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Incomplete reporting of enhanced recovery elements and its impact on achieving quality improvement

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Abstract

BACKGROUND—Enhanced recovery (ER) protocols are widely used in surgical practice. As protocols are multidisciplinary with multiple components, it is difficult to compare and contrast reports. The present study therefore examined compliance and transferability to clinical practice among ER publications related to colorectal surgery.

METHODS—PubMed, EMBASE and Cochrane databases were searched for current colorectal ER manuscripts. Each publication was assessed for the number of ER elements, whether the element was sufficiently explained so that it could be transferred to clinical practice, and the compliance with the ER element.

RESULTS—Some 50 publications met the reporting criteria for inclusion. There were 22 ERAS elements described altogether. The median number of elements included in each publication was 9 with median number of included patients of 130. The most frequent elements included in ER pathways were early postoperative diet advancement in 49 (98%) and early mobilisation in 47 (94%). Early diet advancement was sufficiently explained in 43 (86%) publications but just 22 (45%) reported compliance. The explanation for early mobilisation was satisfactory in 41 (82%) publications but only 14 (30%) reported compliance. Other ERAS elements had similar rates of explanation and compliance. The most frequently analysed outcome measures were morbidity 49 (98%), length of stay 47 (94%), and mortality in 45 (90%) of publications.

CONCLUSIONS—The current standard of reporting is frequently incomplete. In order to transfer knowledge and facilitate implementation of pathways that demonstrate improvements in perioperative care and recovery, a consistent structured reporting platform is needed.

INTRODUCTION

Although fast track (FT) protocols for surgical care were first described over 20 years ago, it is only in the last 5 years that FT and ER protocols have penetrated large segments of surgical practice^{1, 2}. As ER protocols are multidisciplinary and have multiple components, comparing reports from different centres and across different surgical specialties is not easy.

It seems appropriate that reports should describe the various elements of each ER pathway consistently and with sufficient detail that they can be reproduced elsewhere³. Only through such a rigorous approach will clinicians be able to compare outcomes associated with individual programmes. Without complete descriptions, the ability to translate positive results to other centres will be impossible and the ability to capitalise on the current speed of information transmission lost.

Introduction of a standard reporting template for clinical trials has resulted in a significant improvement in the ability to interpret and translate data from these trials into clinical practice^{4, 5}. Development of a similar structured template for the publication of studies examining outcomes for patients treated on ER protocols is likely to have similar benefits.

The purpose of this project was to examine publications related to ER with colorectal surgery, seeking to critically assess the depth and breadth of description in the protocols used. Colorectal surgery was chosen as it is the area containing the greatest number of publications. Evidence of variability in transparency of describing individual ER elements would strengthen the arguments for a standard reporting dataset for all ER manuscripts. This structured reporting would improve the ability to compare outcomes between experiences, translation of protocols from the author's institution to the reader's institution, and provide a structure for quality assessment of future publications.

METHODS

A systematic review of English language publications was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement⁶. PubMed, EMBASE and Cochrane Central Register of Controlled Trials databases were searched for the following specific terms: (“Fast Track” OR “Enhanced Recovery” OR “ERAS” OR “Accelerated Recovery” OR “Multimodal Rehabilitation”) AND (“Colon” OR “Rectum” OR “Colorectal”) AND (“Surgery” OR “Operation” OR “Procedure”). The primary search was carried out by a single researcher, with vetting of the studies done in conjunction with a second researcher. Any discrepancies were resolved by an independent third party.

Results from an initial search strategy of the 3 databases were cross-referenced and duplicates removed to create a single list. Secondary filtering was then performed to eliminate older publications (prior to 2009) and non-original manuscripts (meta-analyses

and reviews). Remaining records were subject to full text review and included in the final analysis if they met the following criteria: reports comparing outcomes between at least 2 cohorts (one of which must have been an ER pathway cohort and one of which must have been a conventional or traditional pathway cohort); inclusion of at least 50 patients; a confirmed focus on colectomy and/or proctectomy. After eliminating publications with significant overlap in patient population and the same primary or senior authorship, a final analysis list was created and assessed in detail (Figure 1).

Articles were entered into an electronic database and their content systematically analysed to determine which elements of ER were stated as being used, whether the stated element was explained, the compliance rate of that element within the study, and the failure rate of the element when applicable. Although all elements were catalogued, particular attention was made to those elements with strong evidence for safety and efficacy⁷⁻⁹. Additionally, the International ERAS Registry variables were reviewed in order to determine which of the elements in this repository were included in the published literature and could, therefore, potentially facilitate audits for future publications.

In order to be given credit for naming an ER element, a publication had to list the element as being involved in their ER pathway in one of the following locations: the manuscript text; a figure, chart, or table within the main publication, appendices or supplements; or an explicit reference to another publication's pathway. If a reference to an outside publication or external website was quoted, this resource was assessed as an extension of the originally reviewed manuscript. The total number of ER elements listed in each publication was determined by the number of discrete elements identified in this way. An element did not have to be implemented in exactly the same manner in different publications to count as the same ER element.

Once an ER element was determined to be named by the publication, it was further reviewed to determine if the element had been explained in detail. Although subjective, the criteria for adequate explanation of an ER element was that the description allowed for sufficient understanding to the level that the reader felt confident that the element could be implemented based on the description. No judgment was made regarding the adequacy or appropriateness of each intervention, only whether it was sufficiently described. For example, a publication that stated 'preoperative medications were given' but did not list the medications was not counted as having sufficiently explained this ER element. Publications were also reviewed to determine whether a corresponding element was adequately described as part of a traditional perioperative pathway, to determine what the ER intervention was changing in the authors' practice.

Level of compliance with the ER interventions was then determined by identifying the number of patients who had received the intervention or evidence that the intervention had been implemented universally across the patient population. For example, a publication which listed the use of oral non-narcotic medications in an effort to limit narcotic administration could satisfy compliance by either listing the percentage of patients that were managed in this manner or by comparing opioid utilisation in the ER group versus the traditional group.

In order to assess ER elements that were subject to failure, transparent reporting of failure rates on an element by element basis was sought covering 5 specific elements. Where nasogastric tube elimination was a component of the ER protocol, was the rate of postoperative nasogastric tube placement disclosed? For those that listed regional/epidural analgesia use, did they indicate the rate of early catheter non-function or haemodynamic lability leading to conversion to intravenous narcotic strategies? Among those that listed early advancement of oral intake, was the rate of postoperative ileus leading to failure of dietary progression stated? Where early and frequent mobilisation were evaluated, was failure to physically progress including adverse events such as falls reported? Finally, where early urinary catheter removal was included, was the rate of urinary retention requiring catheter replacement stated?

Additional information regarding study design, numbers of patients included in each trial, outcomes analysed, whether the number of surgeons or anaesthetists in the practice were listed, implementation process of the ER pathway described, whether discharge criteria were described along with location of the ER pathway were also recorded and analysed.

Quality assessment was performed by using the Downs and Black tool¹⁰, as previously recommended for systematic reviews, to address both randomized and non-randomized studies¹¹. Downs and Black scores were grouped into three quality levels: good (greater than 20), fair (15-19) and poor (less than 14).

Statistics

All statistics were descriptive in nature and listed as numbers with percentages in parentheses. Continuous variables are reported as either means or medians with ranges in parentheses. All statistical analysis was performed using SPSS version 22.0.0.0 (IBM Corp., Armonk, NY, USA).

RESULTS

The initial search strategy returned 569 results from PubMed, 1,226 results from Embase, and 161 results from Cochrane Reviews. After cross-referencing and removal of duplicates, 1,256 publications were identified. Secondary filtering to eliminate older and non-original manuscripts left 527 records that were subject to full text review. After eliminating 8 additional publications with overlap in patient population and the same primary or senior author, 50 publications were identified that met the inclusion criteria and these were assessed in detail (Figure 1).

Of these, 20 (40%) were randomized trials comparing ER and non-ER protocols¹²⁻³¹, while the remaining 30³²⁻⁶¹ described at least one retrospective cohort or used non-random assignment. Some 22 unique ER elements were identified throughout the publications. The median number of implemented ER elements described in these publications was 9 (range: 3-17 elements). The median number of patients included was 130 (range: 50-1,358 patients). Quality assessment scores ranged from 9 to 24 with a median quality score of 17. There were 6 poor quality studies, 29 fair quality studies, and 15 good quality studies.

Only 19 publications (38%) described the implementation process of that ER pathway and only 14 specifically identified the number of surgeons participating in the study. For this subset of publications the median number of surgeons was 3 (range: 1-8 surgeons). Only a single publication listed the number of anaesthetists involved. Most publications, (90%) detailed their ER protocol within the methods section of the same paper, while the remainder referenced another article as containing the ER protocol in use.

The most frequently utilised ER elements in the reviewed publications included early postoperative diet advancement in 49 (98%) and early mobilisation in 47 (94%). How these elements were implemented varied across publications. The method for diet advancement was explained in 43 publications (86%) and compliance with early initiation of diet advancement was reported in 22 (45%). Similarly, early mobilisation was defined in detail in 41 publications (82%) but compliance reported in only 14 (30%). Descriptions of diet and mobilisation strategies used in the comparative traditional recovery pathways were found in 37 (74%) and 27 publications (54%), respectively. In total, 18 publications disclosed failure rates for post-operative diet advancement and 5 reported whether or not any adverse events related to mobilisation occurred.

After these interventions, the next most commonly described interventions were nasogastric tube management in 37 publications (74%), urinary catheter management in 36 (72%), and epidural anaesthesia utilisation in 31 (62%). These elements were explained in detail in 32 (87%), 34 (94%) and 25 (83%) publications that named them as elements, respectively. The corresponding traditional pathway element or management was explained in 22 (60%), 22 (61%) and 22 (73%) publications. Compliance rates for each of these elements were found in 8 (22%), 9 (25%) and 14 (47%) of the publications, respectively. The rate of postoperative nasogastric tube replacement was reported in only 10 (27%) publications. The rate of urinary retention requiring replacement of a urinary catheter was listed in 8 (22%) and the rate of epidural failure was listed in 9 (30%) reports.

Although fewer publications reported or explained in detail the use of minimally invasive surgery or particular types of incisions, those that did name this element, frequently [7/8 (88%)] reported compliance in the form of surgical approach and the use of specific incisions. Other elements that had high compliance reporting were intraoperative fluid restriction 9/15 (60%), postoperative nausea and vomiting prophylaxis 5/8 (63%), postoperative protein supplements 6/10 (60%), and postoperative carbohydrate supplements 2/3 (67%). The elements that had the lowest compliance reporting were: withholding preoperative sedating medications 1/8 (13%), greater than atmospheric inspired FiO₂ treatment 1/5 (20%), premedication administration 1/5 (20%), and reduced preoperative fasting period 6/29 (20%). (Table 1 and Figure 2).

The outcome measures analysed most frequently in the publications were morbidity in 49 (98%) and length of stay (LOS) in 47 (94%). Only 40 (85%) of these publications described utilisation of specific discharge criteria. Mortality was reported in 45 (90%) and readmissions in 41 (82%) publications. These and less frequently reported outcome measures are shown in Figure 3.

DISCUSSION

This project focused on two areas of reporting regarding ER protocols related to colorectal surgery; transparency of reporting individual components of ER protocols and compliance and failure rates with the stated components.

There was significant variation in the completeness of descriptions of ER protocols. The median number of components described was only 9. Despite heterogeneity between studies, most did report a positive effect of ER on short-term outcomes. This may be attributable to the fact that diet advancement and early mobilisation were common to most studies with significant impact on short-term endpoints such as length of stay.

Authors reported inclusion or exclusion of important components such as fluid management, oral non-narcotic analgesia, and routine laxative or prokinetic use, less frequently. When a restrictive fluid management protocol was listed, only rarely did the authors describe their practice, or patient monitoring (e.g. fluid balance or weight monitoring). Importantly, very few manuscripts that recorded neuraxial analgesia reported epidural/regional level, single injection vs. infusion/catheter placement, medications/concentrations used or duration of infusion. The absence of adequate descriptions of ER components significantly impairs the ability to interpret, compare outcomes between studies or translate practice to other centres.

Specific attention to compliance with the most important ER elements also needs to be made clear as not all of the elements (Table 1) are evidence based and known to be important in enhancing recovery^{8, 9}. Compliance and failure rates with stated components of the protocol also varied and few studies actually reported the compliance and/or failure rate of each component of the ER protocol. Without these data it is impossible to determine the efficacy of each step in the pathway and its relative effects on the reported outcome measures. Additionally, detailed description of the corollary traditional pathway was frequently lacking. This is of particular importance when there is no apparent difference between outcome measures for ER and traditional groups.

Recently, there has been a movement towards standard reporting in medical literature. PRISMA, CONSORT and TIDieR recommendations have been proposed for meta-analyses, randomised controlled trials and clinical studies, respectively^{6, 62, 63}. TIDieR guidelines postdate the studies in this review, but additionally do not take into account all of the necessary features in an ER protocol such as component compliance, failure rates, control pathway descriptions, graded complications, and discharge criteria. As such it would not be possible to draw meaningful conclusions about the effectiveness of the applied interventions upon outcome measures using the TIDierR instrument alone.

The present study included a rigorous literature search and strict inclusion criteria that isolated a large number of high-quality studies likely to have high clinical impact. Nevertheless, the non-standardised reporting of these elements meant that some of data collection was subjective, although all findings in the analysis have been transparently reported.

The finding of significant omissions in reporting ER elements in even the highest quality studies including 20 randomised trials, leads to the conclusion that a defined template for reporting these studies would significantly improve the quality of the literature related to ER for colorectal surgery. Based on the deficiencies noted in this analysis a standardised reporting template is proposed (Table 2). While it could prove cumbersome to provide all details within the original publication, the use of appendices or references could be used for complete reporting. Measurement and reporting of compliance for each component has been shown to correlate with patient outcomes^{64, 65}. A clear description of discharge criteria, with differentiation of 'ready for discharge' compared to actual length of stay with reasons for non-medical extension of inpatient hospitalization should also be seen as essential⁶⁶. Adherence with these guidelines should make it easier and more reliable to compare practices and outcomes. It may also reverse the observation that compliance with ER pathway elements drops outside the setting of a clinical trial⁶⁷.

Another important finding in this analysis was the character of the dependent variables assessed in these studies. These were usually crude inpatient indicators of recovery such as morbidity, return of bowel function and length of stay. Patient reported outcomes and information related to costs of care are lacking. Biologic and molecular correlates that might inform future modifications in ER pathways were rarely included. This deficiency has been highlighted before and it does not appear that reporting of these elements has improved⁶⁸.

ER protocols involve multiple components that will naturally have variable success rates. In order to transfer knowledge and facilitate implementation of pathways that demonstrate improvements in perioperative care and recovery, a structured reporting platform needs to be agreed and implemented.

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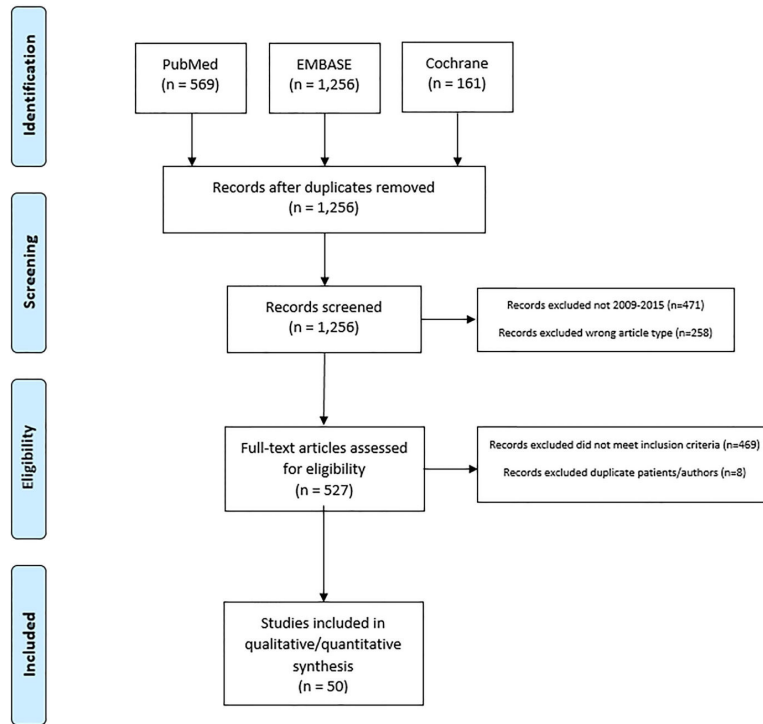


Figure 1. Selection process for identifying publications included in analysis.

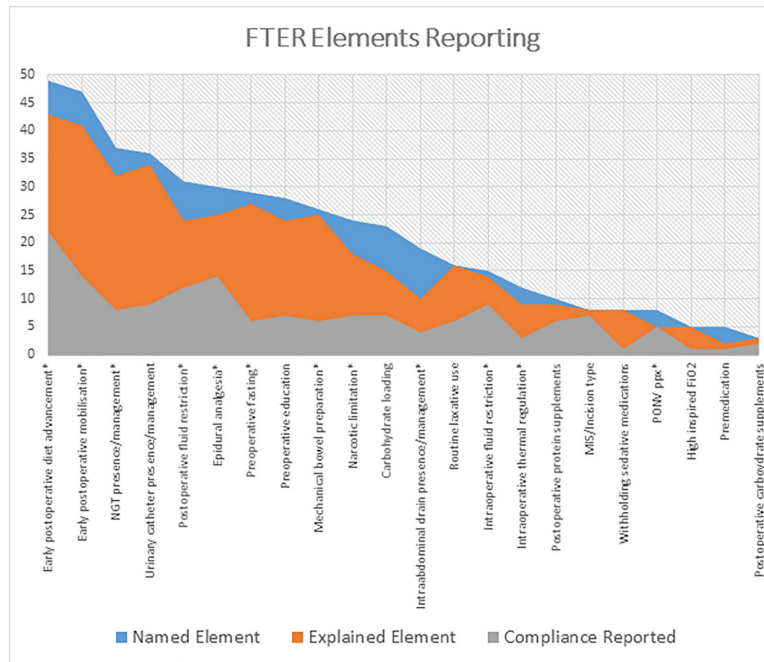


Figure 2. Rate of ER compliance reporting as it relates to ER element naming and explanations. NGT = nasogastric tube, MIS = minimally invasive surgery, PONV ppx = postoperative nausea and vomiting prophylaxis
 * indicates elements with strong supporting evidence for safety and efficacy^{8,9}

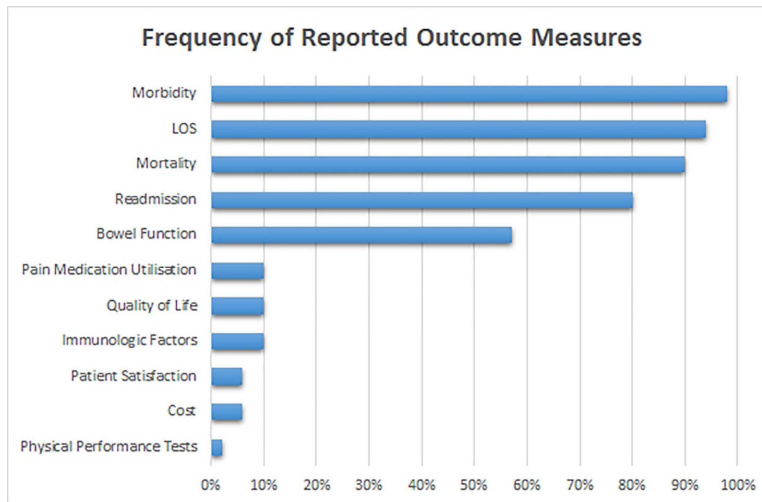


Figure 3. Patient outcome measures assessed as dependent variables in 50 colorectal surgery ER publications. LOS = Length of Stay

Table 1

ER and traditional pathway named elements and explanations with level of evidence and inclusion in the ERAS Registry.

| Factor (22 elements) | Evidence-based ^{8,9} | ERAS registry variable | Named (Total n=50) | ER pathway explained % | Traditional pathway explained % |
|--|-------------------------------|------------------------|--------------------|------------------------|---------------------------------|
| Preoperative education | | YES * | 28 (56%) | 24 (86%) | 16 (57%) |
| Bowel preparation | YES | YES * | 26 (52%) | 25 (96%) | 18 (69%) |
| Reduced preoperative fasting | YES | | 29 (58%) | 27 (93%) | 20 (67%) |
| Carbohydrate Loading | | YES * | 23 (46%) | 15 (65%) | 19 (83%) |
| Preoperative medications | | YES * | 5 (10%) | 2 (40%) | 4 (80%) |
| Withhold sedating medications preoperatively | | YES * | 8 (16%) | 8 (100%) | 6 (75%) |
| PONV ppx | YES | YES * | 8 (16%) | 5 (63%) | 6 (75%) |
| MIS/Incision | | YES | 8 (16%) | 8 (100%) | 6 (75%) |
| Intraoperative thermal regulation | YES | YES * | 12 (24%) | 9 (69%) | 7 (58%) |
| Narcotic limitation | YES | | 24 (48%) | 18 (75%) | 9 (38%) |
| Increased FiO ₂ | | | 5 (10%) | 5 (100%) | 2 (40%) |
| NGT management/presence | YES | YES * | 37 (74) | 32 (87%) | 22 (60%) |
| Epidural use | YES | YES * | 30 (60%) | 25 (83%) | 22 (73%) |
| Intraop fluid restriction | YES | YES * | 15 (30%) | 14 (93%) | 12 (80%) |
| Postop fluid restriction | YES | YES | 31 (62%) | 24 (77%) | 13 (42%) |
| Routine laxative or prokinetic use | | YES * | 16 (32%) | 16 (100%) | 12 (75%) |
| Postop protein supplements | | YES * | 10 (20%) | 9 (90%) | 6 (60%) |
| Postop carbohydrate supplements | | YES * | 3 (6%) | 3 (100%) | 3 (100%) |
| Early postop diet | YES | YES * | 49 (98%) | 43 (88%) | 37 (76%) |
| Early mobilisation | YES | YES * | 47 (94%) | 41 (87%) | 27 (57%) |
| Urinary catheter management/presence | | YES | 36 (72%) | 34 (94%) | 22 (61%) |
| Intraabdominal drain management/presence | YES | YES * | 19 (38%) | 10 (53%) | 8 (42%) |

Named = listed in the manuscript, ER Pathway Explained = enhanced recovery element described with sufficient detail to facilitate transfer to the reader's clinical practice, Traditional pathway explained = traditional pathway element described with sufficient detail to facilitate transfer to the reader's clinical practice. PONV ppx= postop nausea and vomiting prophylaxis, NGT = nasogastric tube.

* Denotes "key" field in registry

Table 2

Recommended reporting elements for studies comparing ER to traditional pathways

| |
|--|
| 1. Tabular reporting of all elements included in the examined ER pathway and corresponding elements of the traditional pathway. |
| 2. Explain all ER elements clearly with particular attention to reporting specific algorithms and pathways used in clinical management where applicable (e.g. IV fluid rates and criteria for goal directed fluid therapy; epidural/regional level, single injection vs. infusion/ catheter placement, medications/concentrations used, duration of infusion; analgesia escalation strategies; drain placement algorithms). |
| 3. Report compliance for all elements named as part of the ER protocol. |
| 4. When failure of an ER element is possible, it should be reported and explained, including adverse events that may be related to an ER element. |
| 5. When length of stay is used as an outcome measure, discharge criteria or the lack thereof should be reported. If a substitute for length of stay such as “readiness for discharge” is used, there should be a report of actual length of stay and reasons for non-medical extension of hospitalisation listed. |
| 6. When morbidity is used as an outcome measure, efforts should be made to grade complications and stratify them according to severity using a standard system^{69, 70} |

ER = Enhanced Recovery