SALTS database: Goldmine or Fool’s Gold?

Advantages and Limitations of the Database of the Swiss Association of Laparoscopic and Thoracoscopic Surgery

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The importance of surgical outcomes research based on large prospective databases has gained a new prominence, partly due to the fact that these studies reflect data gathered from „real world“ patients and complement scientific evidence from prospective randomized clinical trials. The database of the Swiss Association for Laparoscopic and Thoracoscopic Surgery (SALTS), which contains prospective data from tens of thousands of laparoscopic procedures performed in Switzerland, was initially established for purposes of quality control and to enable surgical outcomes research. The efforts needed to create and maintain this database and to prospectively enter patient data were enormous. Nonetheless, some Swiss surgeons have questioned the usefulness of this huge endeavor, criticizing the SALTS database as a „data cemetery“. The objective of the present article is to highlight the strengths as well as the weaknesses of surgical outcomes research based on the SALTS database and to answer the question whether the SALTS database is a goldmine – or just fool’s gold.

Strengths of the SALTS database

Surgical outcomes research based on the prospective SALTS database has a number of important advantages. First, there are no exclusion criteria for patients undergoing laparoscopic procedures; thus, the generalizability of the findings (i.e., the external validity) is very high. This in turn means that the issue of selection bias arising from population-based data collection is less of a concern and the effectiveness – the actual benefit of an intervention in the „real world“ – can be assessed. This is in clear distinction to prospective randomized clinical trials that evaluate a procedure’s efficacy in highly selected populations (e.g., elderly patients, women, or comorbid patients) or in settings of rare diseases or infrequently occurring endpoints. Third and last, surgical outcomes research based on SALTS data enables researchers to answer important questions that are difficult to explore through randomized clinical trials, because the latter would entail prohibitively complex, costly, or even ethically unacceptable practices.

Herein, I will highlight a number of different study designs using examples of investigations based on SALTS data.

Trend analyses

The SALTS data are particularly well-suited for performing trend analyses, because the data were prospectively collected over almost two decades, thus permitting the evaluation of relevant outcomes over time.

Our research group has performed several trend analyses based on SALTS data. In one investigation, we assessed the degree to which outcomes such as intraoperative complications, postoperative complications, conversion rates, reoperation rates, and length of hospital stay in patients undergoing laparoscopic sigmoid resection for diverticular disease changed over time. From the period 1995 – 2006, we identified 2’813 patients who had undergone elective laparoscopic sigmoid resection for diverticular disease. We found a statistically significant and clinically relevant reduction in postoperative complications, conversion rates, reoperation rates, and length of hospital stay over time. This investigation based on SALTS data was the first trend analysis of its kind in the scientific literature and serves as an important benchmark for quality control.

Another trend analysis explored SALTS data from 7’964 patients collected from 1995 - 2006 in an attempt to assess whether misdiagnosis of appendicitis (negative appendectomy) and rates of perforated appendicitis have declined over a 12-year period. This investigation provides compelling evidence that the rate of negative appendectomy has significantly decreased over time – most likely due to increasing use of ultrasound and CT scanning - while the perforation rate remained constant.

Simple descriptive studies for quality control

As I alluded to above, the SALTS database serves as an important source of quality control for laparoscopic surgeons in and around Switzerland. One of the first publications based on the SALTS data was an examination of complications of laparoscopic cholecystectomy. Over a 3-year period, rates of intraoperative complications and conversion rates, as well as postoperative morbidity and mortality were evaluated in 10’174 patients undergoing laparoscopic cholecystectomy. Importantly, the rate of common bile duct injuries was assessed (0.31%) and an inverse relationship between the risk of common bile duct injury and the operating surgeon’s degree of experience was found. Moreover, the authors reported that intraoperative cholangiography did not reduce the risk of common bile duct injury, however, it enabled to recognize such injuries in the majority of patients. This study represents a formidable example of an extremely important and long-awaited quality control for what was at that time a novel surgical procedure only recently introduced into clinical practice.

Comparisons of surgical procedures based on large databases

In an investigation from our group, laparoscopic Nissen fundoplication was compared with laparoscopic Toupet fundoplication by examining a 10-year span of SALTS data (1995 – 2004). A total of 873 patients (Toupet: n = 254, Nissen: n = 619) were assessed for outcomes such as in-hospital morbidity, in-hospital mortality, length of hospital stay and conversion rate. The relatively large sample size for comparatively rare procedures provided sufficient statistical power to enable a meaningful comparison between the two techniques. This is in contrast to randomized controlled trials, which are frequently threatened by a lack of power – or simply are not feasible if rare surgical procedures are under investigation.

Caveats regarding use of the SALTS database

In addition to the advantages discussed above, it is clear that the SALTS da-
tabase also has several inherent limitations and drawbacks. First, the amount of clinically relevant data is limited. For instance, information regarding disease severity, tumor size and lymph node status may be missing. Similarly, the SALTS database does not contain certain important endpoints such as recurrence rate, long-term survival, occurrence of long-term complications including incisional hernias, adhesions, recurrent hernias, postoperative quality of life and functional status. Nonetheless, length of hospital stay, intraoperative complications, postoperative morbidity, postoperative mortality, conversion rate, and rate of reoperations can be ascertained; all of these are relevant outcomes that allow us to address important research questions that have the potential to impact surgical practice.

Second, miscoding and undercoding will likely always present potential problems for surgical outcomes research based on large databases – an observation that may hold true for the SALTS data as well. Although it is unlikely that miscoding would occur in some years more frequently than in others and an assumption can thus be made that any miscoding would be random rather than systematic, it nonetheless represents an inherent limitation of large databases that must be carefully considered when interpreting study findings based on SALTS data.

Third, research based on the SALTS data must be hypothesis-driven and not data-driven. It is of cardinal importance that, as with a randomized clinical trial, an a priori hypothesis be stated, after which one should ascertain whether the SALTS database is well suited to test this hypothesis. When interpreting any investigation based on large databases, it is essential to make the distinction between hypotheses that were created prior to performing the study (a priori hypotheses) versus those stated after the analysis of data (a posteriori hypotheses)\(^1,8\). The former do not carry the risk that the investigator was influenced by readily available data; thus, they are less likely to lead to erroneous conclusions. On the other hand, if hypotheses are stated a posteriori, it is possible that the investigator looked at different patient subsets until significant results are encountered. This phenomenon, often referred to as „data mining“, „data dredging“, or a „fishing expedition“, has an inherently increased risk of both type I (false positive finding) as well as type II error (false negative finding)\(^1,8\).

Fourth and finally, because the SALTS database contains information from tens of thousands of patients and thus even extracted patient samples can be quite large, it is essential to differentiate between statistical significance and clinical relevance\(^3,4,8\). If a sample size is sufficiently large, even tiny differences between study groups may become statistically significant. The question, however, is whether these small differences – statistically significant as they may be – are clinically relevant. It is thus crucial to consider the absolute results of any analysis based on SALTS data as they could conceivably be clinically irrelevant despite being statistically significant.

Conclusions

Despite some inherent drawbacks and limitations, studies based on SALTS data – when carefully planned, thoroughly performed, and correctly interpreted – can provide invaluable information for a variety of research applications. Surgical outcomes research based on SALTS data should be viewed as complementary and not inferior to prospective randomized clinical trials. Therefore, it must be concluded that the prospective SALTS database is a goldmine for surgical research, rather than fool’s gold.

I hope that the present manuscript will stimulate surgeons and surgical residents to engage more actively in surgical outcomes research based on the SALTS data. Over 25 investigations based on SALTS data have been published or been accepted for publication, often in high-impact journals including the Annals of Surgery. However, there are still numerous relevant and intriguing research questions that can be addressed using the SALTS database. Only through the active exploration of such investigational avenues can we achieve the result we all strive for: improvements in patient outcomes and healthcare delivery.

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References