

Enhanced Recovery After Surgery Interactive Audit System: 10 Years' Experience with an International Web-Based Clinical and Research Perioperative Care Database

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Abstract

The Enhanced Recovery After Surgery (ERAS) is a managed care program that has shown the ability to reduce complications following elective colorectal surgery. In 2006, the ERAS[®] Society developed the ERAS[®] Interactive Audit System (EIAS), which has allowed centers in over 20 countries to enter perioperative patient data to benchmark against international practice within the audit system and act as a stimulus for quality improvement. The de-identified patient data are coded in SQL (a relational database), stored on secure servers, and data governance aspects have been secured in all involved countries. A collaborative approach is undertaken within involved units toward research questions with published cohort data from the audit system having demonstrated the importance of overall compliance on improving patient outcomes and less cost of care. The EIAS has shown that collaborative clinical effort can drive quality improvement in a short time frame in an international context.

Keywords

- surgery
- audit
- perioperative care
- outcomes

Managed care pathways demonstrate efficacy in improving the quality of perioperative care. This is especially true for high-volume, high-morbidity procedures such as colorectal surgery. The Enhanced Recovery After Surgery (ERAS) program is a multimodal synthesis of evidence-based care practices, each developed to reduce surgical stress and improve patient recovery.¹ It can be complex, incorporating up to 30 individual interventions. Audit is a key component of the program for two main purposes. First, it has been shown

that the clinical efficacy of the program is directly related to the compliance with the overall protocol and to specific interventions.^{2,3} Second, ongoing research and development of ERAS and perioperative care requires careful audit of key components and outcomes.

The safety of ERAS protocols has been demonstrated in numerous randomized trials and several studies and meta-analyses have shown the efficacy of ERAS. Reduction in morbidity, faster return of bowel function, earlier mobilization,

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lower pain scores, and reduced length of stay have all been demonstrated. What is less well understood is how the ERAS program performs in clinical practice outside the trial setting. Therefore, audit of ERAS and other perioperative care programs should include the recording of both outcomes, such as recovery and complications, and of compliance with the individual care process measures.

Development of the Database

The ERAS Interactive Audit System (EIAS) was developed as a result of a 2001 meeting of five surgical research groups working in the area of surgical stress physiology. The purpose of the meeting was to initiate a review of the literature to develop the optimal perioperative care pathway for elective colonic resection, based on the available evidence.¹ The five groups determined to adopt ERAS protocol this early and evaluate the change in practice. To aid this project, the groups submitted consecutive patients to a common database, implemented, and maintained by the group from Stockholm, Sweden. In this first iteration of the database, de-identified data were submitted in portions to the Stockholm unit and then reformatted and merged manually into the database.

It was quickly apparent that the data collected revealed surprising findings: overall compliance was much lower than anticipated, and moreover the units were not complying in areas where they thought they were. These humbling results established the central role for monitoring and improving compliance in ERAS, leading in time to improved clinical outcomes.² Having differences in practice and compliance between units provided opportunities to share best practice, address poor compliance, and deal with resistant departments or late adopters.

In 2006, the database moved to a more robust architecture that also incorporated a web-based interface, allowing participating units to enter their data directly using a standard web browser. The data fields and their options, formats, and help texts were thoroughly reworked and expanded at this stage. Standard classifications and definitions were used when possible, such as the Clavien grading scale for adverse events and the VA TPN trial definitions and classification of complications.^{4,5} The scope of the database widened somewhat to include small bowel, colonic, and rectal surgery. Individual units could download their own data and request specific comparisons to data from the group as a whole.

In 2010, a nonprofit organization, the ERAS Society, was developed out of the aforementioned work. This initial ERAS study group expanded into a network comprising centers of excellence and those in development, from more than 20 countries in Europe, North and South America, Asia, Africa, and Australasia, and it is currently expanding to additional countries. A commercial company (Encare AB, Stockholm, Sweden; www.encare.net) was launched in 2009 to develop and run the EIAS as a highly interactive web-based information system (www.erassociety.org) for the ERAS dataset as well as offering training to health care professionals on the ERAS protocols. The resulting current EIAS is thus wider in scope, and the number of data fields has been reduced

somewhat in response to user feedback to make data entry more workable.

Aims of the Database

The EIAS is focused on aspects of perioperative care delivered before, during, and up to 30 days after surgery. It currently includes modules for colorectal, pancreatic, gynecological, and urological surgical procedures. The EIAS is used as a tool to help units in implementing ERAS to see what is actually ongoing in their units. By doing this and training the units to work as ERAS teams holding regular meetings to audit their practice, the data serve as a tool for directing actions and keeping track of outcomes. It also helps the units to understand why certain adverse outcomes may be occurring more frequently than others by revealing what was done, or not done, specifically with the patients affected. The change management taught in these training programs revolves around data coming from this system.

The EIAS thus monitors all aspects of audit concerning surgical procedures, volumes, the quality of perioperative care, and short-term outcomes. It does not compete with, or duplicate, audits regarding other aspects of care such as audits of long-term oncological outcomes or long-term functional outcomes following restorative proctocolectomy.

Governance

Having a database that collects data across national boundaries presents particular challenges. The data entered are de-identified and no identifiable data are entered into the system. Each patient is identified by a unique ERAS number. The units entering data may elect to maintain a key linking the unique ERAS numbers to patient identifiers. Thus, no identifiable data are ever stored in the EIAS.

Governance directives regarding consent for participation in databases also vary according to the individual country. For instance, in the United Kingdom, as the data input is anonymized and qualifies as an audit, no specific patient consent is required. Conversely, in Norway and Switzerland, patient consent is taken as a routine for entry of data into the ERAS database.

Security is provided at a level which equals that of consumer banking portals. The web portal is optimized for personal computers, although it also displays normally on tablets.

Data Collection

Each patient's data field contains approximately 150 different variables. Data include patient demographics, baseline health status, and surgical and anesthetic data. Some 20 key compliance parameters are collected, such as whether preoperative carbohydrate treatment was used and whether intravenous fluid therapy was stopped on the day after surgery. Importantly, for interventions where the care is noncompliant (e.g., the continuation of intravenous fluids past the day after surgery), the system records the reason for the failure of compliance.

Finally, a range of key postoperative outcome parameters are collected, including time to achieve targeted mobility and diet, the number of postoperative nights until the patient fulfils the predetermined discharge criteria, the number of postoperative nights spent in hospital and all adverse events within 30 days including mortality.

Interactivity

One of the key benefits of the EIAS is that it is not just a static data repository. The format allows individual submitting units to compare their own practice and outcomes with other submitting units on an de-identified basis, providing “benchmarking.” The EIAS permits individual operations, patient types, complication, or other metrics to be isolated and then potential variables compared to provide a deeper understanding of clinical practice within the submitted population (► Fig. 1). This format allows unit to drive quality improvement strategies through the development of Plan-Do-Study-Act cycles based on the data within the ERAS dataset.

Using the Database: Assessing Who Might Benefit from ERAS?

One of the first major projects to use the database involved evaluation of postoperative outcomes within an ERAS program in relation to adverse nutritional risk (body mass index <20), advanced age (>80 years), and comorbidity in 1,035 patients undergoing colorectal resection.⁶ Morbidity and mortality were compared with those predicted using the Portsmouth Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (P-POSSUM), and a multivariable model was used to determine independent predictors of outcome. Postoperative morbidity was lower than predicted. Thus, in the context of open colorectal surgery, ERAS certainly seemed safe and even might be of benefit for major clinical outcomes. Old age and nutritional status were not independent determinants of morbidity or mortality. Thus, ERAS care seemed to be of benefit for previously thought high-risk groups such as the old and the malnourished. Finally, pre-existing comorbidity was an independent predictor of several outcomes (such as length of stay), thereby emphasizing the need for consideration for prehabilitation of certain “at risk” groups. However, an analysis of 513 consecutive patients displayed similar compliance in older patients compared with younger, with similar postoperative complication rates.⁷

Using the Database: Assessing the Importance of Overall Compliance

One of the areas requiring elucidation is how many, and which, of the multitude of ERAS components are necessary to influence perioperative outcome. A study (that did not use the database) undertaken in the United Kingdom compared the outcomes of patients receiving ERAS care within a randomized controlled trial (RCT) to standard practice outside the RCT, within the same surgical unit using the same

protocol.⁸ The patient group within the RCT had marginally higher compliance, but little difference was seen in the development of complications or length of postoperative hospital stay. The study was limited by gross contamination of the two modes of care within the same institution, lack of blinding, and lack of independent determination of key outcomes such as length of stay. However, in a larger single-center study in Sweden that used the database, Gustafsson and colleagues showed increasing compliance had a positive effect on surgical outcome.² As the ERAS protocol became more embedded over time, compliance improved. This improved compliance was associated with reduced postoperative complications and symptoms delaying recovery. In a subsequent study, this cohort was followed-up for 5 years and it was found that long-term survival (an index of oncological outcome) was improved in patients with better ERAS protocol compliance.⁹ The mechanism behind this novel finding may be related to the lower frequency of complications following surgery, previously shown to be associated with higher long-term mortality.¹⁰

The aforementioned findings needed exploration in a larger cohort and the international, multicenter ERAS database was ideally positioned to further investigate these hypotheses. The ERAS Compliance Group was formed for this purpose and investigated outcomes on over 2,300 patients undergoing elective colorectal cancer surgery between 2007 and 2013 entered into the EIAS. Outcomes from 13 centers for primary colorectal cancer resection were assessed. Pre- and intraoperative factor compliance was analyzed, as it is recognized that postoperative compliance is often compromised by the clinical status of the patient. Compliance was then adjusted for patient, disease location, and operative factors. The primary outcomes were the development of postoperative complications and length of postoperative stay. The study found that as ERAS perioperative factor compliance increased, both complications and length of stay decreased in multivariate analysis (► Fig. 2). For both outcomes, the improvement seemed to be “dose-dependent” in that some benefit was found with 75% compliance, when compared with less than 50%, but that 90% or more compliance achieved further reduced complications and length of stay. Similar findings have recently been reported from Alberta, where the Alberta Health Service have embraced the ERAS Society model of implementation in the entire state. In their implementation program, they studied the cost aspects reporting major savings¹¹ and a high return on investment.¹² The combined dataset of the ERAS Society allowed this analysis to be undertaken and is a prime example of how quality improvement can be defined and delivered using large datasets collected centrally from many participating centers.

However, compliance can increase and decrease and just as important as implementation is sustainability. Innovations, such as ERAS, require continual work and it is often difficult to maintain early positive results. Around 40% of public health interventions are not maintained after the implementation phase and funding have ended.¹³ ERAS is a complex, multimodal, multidisciplinary intervention and presents a particular challenge for sustainability. On the other hand, with consequent use of the database and the

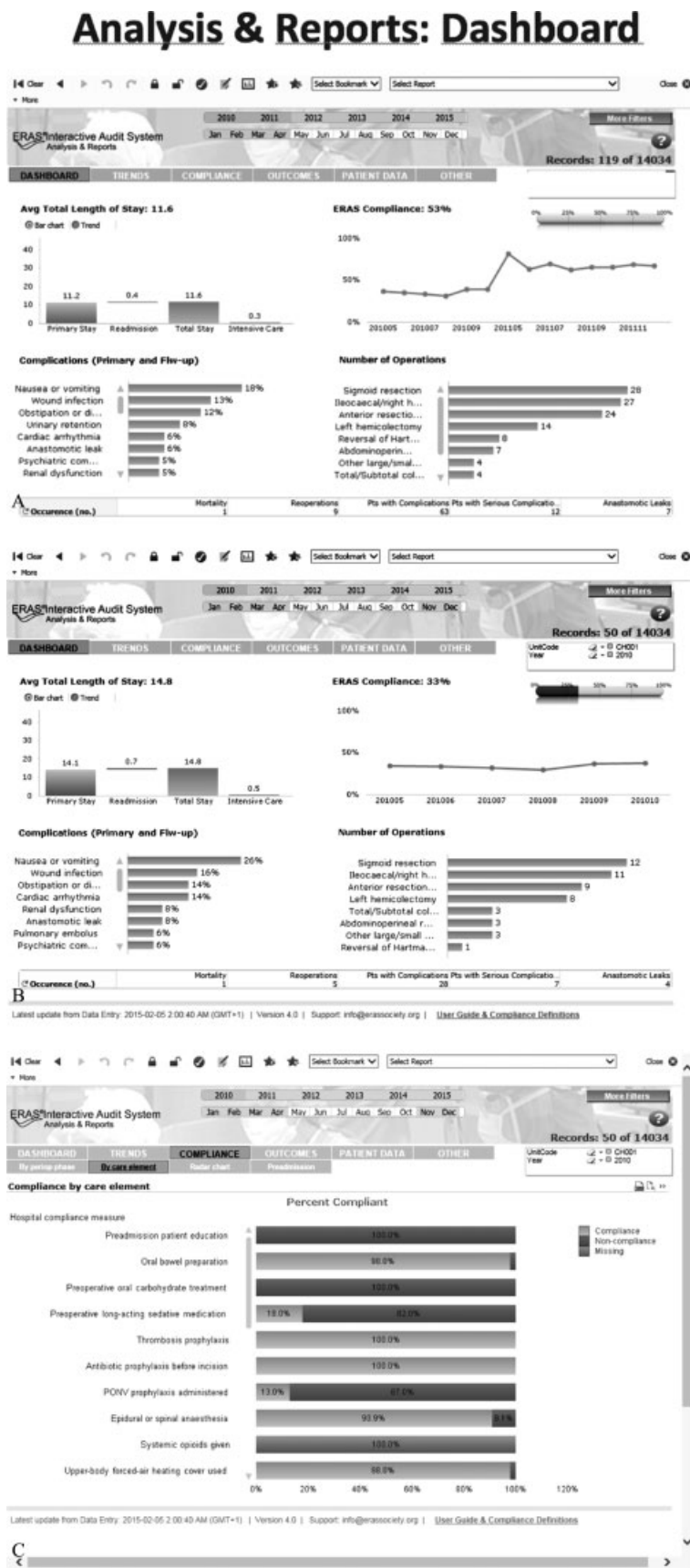


Fig. 1 Evolution of Enhanced Recovery After Surgery (ERAS) practice in the ERAS dataset. (A) Dashboard. (B) Pre-ERAS outcomes. (C) Pre-ERAS compliance. (D) After ERAS training. (E) Compliance after ERAS training.

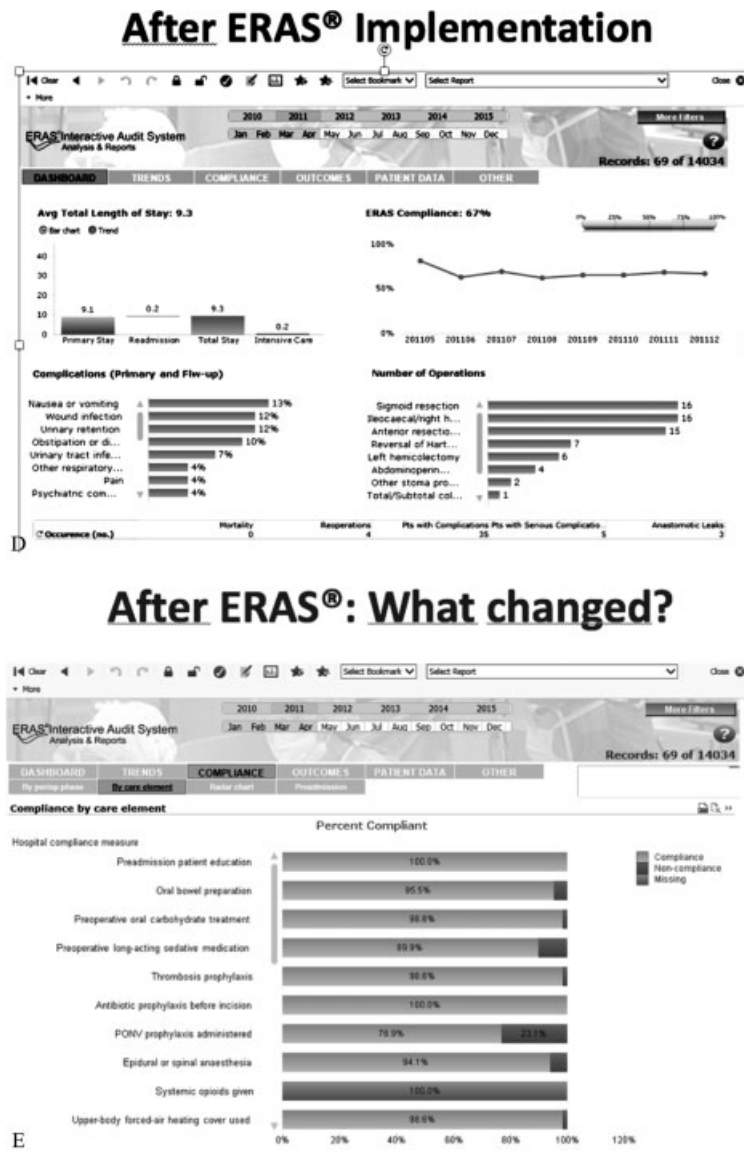


Fig. 1 (Continued)

interactive audit system, application of the institutional ERAS pathway could be maintained in the first 4 years after implementation leading to sustained improved functional recovery and clinical outcome.¹⁴

A further single-center study in Holland examined results after colectomy for cancer using the ERAS dataset and demonstrated that during the implementation phase of ERAS, hospital stay and complications decreased significantly.¹⁵ However, in the 2 years after implementation, the compliance with several fields fell and there was a concomitant increase in overall length of stay, despite many participating units being ERAS pioneers. The Dutch authors concluded that “a protocol is not enough” and audits together with continual evaluation of data are essential to deliver and maintain the improvements in perioperative care that are offered by the enhanced-recovery concept. Moreover, with the use of the database and the analysis of 267 patients, it was suggested that nursing workload decreases significantly since the introduction of ERAS in a Swiss surgical depart-

ment. In addition, with increased ERAS compliance, the nursing workload was more decreased.¹⁶

Advantage of Cohort Data

For many years, the virtues of RCTs have been vigorously espoused and deficiencies of surgical research highlighted.¹⁷ However, RCTs are subject to selection bias and may not reflect the reality of practice. Cohort data, particularly when derived from carefully controlled databases, can contribute to our understanding and development of surgery. Basse et al reported dramatic improvements in recovery after implementing enhanced recovery protocols as early as 2000,^{18,19} questioning the value of laparoscopic surgery in colorectal cancer resection. Despite this, during the next 14 years, only 600 patients were included in multicenter randomized clinical trials comparing laparoscopic and conventional open surgery when both modalities were enhanced using an ERAS protocol.^{20,21} As described, data analyzed on 2,300 patients within the multicenter ERAS

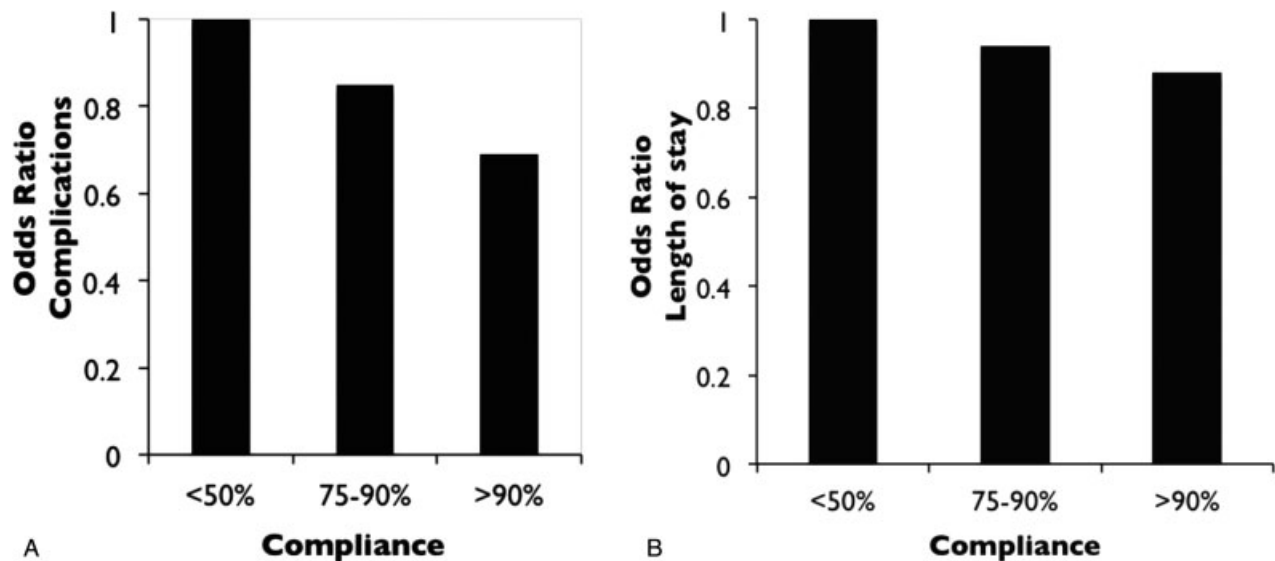


Fig. 2 (A, B) Impact of Enhanced Recovery After Surgery (ERAS) compliance on the development of complications and length of stay. Adapted from ERAS Compliance Group³ article.

database undergoing colon or rectal cancer resection revealed that laparoscopic resection decreased both hospital stay and complications, confirming the conclusions reported from the small RCTs mentioned. This confirmatory evidence, derived from a different research approach, can only enrich our understanding of outcomes and contribute to improvements in surgery. It is important, however, to follow the guidance from the IDEAL framework recommendations²² that emphasize the inclusion of consecutive patients in such studies, so that conclusions concerning clinical utility are more robust. Where consecutive data are not available, information regarding those excluded provides context to improve the accuracy of interpretation.

Future Opportunities

The ERAS database has shown that collaborative clinical effort can drive quality improvement in a short time frame in an international context. In the near future, the database aims to act as an electronic case report form. This will allow the use of the system as the core data collecting system within randomized clinical trials and should make the latter as efficient as possible. The use of the system within clinical trials will not only make data collection more robust, but the compliance component of the system should ensure optimal adherence to protocol and thus maximize the signal-to-noise output from any trial. Reducing clinical care variability is key to examining the influence of individual components of an ERAS protocol especially if the trial is multicenter and involves multiple clinicians at each site.

The future expansion in the use of the dataset will focus on the impact of the perioperative period on long-term patient outcomes. There is increasing evidence that modulating aspects of perioperative care can influence the cancer pathway. Defining the impact of individual ERAS factors and overall compliance on longer-term outcomes such as cancer survival or disease recurrence in inflammatory bowel disease are

important future topics in perioperative research and the ERAS Society database is ideally placed to address these questions.

Dedication

This article is dedicated to the memory of Professor Kenneth Fearon, who unfortunately passed away during the construction of this article. He was a founding member of the ERAS group and the ERAS Society and his commitment to improving patient outcomes after colorectal surgery has inspired the international evolution of the ERAS project.

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