Response to "Lessons Learned from a National Cosmetic Surgery Insurance Database"

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Aesthetic Surgery Journal
2016, Vol 36(4) NP173–NP176

DOI: 10.1093/asj/sjv274
www.aestheticsurgeryjournal.com
OXFORD UNIVERSITY PRESS

Accepted for publication December 28, 2015; online publish-ahead-of-print February 9, 2016.

We appreciate Dr Swanson's careful reading and comments[1] on our recently published articles[2,3] and take this opportunity to emphasize the study design, analytical methods, interpretation, and importance of these studies derived from the CosmetAssure data (Aesthetic Surgeons' Financial Group, Birmingham, AL).

The goal of a cohort study is to identify an outcome-free population, determine its exposure status at baseline, and then follow it over time until the outcome of interest occurs. Because exposure is identified before the outcome, cohort studies (prospective or retrospective) have a temporal framework to assess causality and thus have the potential to provide the strongest scientific evidence.[4] The distinguishing feature of a prospective cohort, such as the CosmetAssure database, is that at the time that the subjects are enrolled and baseline exposure information is collected, none of the subjects has developed any of the outcomes of interest.[5] Additionally, as in CosmetAssure, information on all subjects is collected in the same way using identical questions and data collection methods in order to have accurate information about exposures before outcome develops in any of the subjects. However, data analysis cannot take place until outcomes have occurred and, thus, is always retrospective regardless of how the cohort was determined. In contrast, in retrospective cohort studies both exposure status and outcome are ascertained retrospectively.[6] In order to ascertain exposure status, the investigator has to go back to preexisting data that was not necessarily acquired in a precise, predetermined way.[5] The existing data may be incomplete, inaccurate, or inconsistently measured between subjects.[4] This is particularly relevant in designing multicenter cohorts because information may be recorded differently in different electronic health record platforms and some practices may still be using paper charts making data abstraction more challenging. Thus, the primary disadvantage of retrospective cohort study design is the limited control the investigator has over data collection.

With cohort studies, investigators typically start out to evaluate a specific exposure. However, the data collected from the cohort can be used to answer many questions and test many possible determinants, even factors that were not

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considered when the study was originally conceived.[6] New hypotheses are evaluated in light of evidence existing at that time and may require new Institutional Review Board (IRB) approval based on risks posed to the study population. An IRB approval prior to collection of any existing health data by a private insurance provider is not a *sine qua non* of prospective cohort studies. Levels of evidence ratings take into account the quality of data and methodological details rather than the source of data.[7]

All the advantages of prospective cohort studies that Dr Swanson has enumerated apply to the CosmetAssure cohort. The exposure information (age, gender, height, weight, diabetes, type of facility, and type of procedures) were ascertained using a specific and uniform data collection instrument prior to patients undergoing surgery and developing complications. Eligibility criteria were broad and included all patients undergoing any covered procedure at participating practices. Inclusion rate was maximized since every patient at participating practices was required to be enrolled in the insurance program. Record-keeping was rigorous for auditing and actuarial purposes.

Contrary to Dr Swanson's assertion, rating scales used by plastic surgery journals do not automatically award a higher level of evidence rating to prospective studies compared to retrospective cohort studies. The evidence rating scale for prognostic/risk factor studies, which is used by the journals in which our articles appeared,[2,3] define level 2 evidence as "Lesser-quality prospective cohort or comparative study; retrospective cohort or comparative study; untreated controls from a randomized controlled trial; or a systematic review of these studies."[7] Dr Swanson has referred to his own CLEAR (Cosmetic Level of Evidence And Recommendation) classification for level of evidence[8] that has not been adopted by the journals in which our papers have been published. Dr Swanson has cited another one of his articles[9] to state, "The mean hematoma rate among 40 predominantly retrospective studies of facelifts is 3.8%, vs a mean rate of 6.7% in 6 prospective studies."[1] On review of the cited article it is unclear if the reported means represent meta-analysis of the pooled data or merely a grand mean of all means. Moreover, by author's own admission in the cited paper, these hematomas included fluid collections treated with needle aspiration in the office.[9] Another study[10] that Dr Swanson discussed in his article,[9] which we have also cited,[10] indicated that expanding hematomas represent fewer than half of these fluid collections. That paper was a meta-analysis of 41 studies and found a 1.8 percent (95 percent CI, 1.3-2.5 percent) incidence of expanding hematoma formation following facelift.[10] The largest facelift complication survey to date (570 respondents, 12,325 facelifts) suggested an operative hematoma rate of 1.3% in females and 4.4% in males that is fairly close to our findings.[11]

As we have emphasized throughout our articles,[2,3] we have only looked at major complications that we have defined as requiring emergency room (ER) visit, reoperation, or hospital admission within 30 days of the procedure. The incidence rates and distribution that we have reported pertain to this specific subset of complications. We have stated that the CosmetAssure database does not include minor, but clinically significant, complications (including neuropathies and scar deformities) since these are managed in the office. We have acknowledged that these complications are significantly more common than major complications and important to cosmetic outcomes as well as patient perceived results. Assessment of these complications was not the aim of our papers and there is abundant literature studying these outcomes.[12-19] The proportion of hematomas is reported as a fraction of major complications only, as per our definition. Most plastic surgeons would consider a hematoma that requires reoperation to be a much more severe condition than a hematoma that can be aspirated in the office on the first postoperative visit. While in both scenarios the condition may be temporary, the severity and potential consequences for the patient are very different.

Dr Swanson calls into question our interpretation of risk associated with combined procedures.[1] As noted in our papers,[2,3] the majority of abdominoplasties (64.8%) and facelifts (57.4%) were performed in combination with other aesthetic surgical procedures. Thus, we owe it to ourselves and to our patients to be well informed about the risks associated with different combined procedures. In both papers we found that combined procedures developed complications more frequently. We have left it to our readers to determine if certain combined procedures pose a significant enough increase in risk to potentially avoid in their own patients. We have stated that even though the increase in complication rate in combined procedures is less than the sum of the complication rates of each procedure done separately, it still requires careful consideration, especially as this represents major complications following elective, non-medically necessary surgery. For example, abdominoplasty done alone had a complication rate of 3.1% however when combined with liposuction and another body-contouring procedure major complications occurred in 10.4%. Dr Swanson has stated, "It would be a shame for patients to forego the advantages of complementary procedures that are known to improve patient satisfaction out of concern that the combination is unsafe … To the patient, the advantages of one operation, one recovery period, and a lower cost are highly practical considerations."[1] Does it imply that our practice of plastic surgery be driven entirely by patient demand and satisfaction with no consideration to safety regardless of the evidence? How does that serve to distinguish our esteemed profession from the "unscientific" practice of cosmetic surgery by imposters that we collectively denounce? As surgeons our highest consideration should be to adhere to our maxim of "*Primum non nocere*", to work in our patients' best interests even if it contradicts their presumptions and aspirations. It would be a major disservice to our patients if we fail

to even inform them of these risks, especially when it includes potentially life-threatening complications requiring hospital admission, reoperation, or an ER visit. Ultimately, our goal is to improve surgeon-patient communication, which are vital to obtaining informed consent and setting realistic patient expectations. These studies will hopefully enable surgeons to anticipate these complications and work to mitigate some of the risks.

There is significant literature reporting that aesthetic surgery performed by board certified plastic surgeons at accredited office-based surgical suites is safe.[20-22] Our data reinforces these findings and gives us as opportunity to compare the outcomes among accredited office-based surgical suites, ambulatory surgery centers, and hospitals. In both articles,[2,3] we have stated that our data lacks information on factors such as the American Society of Anesthesiologists Physical Status classification (ASA), cardiovascular, and other major comorbidities. We have acknowledged that patients with more comorbidities may be preferentially treated in hospitals and these confounding variables may contribute to the higher complication rates observed in hospitals. Equally plausible is the possibility that increased hospital complications could be related to operating room and anesthesia staff who are not as experienced with aesthetic plastic surgical procedures or hospital acquired infections. We have been very careful in reporting this data and have attached multiple caveats to its interpretation. Contrary to Dr Swanson's assertion, we have not highlighted this finding in our conclusions. The question that needs to be answered in future studies is whether office-based surgical suites are actually safer than other facilities for fully risk-adjusted patients. How many ASA class 4 patients do we operate on and are they all treated at hospitals? Even with the limited set of factors available to us in the CosmetAssure database we found that the prevalence of smoking, diabetes and obesity is significantly lower in cosmetic surgery patients than in general population.[2,3]

Dr Swanson seems to have misinterpreted the statistical analysis of the abdominoplasty article.[3] We have reported that in the entire CosmetAssure cohort of 129,007 patients, 2506 developed major complications. The rest of the analysis, including risk factor assessment, is limited to 25,478 abdominoplasty patients of whom 1012 had complication (s) as shown in Table 2 of the abdominoplasty article.[3] We have reported details of univariate analysis (data and *P*-value) for this group. We have stated, "On univariate analysis, male sex, diabetes, increasing age, and high body mass index were associated with increased complications. Morbidly obese patients (body mass index $\geq$ 40 kg/m^2) had nearly double the complication rate compared with normal-weight patients (body mass index of 18.5 to 24.9 40 kg/m^2) (6.4 percent versus 3.3 percent, respectively; $P < .01$). Male patients had a complication rate of 6.1 percent compared with 3.9 percent in women ($P < .01$). Patients aged 60 years or older had a complication rate of 5.3 percent compared with 3.9 percent in younger patients ($P < .01$). Diabetic patients had a 5.8 percent complication rate compared with 3.9 percent in nondiabetics ($P = .01$). An increased complication rate was also seen with combined procedures. Smoking was not found to be a significant risk factor (4.5 percent versus 3.9 percent; $P = .23$). An increased complication rate was seen in hospital-based procedures (4.3 percent) compared with accredited surgical centers (4.1 percent) and office-based surgical suites (2.7 percent) ($P < .01$)." As previously stated, 64.8% of abdominoplasties were performed as combined procedures. What Dr Swanson is alluding to is the subgroup analysis that we performed on patients who underwent abdominoplasty as a single procedure. There is little merit in reporting every statistic of every subgroup analysis. It is a far inferior statistical method than the multivariate regression, as we have reported, that adjusts for those particular subgroups. In the regression analysis we controlled for the effect of combined procedure and thus accounted for the confounding effect of different procedures.

We encourage our readers to critically review these[2,3] and upcoming papers from our group and ascertain their utility for their practices. We believe that the CosmetAssure data is a unique and reliable resource for plastic surgeons and their patients. For the first time we have a narrowly defined, high quality cohort specific to cosmetic surgical procedures. Participating practices are contractually obligated to enroll every patient undergoing any covered procedure(s) in the program. Thus, it is not possible to select only high-risk patients to opt for the insurance, which may artificially inflate complication rates. We have reported outcomes only for board certified plastic surgeons operating at accredited facilities. This multicenter database encompasses hospitals, ambulatory surgery centers, and accredited office-based surgery suites, making the results generalizable to a wide variety of practice models. The outcomes we have evaluated are objective and well defined. Since CosmetAssure offers a significant incentive to a surgeon for reporting a complication, in form of payment of the claim, this database offers a major advantage over databases that rely on voluntary self-report by potentially minimizing the under-reporting of complications. CosmetAssure, being a private insurance company, has a vested interest in maintaining an accurate database for actuarial and audit purposes. Moreover, participating practices are subject to random audits to ensure compliance. A cohort with such high degree of ascertainment of exposure and outcome data is necessary for precise determination of the incidence of major complications and their risk factors. We would certainly invite similar high quality data from practitioners affiliated with other boards to allow for an even comparison. Dr Swanson has drawn attention to complications related to fluid management, which raises interesting questions. Comprehensive evaluation of these complications is beyond the scope of current articles but may be analyzed in our future studies.

Disclosures

Dr Grotting is a founder and shareholder of CosmetAssure (Birmingham, AL). He also receives book royalties from Quality Medical Publishing (St. Louis, MO) and Elsevier (New York, NY), and is a shareholder in Keller Medical, Inc. (Stuart, FL) and Ideal Implant, Inc. (Dallas, TX). The other authors have nothing to disclose.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

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