH, et al. Do not use epinephrine in digital blocks: Myth or truth? *Plast Reconstr Surg.* 2001;107:393–397.
38. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med.* 2000;342:1887–1892.