Quality of Clinical Studies in Aesthetic Surgery Journals: A 10-Year Review

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BACKGROUND: Evidence-based medicine (EBM) has earned increasing attention in all fields of medicine. However, the implementation of EBM is not yet universal, especially in surgery and its subspecialties. A critical assessment of the quality of scientific evidence in the aesthetic surgery literature is needed to promote the practice of EBM.

OBJECTIVE: This study seeks to evaluate the research designs of aesthetic surgery studies published in 3 leading plastic surgery journals during the past 10 years.

METHODS: All studies published in Plastic and Reconstructive Surgery, Annals of Plastic Surgery, and Aesthetic Surgery Journal between January 1, 1998 and December 31, 2007 were reviewed. Articles pertaining to aesthetic surgery were tabulated according to their study design into the following groups: randomized, controlled trials; prospective cohort studies; retrospective cohort studies; and “others” (case series, case reports, expert opinions, and noncritical reviews).

RESULTS: Of the 1419 manuscripts included in the study, 45 papers (3.2%) were classified as randomized controlled trials. Sixty studies (4.2%) were prospective cohort studies. Ninety papers (6.3%) were retrospective cohort studies. The remaining 1224 articles (86.3%) were case series, case reports, reviews, or expert opinions. The percentage of research representing levels 1 and 2 evidence increased from the first to the second half of the decade (from 10.1% to 16.8%).

CONCLUSIONS: Aesthetic surgery literature is inundated with uncontrolled case series, case reports, and expert opinions. Continued efforts are needed to provide scientifically rigorous data on which to base clinical practice in aesthetic surgery. (Aesthetic Surg J 2009;29:144–149.)

The practice of medicine has always been guided by experience, whether personal or collective. The phrase “evidence-based medicine” (EBM) was coined in the 1980s in response to a growing trend toward literature-supported clinical practice.¹,² The influence of EBM continues to grow and is now an essential component of the curriculum in most medical schools.³ Recently, the British Medical Journal identified EBM as one of the 15 most important medical milestones since the journal’s inception.¹ Despite this, the practice of EBM has yet to become universal, particularly among surgeons. A recent study demonstrated that only 24% of surgical interventions are based on randomized; controlled trials (RCTs), compared to 53% in general inpatient medicine.²,⁴

Clinical trials with rigorous study designs are the cornerstone of EBM. The RCT is considered the “gold standard” in scientific design and includes a control group for comparison and the use of randomization to minimize the effects of confounding variables. Cohort studies are considered to be less rigorous than RCTs, but superior in scientific merit compared to case series or retrospective analyses.⁵–⁸

Many systems have been developed to rank evidence by its quality. A common stratification is described by Phillips et al⁸ and was adopted by the Centre for Evidence-Based Medicine in Oxford, United Kingdom. In this system, level 1 evidence consists primarily of RCTs and systematic reviews of RCTs. Levels 2 and 3 evidence include cohort studies and case-controlled trials, respectively, as well as the corresponding systematic reviews. Level 4 evidence includes case series and cohort studies of poor quality. Level 5 consists of retrospective analyses, case reviews, and expert opinions (Table 1).

The application of EBM in surgery and its subspecialties has been hindered by the paucity of well-conducted trials. In a review of more than 289,000 articles published in 5 leading surgical journals between 1966 and 2000, only 3.4% were RCTs.⁹ An analysis of publications in neurologic surgery, otolaryngology, and pedi-

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Table 1. Levels of evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Evidence</th>
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<tbody>
<tr>
<td>1</td>
<td>Systemic review of RCT, individual RCT, all or none</td>
</tr>
<tr>
<td>2</td>
<td>Systemic review of cohort studies, individual cohort study, outcomes research</td>
</tr>
<tr>
<td>3</td>
<td>Systemic review of case-controlled studies, individual case-controlled study</td>
</tr>
<tr>
<td>4</td>
<td>Case series</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion without critical appraisal or based on physiology, bench research, or “first principles”</td>
</tr>
</tbody>
</table>

RCT = randomized, controlled trial. Adapted from Phillips et al with permission.

Table 2. Number of publications by study design

<table>
<thead>
<tr>
<th>Study Type</th>
<th>No. of Studies</th>
<th>Percentage of Total</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>45</td>
<td>3.2</td>
<td>1</td>
</tr>
<tr>
<td>Prospective cohort</td>
<td>60</td>
<td>4.2</td>
<td>2</td>
</tr>
<tr>
<td>Retrospective cohort</td>
<td>90</td>
<td>6.3</td>
<td>2</td>
</tr>
<tr>
<td>Case series, expert</td>
<td>1224</td>
<td>86.3</td>
<td>4 and 5</td>
</tr>
<tr>
<td>opinions, non-systematic review articles</td>
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RCT = randomized, controlled trial.

Results

In Plastic and Reconstructive Surgery, Annals of Plastic Surgery, and Aesthetic Surgery Journal, a total of 1419 manuscripts met the inclusion criteria for the 10-year period. Forty-five papers (3.2%) were classified as RCTs. Sixty studies (4.2%) were prospective cohort studies. Ninety papers (6.3%) were retrospective cohort studies. The remaining 1224 articles (86.3%) were case series, case reports, reviews, or expert opinions (Table 2).

The survey of RCTs was further divided into two 5-year intervals: January 1, 1998 to December 31, 2002, and January 1, 2003 to December 31, 2007. In the first 5 years of this study, eight RCTs were reported in the aesthetic surgery literature, comprising 1.2% of all studies during that interval. The more recent 5-year interval demonstrated 37 RCTs (4.8%), a fourfold increase. During the same intervals, the percentage of retrospective cohort studies also increased from 4.6% to 7.8%. Prospective cohort studies remained relatively unchanged at 4.3% and 4.2%, respectively (Table 3). Further subdivision of the data into levels 1 and 2 evidence was performed and is shown in the Figure. Over the 10-year study period, the overall trend was toward an increasing percentage of publications representative of both RCTs and levels 1 and 2 evidence.

Discussion

The practice of EBM involves the integration of clinical expertise with the best available clinical information to deliver optimal patient care. Knowledge based on expert opinions, pathophysiologic reasoning, noncritical reviews, and the tradition of experience is no longer sufficient in guiding medical decisions. The importance of well-conducted trials with sound methodology cannot be overstated. This study provides a 10-year review of leading plastic surgery journals, specifically evaluating study design in aesthetic surgery publications. In this period, the vast majority (86%) of studies provided level 4 or 5 evidence, consisting predominantly of case series and expert opinions.

Despite the increase in the use of RCTs from the first to the second half of the decade under examination, the
availability of rigorous, well-designed studies remains extremely limited, particularly for surgical interventions. Most of the RCTs and prospective cohort studies involved nonsurgical interventions such as laser treatments and pharmaceutical adjuncts. Randomized trials and cohort studies on surgical procedures appeared to be disappointingly few. In addition to primarily relying upon uncontrolled study designs, it also appeared that much of the existing research failed to assess outcomes with validated and reliable measures, instead using subjective assessments or arbitrary metrics. Based on our findings, we must conclude that the data needed to institute evidence-based aesthetic surgical practice are largely lacking in both quality and quantity.

Many factors may have contributed to the lack of well-designed trials. First, many current procedures were developed long before the widespread use of randomized surgical trials. These techniques have become gold standards in surgical practice despite the lack of evidence for their efficacy. For example, no RCT-based evidence exists for the excision of benign skin lesions, although it remains one of the most commonly performed surgical interventions. Similarly, before a recent RCT, surgical treatment of symptomatic macromastia with bilateral breast reduction was supported by only a handful of poorly designed prospective studies and retrospective analyses.

Second, some experts feel that the majority of surgical treatments cannot be subjected to RCTs under “real-world” conditions. Surgical techniques are rarely standardized and an inherent variation in performance exists between surgeons. This variation is further exacerbated by the frequent need for procedural modification in response to individual circumstances. Exclusion of cases secondary to these variations introduces serious biases and may ultimately result in underpowered studies. In addition, the learning curve associated with many complex procedures may place newer techniques at a disadvantage when compared to well-established interventions. Patients also often reject the randomization process because they do not wish their treatment to be decided by chance. Although the implementation of evidence-based guidelines has been promoted by major payors including private insurers and the Center for Medicare and Medicaid Services, with the goal of improving quality of care and minimizing surgical complications, the economics of aesthetic surgery may insulate cosmetic surgeons from these financial pressures and further decrease the motivation to perform well-designed trials.

As society increasingly demands critical evaluation of and justification for healthcare interventions, the aesthetic surgery community must develop strategies to meet these challenges. An evolution from experience-based to EBM will not be easy because it requires departure from a tradition of reliance on anecdotal evidence and a change in the focus of our literature from “how” to “why.” Although RCTs have already been used in evaluating perioperative therapies, medications, and interventions such as laser therapy and suction-assisted lipectomy, they are not feasible for all aspects of aesthetic surgery. Fortunately, the proper use of EBM does not always require an RCT; some clinical questions can be answered without a randomized trial. In the aesthetic surgery literature, it is paramount that the number and proportion of well-designed RCTs and cohort studies continue to increase, allowing plastic surgeons to provide optimal patient care through an evidence-based approach.

**CONCLUSIONS**

Aesthetic surgery literature is inundated with uncontrolled case series, case reports, and expert opinions. Although an increase in the number of studies with high levels of evidence in the last 4 to 5 years suggests an increased awareness of the need for well-conducted trials, continued efforts are needed to provide scientifically rigorous data on which to base clinical practice in aesthetic surgery.

**DISCLOSURES**

The authors have no disclosures with respect to the contents of this article.
REFERENCES


COMMENTARY

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The current study by Chang et al is a commendable effort to clarify the state of evidence-based medicine (EBM) in aesthetic surgery practice during the last 10 years. Congruent with the expansion of aesthetic surgery publications identified by the authors, the results of several literature searches conducted during the composition of this commentary allow this conclusion to be broadened. These searches revealed that the rate of biomedical literature publication as a whole is increasing. Since 1950, this rate has increased approximately 3.5% annually on average; over the last 10 years, the increase has been approximately 4.8%.

More specifically and relevantly, literature related to “surgery” seems to be expanding at a rate somewhere between 4.0% and 5.2% per annum since 1950. The rate of publication of literature specifically related to “plastic surgery” or “reconstruction” has been trending upwards between 4.3% and 10.2% per year since 1950, with higher-compounding rates within the last decade. These numbers represent the total number of reports in these areas, including all levels of evidence as outlined by Chang et al. In 2005 alone, more than 100,000 reports were recorded with the keyword “surgery” and more than 3000 published papers related to “plastic surgery.” Taken at face value, these numbers represent encouraging progress towards placing increased emphasis on the incorporation of the “science of surgery” into patient care. However, as cogently argued by Chang et al, this dramatic increase in the quantity of surgery-related investigations has not necessarily translated into the development of a scientifically sound body of knowledge that aesthetic surgeons (and surgeons as a whole) can draw upon to guide their surgical practice. Therefore, one is prompted to inquire further as to both the source of this disparity and what needs to be done to improve the “quality” of aesthetic surgery literature.1,2

Aesthetic surgery—and surgery in general—has long been faced with criticism of its evidence base. Surgeons, unlike other medical practitioners, are faced with a number of physical and/or mechanical “problems” in their...