Utilizing Evidence Based Outcome Measures to Develop Practice Management Guidelines: A Primer

Eastern Association for the Surgery of Trauma (EAST) Ad Hoc Committee on Practice Management Guideline Development

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Introduction:

The structure and organization of health care delivery are in the midst of rapid change. Increases in health care costs, competition, and regulation are prompting health care providers from a variety of disciplines to define their practice in measurable ways and to identify the outcomes to which they contribute. Methods to determine and implement optimal practices are also being developed. One such method is evidence-based outcome evaluation and clinical practice guideline utilization. Practitioners must acquaint themselves with the language and process of outcomes data so they become educated and recognized as significant players in the process of collecting and interpreting outcomes. This primer will attempt to provide insight into the concept of evidence based medicine, describe the development of clinical practice guidelines, and provide examples of guideline implementation.

Evidence-based Medicine:

Evidence-based medicine is an approach to practice and teaching established on the knowledge of the evidence upon which the practice is founded and the strength of that evidence. It involves integrating best current evidence with clinical expertise, pathophysiological knowledge, and patient preferences into the decision-making process for the care of individual patients. The relevant skills include precisely defining a patient problem, proficiently searching and critically appraising relevant information from the literature, and deciding whether, and how, to use this information in practice. These skills are now being incorporated into the training of primary care providers and continuing medical education. Efficient literature searching and proficient critical appraisal skills are necessary for the acquisition of valid and current information on the most important clinical and economic aspects of a disease. When evidence becomes the neutral arbiter of optimal practice, and all members of a multidisciplinary team are empowered to share relevant evidence, a more coordinated, holistic approach is likely to emerge. Evidence about the most effective methods of changing clinician behavior can be incorporated into disease management programs and thus, clinical and economic outcomes can be improved by reducing variation around optimal practice. If adequate research is unavailable, no specific recommendations can be made, thus avoiding inappropriate decision making and allowing for clinical flexibility. By identifying the inadequacies in research, the concept of evidence-based medicine can help formulate a prioritized research agenda in a setting where random and systematic errors caused by different practice styles are minimized. Steps for developing an evidence-based disease management program are shown below:

1. Formulate a clear definition of the disease, its scope, and its impact over time using a multidisciplinary team.
2. Develop comprehensive baseline information to understand current health care delivery and resource utilization.
3. Generate specific clinical and economic questions and search the literature.
4. Critically appraise and synthesize the evidence.
5. Evaluate the benefits, harms, and costs.
6. Develop evidence-based practice guidelines, clinical pathways, and protocols.
7. Create a system for process and outcome measurement and reporting.
8. Implement the evidence-based guidelines, pathways, and protocols.
9. Complete the quality improvement cycle.

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Clinical Practice Guidelines:

Clinical practice guidelines are evidence-based outlines of accepted management approaches, which may be disease, problem, or process specific. They are systematically developed statements that are used to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. The goals of such guidelines are to identify all treatment options and possible outcomes, weigh the benefits against the risks and costs, and, in the broadest context, factor in logistics, ethical, economic, societal, and legal considerations. Ideally, clinical practice guidelines are derived from the data sources available and used to guide health care professionals through a continuous quality improvement effort in which the process involved in health care delivery is analyzed, changes recommended, patient outcomes defined, variances from expected outcomes evaluated, and the process reassessed. Utilizing this approach, health care is delivered in an evidence-based outcome model. A step-by-step process for evidence-based outcome evaluation (EBOE), from which practice management guidelines are developed, has been derived and applied by the members of the Eastern Association for the Surgery of Trauma (EAST). This has been largely adapted from recommendations set forth by the Agency for Health Care Policy and Research (AHCPR). This process ensures a combination of rigorous methodology and practical feasibility that can be adapted to clinical decision making at any institution. In essence, the model used consists of development, implementation, measurement, and revision stages. The following steps outline the approach that EAST has taken for the development of practice management guidelines for trauma. Please refer to the timeline at the end of this section when reading the following.

Step 1. Topic selection: Topics should be selected based on volume, associated hospital costs, and implications for quality improvement or quality assurance. In general, guidelines will be disease, process, or problem specific. At present, it is recommended that a consensus be obtained by the organization developing guidelines as to the prioritization of topic selection. This must take into account the feasibility of formulation of a guideline, time required for development, and the availability of data with which to make recommendations.

Step 2. Section of a panel: Panels and panel chairpersons should be selected for each topic selected. Members of the panel may include physicians, nurses, pharmacologists, methodologists, health economists, and other disciplines.

The size and composition of the multidisciplinary panel should be tailored to the particular topic being addressed. It is important that a core group of experts, led by a trauma/critical care attending, coordinate the development of all guidelines in order to provide consistency in the process. It is recommended that all disciplines that will be affected by a particular guideline be represented on the panel. In general, a panel should consist of at least 5 members.

Step 3. Clarification of purpose and scope of the guideline: Objectives of the guideline need to be defined as clearly and concisely as possible at the outset of EBOE. This includes specification of the condition, type of patient, and clinical presentation for which the guideline is intended. Appropriate inclusion criteria would then target the patient population and the clinical setting in which the guideline was to be used. Exclusion criteria, particularly the excluded patient population and the coexisting conditions or events that would preclude guideline use, should also be developed.

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Step 4. Listing of goals and specification of questions: This should be done in conjunction with the clarification of purpose and topic selection. The panel should decide, prior to the literature search, what the goals of the guideline should be. Identification of anticipated health outcomes such as lowering morbidity, changing practice behavior and delivery patterns, and lowering costs need to be listed. Along with this, an assessment of clinical benefits and potential harms should be outlined based on what is best for the patient. More important is formulation of *specific questions* that the guideline will address. This must be done so that the panel is clear as to what they are trying to specifically address. Omission of this critical step leads to a diffused, nonfocused process.

Step 5. Assessment (grading) of scientific evidence: All relevant empirical data should be evaluated for clinical benefits and harms of the various interventions. Attempts should be made to collect as much quality scientific data as possible. This should include utilizing national consensus based guidelines when they exist. Proper methods, including a variety of databases and cross checking of citations, need to be used to ensure that these standards are met and biases avoided. The current recommendation is to conduct a standard Medline search over a 10 year period. More recently, Embase, a European Medline equivalent has been developed and future guidelines should search this database as well so that important European literature is not missed. Reference sections of the articles identified should be utilized to gather additional articles and the Cochrane database should be utilized to assure that all prospective randomized controlled trials have been identified and collected for review. The scientific evidence assessment methods employed by the Canadian and U.S. Preventative Task Force should be applied when classifying the articles identified for review. For purposes of practice management guidelines for trauma, the data will be classified as follows:

Class I: Prospective randomized controlled trials (PRCTs) - the gold standard of clinical trials. Some may be poorly designed, have inadequate numbers, or suffer from other methodological inadequacies.

Class II: Clinical studies in which the data was collected prospectively, and retrospective analyses which were based on clearly reliable data. Types of studies so classified include: observational studies, cohort studies, prevalence studies, and case control studies.

Class III: Studies based on retrospectively collected data. Evidence used in this class indicate clinical series, database or registry review, large series of case reviews and expert opinion.

Technology assessment: The assessment of technology, such as ICP monitoring devices, does not lend itself to classification in the above-mentioned format. Thus, for technology assessment, the devices are evaluated in terms of their accuracy, reliability, therapeutic potential, and cost effectiveness.

Prospective Randomized Clinical Trial-Studies, typically drug investigations, that test for the effect of some treatment on a disease variable. These studies are often single or double blinded. Randomization is done to insure that there are no selection biases to groups by spreading any suspected biasing factors across groups equally.

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Observational Studies-These studies can also be termed Field Studies or Unobtrusive Studies. These studies are done to assess the status of a variable typically when the investigator feels informing the subject might bias the factor being observed. These studies are non-experimental because no variable manipulation occurs, no treatments are performed.

Cohort-Studies that by definition are prospective. An investigator enrolls a cohort (group) to study that are typically disease free at time of enrollment. Patients are stratified into groups based upon the existence of some risk factor and waits for disease to occur. The main goal is to establish a link between a risk factor and disease. Advantages are that the researcher knows when and how disease occurs. Disadvantages are cost, time, and that the study of rare disease is very difficult.

Prevalence-Done to determine the percentage or proportion of individuals with a certain trait or disease. Often done to obtain descriptive information of a sample. Not necessarily observational because subjects are often surveyed or information is gathered.

Case-Control Studies-Studies that by definition are retrospective in nature. Patients are stratified into disease positive and negative groups, and then presence or absence of some risk factor is determined. The goal is to establish a link between risk factor and occurrence of disease. Advantages are that Case Control Studies are cheap, quick, and the study of rare disease is possible. Disadvantages are related to the use of secondary data, recall from patients, and inaccuracy of medical records.

At times it is difficult for non-methodologists to feel confident in classifying data and because of this the following recommendations should be followed in order to eliminate bias and classify the data in a valid manner:

Critical evaluation of the article should begin with an assessment of the study design and methods. This will allow for a preliminary classification of the data. For Class I articles, the design and method section will be evaluated according to the validity scale described by Jadad et al and published in Controlled Clinical Trials in 1996. This scale has not been used to date but all future guidelines will utilize it to assess the validity of Class I articles.

The article is graded on a 5 point system: was the study described as randomized (0 or 1), was the study described as double-blind (0 or 1), was there a description of withdrawals and drop outs (0 or 1), was the randomization appropriate (-1 or 1), was the blinding appropriate (-1 or 1)) where articles scored < 3 are considered to have poor design and/or methodology and this will need to be considered by the subcommittee in formulating final recommendations.

For Class II and III articles, objective validation scales do not exist and as such each article should be read by at least 2 members of the panel in order to evaluate design and method.

Subsequent to this, a quality assessment needs to be performed. Quality is evaluated by assessing if a hypothesis is set forth, the methods are well described and adhered to, the results are accrued according to the described methods, and the conclusions are supported by the results and address the hypothesis (see Table 1). After this has been done the reviewer gives a final classification of the article and

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comments (Table 2). Realize that both classification and quality of the data must be considered in the final determination of what recommendations will be made.

Should there be a difference of opinion with regards to classification or question as to the article's relevance or quality, the panel chairperson will act as arbitrator. The panel chairperson will also be responsible for reviewing all Class I articles as a cross check on the validity.

As the articles are assessed, an evidentiary table should be compiled that has the following columns: first author, year of publication, reference title and journal citation, classification, and conclusions taking into account the design, methods, and quality of the article. After compilation, the questions set forth initially should be answered in the best possible fashion and based on the strength of the data, recommendations should be drafted.

Step 6. Establishing the Recommendations:

Level 1: The recommendation is convincingly justifiable based on the available scientific information alone. This recommendation is usually based on Class I data, however, strong Class II evidence may form the basis for a level 1 recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, low quality or contradictory Class I data may not be able to support a level 1 recommendation.

Level 2: The recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert opinion. This recommendation is usually supported by Class II data or a preponderance of Class III evidence.

Level 3: The recommendation is supported by available data but adequate scientific evidence is lacking. This recommendation is generally supported by Class III data. This type of recommendation is useful for educational purposes and in guiding future clinical research.

Step 7. Drafting and validation of the document: A final document should be drafted by the panel presenting a synthesis of the literature review and of the opinion of the panel members. The draft document should be outlined as follows:

Statement of the problem should describe why the particular topic was chosen and why it was felt to be a priority for the organization. Such statements should include information on volume, cost, quality assurance, and the degree of practice variation.
A **List of specific questions** should be documented so that the reader understands what part(s) of the problem the guideline is going to address.
Process sections should be drafted to explain to the reader how data was obtained and classified. Also, the composition of the committee should be described.
Recommendations should be listed next in order, i.e. 1, 2, or 3 for each question addressed. At times, these recommendations will be used to develop algorithms that can be clinically applied.
A **Scientific discussion** should follow the recommendations and reference the literature review and the recommendations made. This section should be an in depth breakdown of why and how the recommendations were derived.
Summary paragraphs should follow the discussion and conclusions should support the recommendations.
Areas for future investigation should be addressed next and based on gaps in the available information as well as new questions that need to be answered.
References are then listed chronologically.

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The **Evidentiary tables** are the last piece of the document and are provided so that the reader may review and potentially question and improve upon the quality of the review.

The draft document would then be submitted to all members of the panel for review and modification. Subsequent to this the guidelines should be forwarded to the chairman of the EAST ad hoc committee for guideline development. Final modifications will be made and the document forwarded back to the individual panel chairpersons.

Step 8. Presentation: The guidelines are then presented to the EAST membership. This can be accomplished in two ways, oral presentation at the national meeting or via the Internet. This allows the members an opportunity to ask questions, make suggestions, and improve the guidelines. Approximately 3 months after presentation, final revisions will be made to the document and the guidelines will be submitted to the Guideline Editorial Review Board. This board will be made up of members of the AAST. The purpose of this review will be to assure that the recommendations are supported by the evidence, that all the evidence pertinent to the guideline has been collected, and to offer expert opinion in areas where there is debate or lack of adequate data. The revised document will then be sent back to the panel chairpersons and the chairman of the guidelines committee. After completing the revisions, the guideline will be forwarded to the Journal of Trauma and to the EAST web page. Authorship will be inclusive of the EAST subcommittee as well as the AAST editorial review committee.

Step 9. Implementation: Once the guidelines have been finalized they must be implemented. Implementation involves extensive education and inservicing of nursing, resident, and attending staff members and has one important guiding principle: the guidelines must be available to the clinicians in real time while they are actually seeing the patient. The two most common ways to apply these are by using either a critical pathway or a clinical management protocol. A critical pathway is a calendar of expected events that has been found to be very useful within designated DRGs. In trauma, where there are multiple DRGs used for one patient, pathways have not been found to be easily applied with the exception of isolated injuries. Clinical management protocols (CMPs), on the other hand, are annotated algorithms that answer the “if, then” decision making problems and have been found to be easily applied to problem-, process-, or disease-related topics. The CMP consists of an introduction, an annotated algorithm and a reference page. The algorithm is a series of “if, then” decision making processes. There is a defined entry point followed by a clinical judgment and/or assessment, followed by actions which are then followed by outcomes and/or endpoints. The advantages of algorithms are that they convey the scope of the guideline, while at the same time organize the decision making process in a user-friendly fashion. The algorithms themselves are systems of classification and identification that should summarize the recommendations contained within a guideline. It is felt that in the trauma and critical care setting, CMPs may be more easily applied than critical pathways, however, either is acceptable provided that the formulated guidelines are followed. After appropriate inservicing, a pretest of the planned guideline should be performed on a limited patient population in the

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clinical setting. This will serve to identify potential pitfalls. The pretest should include written documentation of experiences with the protocol, observation, and suggestions. Additionally, the guidelines will be forwarded to the chairpersons of the multi-institutional trials committees of EAST, WEST, and AAST. Appropriate guidelines can then be potentially selected for multiinstitutional study. This process will facilitate the development of user friendly pathways or protocols as well as evaluation of the particular guidelines in an outcome based fashion.

Step 10. Evaluation and Revision: This is necessary and paramount to determine whether the guidelines have altered practice patterns, improved efficiency and health outcomes, maintained quality of care, and met the goals set forth. Each guideline will have outcomes that will need to be followed in order to determine their benefits and risks. Outcomes will be followed by individual institutions and in selected cases by the multi-institutional trials committee. Each guideline should be reviewed on a yearly basis. This review would entail a new literature search to identify new data, a review of the outcomes at several institutions, and any information forwarded by the multiinstitutional trials committees. Additionally, the EAST web site (www.east.org) will allow for review of the guidelines as well as directing comments to the panel chairpersons. The collection of such information will allow for the creation of a "living" document that changes as per the outcomes associated with its use. The original panel or their designee will be responsible for the yearly revisions and these will be presented at the practice management guidelines committee meeting at the annual EAST meeting.

Summary:

Guidelines are an expected part of medical practice in today's society. However, they cannot be blindly accepted nor considered inviolate. If that were the case they would cease to be guidelines and would become standards or even mandates. Guidelines in our application must be directed primarily toward the well being of the patient. The balance between quality of care and the imposition of managed care must be kept in mind when developing guidelines, and quality of care must never be compromised. Issues for guideline development should be identified based on volume, cost, and potential for quality improvement. The development process should include those disciplines likely to be affected by their implementation, and the guidelines should be based on appropriate data and research with room for expert opinion. Timelines for development must be imposed and the guidelines should be constantly monitored, evaluated, and revised based on an ongoing database. In this manner, the guidelines will serve to improve the quality of care and hopefully will translate into new knowledge. Once developed, the guidelines should be made available to practitioners in a user friendly format at the bedside.

The following pages provide a timeline for development and an example of an evidence based guideline and clinical implementation tool.

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PRACTICE MANAGEMENT GUIDELINES

FOR PENETRATING INTRAPERITONEAL COLON INJURIES

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Practice Management Guidelines for Penetrating Intraperitoneal Colon Injuries

I. Statement of the Problem

Management of penetrating colon wounds has been evolving over the last three decades. Prior to that time, the most colon wounds in the civilian population were managed by exteriorization of the wound or proximal colostomy because of a fear of a high rate of breakdown. In the past 20 years, there has been an increasing trend toward primary repair. Advantages of primary repair are the avoidance of colostomy, with the subsequent reduction in the morbidity of the colostomy itself and the cost associated with colostomy care and the subsequent hospitalization for closure. Potential drawbacks of primary repair are the morbidity and mortality associated with failure of repair. If there is no difference in morbidity between the approaches, primary repair would be preferred. In recent years, there have been several prospective studies that support primary repair over colostomy, however, there is continued confusion as to when primary repair is appropriate.

II. Process

A computerized search of the National Library of Medicine was undertaken using Knowledge Server software. English language citations during the period of 1979 through 1996 using the words colon injury and colon trauma were identified from the data base of journal articles. Of the 113 articles identified, those dealing with either prospective or retrospective series of injuries were selected. The following groups of articles were eliminated from analysis: 1) literature review articles; 2) wartime experiences; and 3) articles from institutions which were duplicative. This left 42 articles that were institutional studies of groups of patients sustaining penetrating abdominal trauma with intraperitoneal colon injury and in which the article evaluated the method of surgical management. Another group of articles reported on colostomy closure following penetrating injury. The articles were reviewed by a group of five trauma surgeons who collaborated to produce this practice management guideline.

III. Recommendations

A. Level I

There is sufficient Class I and Class II data to support a standard of primary repair for *nondestructive* (involvement of < 50% of the bowel wall without devascularization) colon wounds in the absence of peritonitis.

B. Level II

1. Patients with penetrating intraperitoneal colon wounds which are *destructive* (involvement of > 50% of the bowel wall or devascularization of a bowel segment) can undergo resection and primary anastomosis if they are:

Hemodynamically stable without evidence of shock (sustained pre- or intraoperative hypotension as defined by SBP < 90 mm Hg);

Have no significant underlying disease;

Have minimal associated injuries (PATI < 25, ISS < 25, Flint grade < 11);

Have no peritonitis.

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2. Patients with shock, underlying disease, significant associated injuries, or peritonitis should have destructive colon wounds managed by resection and colostomy.

3. Colostomies performed following colon and rectal trauma can be closed within two weeks if contrast enema is performed to confirm distal colon healing. This recommendation pertains to patients who do not have non-healing bowel injury, unresolved wound sepsis, or are unstable.

4. A barium enema should not be performed to rule out colon cancer or polyps prior to colostomy closure for trauma in patients who otherwise have no indications for being at risk for colon cancer and or polyps.

Scientific Foundation

A. Historical Background

Repair of colon wounds was historically a failure from the first description in the Book of Judges until World War I, when occasional success was noted. Due to the high failure rate with primary repair during World War I, colostomy was mandated by Major General W. H. Ogilvie, the consultant surgeon of the Middle East Forces in the East African Command in 1943. The reasons for the high failure rate were delays in therapy as well as high velocity wounds, delay in effective resuscitation with an absence of blood banks, and minimal antibiotic development at that time. Improvements in trauma care resulted in decreased mortality from these wounds by the time of the Korean and Vietnam conflicts. In the 1950s, there were some surgeons who began to challenge the concept that colostomy was mandatory for management of all civilian colon injuries. The first prospective study done in 1979 laid the foundation for the modern treatment of colon injuries by confirming the safety and efficacy of primary repair in selected patients.[1] During the 1980s, this concept has been advanced by other investigators. Exteriorization of colon repair with early drop back (5 - 7 days) into the peritoneal cavity was occasionally done during the period of time between 1960 and 1970, but has been abandoned in recent years. It is now recognized that almost all of those patients can be more appropriately treated by primary repair. The past decade witnessed an increasing interest in primary repair of colon wounds, and some have taken this concept one step further to colocolostomy after resection of destructive wounds of the colon.

B. Risk Factors for Complications in Colon Injury Management

Besides the severity of injury to the colon, a host of other factors have influenced the choice and results of operative treatment. Several risk factors have been identified by different investigators to identify those patients suited for definitive methods of repair and to differentiate them from patients at high risk for postoperative complications, especially anastomotic leak and intra-abdominal abscesses. The majority of these studies are either class II or class III studies. The five class I studies found either lower or similar septic complications and septic morbidity after primary repair as compared to colostomy. 1-5

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Shock: Several series documented that transient hypotension pre- or intraoperatively did not seem to affect the incidence of postoperative complications. There is evidentiary support, however, that mortality is significantly increased in the presence of sustained hypotension pre-and intraoperatively.[6-8,11,12,19]

Duration from injury to operative control: Traditionally, delayed treatment of colon injuries is considered a significant predictor of postoperative morbidity. Some investigators have suggested that morbidity is not increased when treatment is delayed up to 12 hours.[7,19,27]

Fecal contamination: Of all the variables that may potentially affect colon injury management, fecal contamination has been the most difficult to quantify. Several class II and III studies noted an increase in the rate of abscesses and septic deaths in patients with major fecal contamination although others did not consider gross fecal spillage a contraindication to repair or anastomosis. Major contamination, defined as contamination on more than one quadrant of the abdomen, was a significant contributor on multiple regression analysis in one class II study [6] and one class III study.[12] Some attempt should be made to establish an objective method of evaluating the degree of contamination.

Associated injuries and injury severity assessment: Some retrospective series emphasized multiple organ injuries as contraindications to repair of the colon injury. More recent class I series, though conceding that mortality and septic morbidity is higher in patients with a greater number of associated organ injuries, do not consider them a contraindication to primary repair of nondestructive wounds. Several class I studies and a large number of class II and class III studies suggest that associated injuries greater than two are associated with increased septic complications. PATI of more than 25, and ISS greater than 25, Flint grade greater than 11 are found to be significant for postoperative complications.

Blood transfusions: The number of units of transfused blood has been shown to be an independent risk factor for postoperative morbidity by several series, some class I and most class II and III. Four units were mentioned as a critical level, beyond which the risk for postoperative morbidity is increased.[6,12,20] The conclusions were based on logistic regression of a large number of patients.

Anatomic location of the injury: Several class I, II, and III articles did not find any significant difference in complications between right and left colon for primary repair.

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C. Evaluation of the Evidence Supporting Primary Repair

There have been five class I studies reported. In those studies, 206 patients were randomized to either primary repair for nondestructive colon wounds or resection and anastomosis for destructive wounds (166 primary repair, 40 resection and anastomosis) and these were compared to 193 patients randomized to colostomy. One of these studies selected patients with less severe injuries for randomization as this was the first study of primary repair for colon injuries.[1] In that study, there were 67 patients randomized to primary repair and 72 to colostomy; the 139 patients that were randomized represented 50% of colon injuries at the institution over the time of the study. In the remaining four class I studies, there were 99 nondestructive colon wounds primarily repaired and these studies included all patients with colon injuries regardless of severity. Additionally, one of the class II studies included all patients with nondestructive colon wounds to have primary repair because of degree of injury.[6] There were 83 patients in that study. Combining the four class I and one class II studies resulted in 182 nonselected patients who underwent primary repair. Of these 182, there were two suture line leaks, and one of these closed spontaneously without operative intervention. There were no deaths associated with primary repair.

There were three additional class II studies comprising 407 patients with primary repair. Those series were selected in that they included approximately 50% of patients with colon wounds with the remaining 50% being more severely patients who underwent colostomy or exteriorization. There were three suture line failures in those 408 patients having primary repair and one of these three patients with leak died.

There were 18 class III studies which provided sufficient data to evaluate suture line leaks in those patients undergoing primary repair for nondestructive wounds. Those class III studies in general performed primary repair on approximately 42% of the patients included in their reports. From those studies, there were 1,272 instances of primary repair. There were 15 suture line failures (1.1%) and two deaths associated with these failures; one death was documented to be in a patient with advanced gastric carcinoma . 31

valuation of the class I, II, and III studies would indicate that there has been approximately a 1% failure rate for all primary repairs. This failure rate is less than that for elective colorectal surgery. Mortality associated with a suture-line failure was uncommon. The decreased morbidity associated with avoidance of colostomy, the disability associated with the interval from creation to closure of the colostomy, and the charges associated with colostomy and the closure of the colostomy all support a standard for primary repair of nondestructive penetrating colonic wounds.

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D. Evaluation of the Evidence Supporting Resection and Anastomosis for Destructive Wounds

In the four class I studies which included destructive wounds in the randomization process, there were 40 cases that underwent resection and anastomosis.[2-5] Of these 40 cases, there was one anastomotic leak (2.5%) without mortality. In class II studies, there were 12 patients reported who had destructive wounds undergoing resection.[6] From these 12, there was one anastomotic leak (8.3%) without mortality.

There were 14 class III reports which included patients with resection and anastomosis. In those reports, there were 303 cases in which resection and anastomosis for destructive colon wounds were performed. There were 16 failures (5.2%). Of those 16 failures, there were three deaths (19%).

Although the results with resection and anastomosis were good in class I and class II studies, there was a paucity of cases. Though 331 cases reported in the class III data is a substantial number, the results are marginal, especially considering the mortality associated with suture line failure. Most failures with resection and anastomosis have been in patients who have significant associated injuries and/or associated disease processes. The data would support resection and anastomosis for stable patients without significant associated injuries. Patients with serious injuries or significant underlying disease have better results with resection and colostomy.

E. Evaluation of Evidence for Colostomy Closure

The mortality for colostomy closure has been consistently 0% in many series.[33-42] The morbidity rates have ranged from 4.9% to 26.3% with some of the variation attributable to somewhat different definitions of complications. Recent series have reported lengths of stay for colostomy closures ranging from 4 to 151 days.[36-39,42]

There is one randomized, prospective trial performed by Velmahos et al. on 49 patients with colostomies.[33] All patients had undergone a contrast enema in the second postoperative week to assess distal colon function healing. Patients were excluded from early closure for non-healing of the bowel injury, resolving wound sepsis, or an unstable condition. The remaining 38 patients were allocated to either early or late colostomy closure. The mean day of colostomy closure for patients with early closure was 11.8 days, with a range of 9 to 14 days. The mean day of colostomy closure for the late closure patients was 104.8 days, with a range of 92 to 118 days. There was no significant difference in morbidity between the two groups. Technically, the early colostomy closure was far easier than the late colostomy closure and required significantly less operating time ($p=0.036$) and less intraoperative blood loss ($p=0.02$).

A study by Machiedo et al. performed at the New Jersey College Medical School affiliated hospitals between 1974 and 1978 was not randomized but patients were divided into three groups.[34] Group 1 consisted of patients in whom colostomy was closed within 6 weeks, and Group 2 consisted of those who were undergoing colostomy closure after 3 months. Lower infection rate than in Group 3. Patients in Group 2 exhibited a lower postoperative infection rate and a shorter postoperative length of stay than patients in Group 1.

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Colostomies performed following colon and rectal trauma can be closed within 2 weeks if contrast enema is performed to confirm distal colon healing. This recommendation pertains to patients who do not have non-healing bowel injury, unresolved wound sepsis, or are unstable.

A study by Atweh et al. revealed that none of 84 patients had unsuspected colon lesions on barium enema at the time of colostomy closure.[40] They recommended contrast studies or endoscopy only for injuries below the peritoneal reflection. Crass et al. used contrast of the distal segment only if that segment contained the injury.[38]

Thus, a barium enema should not be performed to rule out colon cancer or polyps prior to colostomy closure for trauma in patients who otherwise have no indications for being at risk for colon cancer and/or polyps.

V. Summary

The decreased morbidity associated with avoidance of colostomy, the disability associated with the interval from creation to closure of the colostomy, and the charges associated with colostomy and the closure of the colostomy all support a standard for primary repair of non-destructive penetrating colon wounds.

For destructive penetrating colon wounds, the data would support resection and anastomosis for stable patients without significant associated injuries. Patients with serious associated injuries or significant underlying disease have better results with resection and colostomy.

VI. Future Investigations

Future studies should be conducted in a prospective, randomized fashion concentrating on the role of colostomy and timing of closure for destructive colon injuries.

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