Evidence-based Clinical Practice Guidelines on the Operative Management of Penetrating Colonic Injuries

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Controversy has always beleaguered the care of the injured as far back as history can tell. Of these issues, none has been as controversial as the management of colon trauma.

From its first description in the Book of Judges[1] until World War I, the repair of colon injuries has been fraught with abject failure. Due to poor outcome, Major General W.H. Ogilvie, consultant surgeon of the East African Command during the First World War, mandated obligatory colostomy for all colonic injuries.[2] The dictum was then adopted into civilian practice. For nearly 60 years, patients with colonic injuries were condemned to outright colostomy.

Traditionally,[3,60] the criteria for obligatory colostomy were as follows:

1. Shock, preoperative BP <80/60 mmHg;
2. Hemorrhage, intraperitoneal blood loss > 1000ml;
3. Organs, > 2 intra-abdominal organ systems injured;
4. Contamination, significant peritoneal soilage by feces;
5. Time operation begun, >8 hours after injury;
6. Colon wound so destructive as to require resection;
7. Abdominal wall, major loss of substance/mesh placement.

Developments in trauma care and experience in the Korean conflict and Vietnam War led some surgeons to challenge this long held concept. The landmark prospective study of Harlan Stone and Timothy Fabian comparing primary closure and exteriorization in 1979, laid the foundation for the modern day treatment of colon injuries. Subsequently, several studies confirmed the efficacy and safety of primary repair in selected patients.

The potential drawbacks of primary repair are the morbidity and mortality associated with suture line failure. If there is no difference in the morbidity and mortality between primary repair and colostomy, primary repair would be preferred; however there is continued confusion as to when primary repair is appropriate.

In an attempt to better define the appropriate roles of the surgical options (colostomy vs. primary repair) for penetrating colonic injuries, the Philippine College of Surgeons (PCS) through the Committee on Trauma decided to formulate these "Evidence-Based Clinical Practice Guidelines on the Management of Penetrating Colonic Injuries". It is envisioned that the application of this set of standards will be rewarded with decreased incidences of unnecessary colostomy and ill-advised primary repair for traumatic perforations of the colon. With proper use of the recommended management strategies, surgeons may be able to realize a higher rate of primary repair with its attendant lower morbidity and comparable mortality rates as compared to colostomy.

The following were the clinical questions formulated by the Technical Working Group (TWG):

1. Can non-destructive penetrating colon injuries be repaired primarily?
2. What factors would make primary repair for non-destructive colon injuries a less likely option?
3. Can destructive penetrating colon injuries be repaired primarily?
4. What factors would make primary repair for destructive colon injuries a less likely option?

The draft guidelines were presented to stakeholders during the Philippine College of Surgeons' Annual Convention held at the EDSA Shangri-la Hotel, Mandaluyong City on December 4, 2002. The invited participants included practicing surgeons and surgical residents.

The Evidence-Based Clinical Practice Guidelines in the Management of Penetrating Colonic Injuries were then submitted to the 2003 PCS Board of Regents for final approval in March, 2003.

Disclaimer of Liability

The information contained in these guidelines reflects the current state of knowledge at the time of completion, October, 2002.

The recommendations contained in these guidelines may not be appropriate for use in all circumstances. The decision to adopt any particular recommendation contained in these guidelines must be made by a treating physician in the light of all the facts and circumstances in each particular case and on the basis of the available resources.

In view of the facts that there will be future developments in scientific information and technology, it is anticipated that there will be a periodic review and updating of these guidelines. The validity of these guidelines is dated at 3 years.

Methods

The Technical Working Group (TWG) was composed of :

1. Teodoro J. Herbosa, MD, FPCS - Chairman, PCS Committee on Trauma
2. Hermogenes R. Regal, MD, FPCS - Vice Chairman, PCS Committee on Trauma
3. Harry L. Go, MD, FPCS - Member, PCS Committee on Trauma
4. Joel U. Macalino, MD, FPCS - Member, PCS Committee on Trauma
5. Orlando O. Ocampo, MD, FPCS - Member, PCS Committee on Trauma
6. Eric SM. Talens, MD, FPCS - Vice President, Philippine Society for the Surgery of Trauma
7. Daniel A. Dela Paz, Jr. , MD, FPCS - Member, Philippine Society of General Surgeons
8. Hermogenes J. Monroy , MD, FPCS - Member, Philippine Society of Colon and Rectal Surgeons
9. Manuel Francisco T. Roxas, MD, FPCS - Member, PCS Committee on Research
10. Eduardo C. Ayuste, MD - Trauma Fellow, Philippine General Hospital
11. Benedict Edward P. Valdez, MD - Trauma Fellow, Philippine General Hospital

12. Leonardo L. Cua, MD, FPCS - Member, Board of Regent, PCS
13. Maximo H. Simbulan, MD, FPCS - Member Board of Regents, PCS

A comprehensive computerized search was undertaken using Medline, Cochrane and Herdin libraries, the search included citations from 1975 to 2001 using the MeSH terms "colon injury/injuries", "colon trauma" and "colon repair". Textbook and relevant historical bibliographical articles were reviewed and hand searched. From the search results, the TWG evaluated the abstract and selected relevant articles for full text retrieval.

Of the 269 citations initially identified, the following groups of articles were eliminated from analysis:

1. Review articles
2. Letters to the editor
3. Animal studies
4. Articles dealing with technique and non-traumatic colon injuries

Of the 120 articles that remained, 91 were chosen based on nominal group technique. Upon further evaluation, articles from institutions that were duplicative in nature were also excluded.

A total of 60 articles evaluated and appraised by the TWG were included in the final analysis. The clinical evidence was then rated according to the assessment system of the Infectious Disease Society of America:

Level I - Evidence from at least one properly designed randomized controlled trial or meta-analysis

Level II - Evidence from at least prospective cohort or case-control analytic studies, from multiple time-series studies, or from dramatic results in uncontrolled experiments.

Level III- Evidence from opinions of respected authorities on the basis of clinical experience, descriptive studies, retrospective studies, or reports of expert committees.

Members of the TWG prepared the evidence-based report based on the articles retrieved and appraised. The TWG together with the panel of experts reviewed the interim report on October 22, 2002 at the PCS Conference Room. The evidence and recommendations were scrutinized and the participants given the opportunity to express their opinions and views. The modified Delphi Technique, moderated by Dr. Earl Castillo (an epidemiologist), was then used to determine the degree of consensus regarding the recommendations. The strength of the recommendations was categorized according to the level of agreement of the panel of experts after a vote by the participants:

Category A - Recommendations that were approved by consensus (75% of the expert panel)

Category B - Recommendations that were somewhat controversial and did not meet consensus.

Category C - Recommendations that caused real disagreement among members of the panel.

The panel of experts included:

1. Bernardo M. Cuevas - Philippine Society of Colon and Rectal Surgeons
2. Beda R. Espineda - Philippine Society of Pediatric Surgeons
3. Celso M. Fidel - Philippine Society for the Surgery of Trauma
4. Dionisio T. Lopez - Philippine Association of Military Surgeons
5. Adriano V. Laudico - American College of Surgeons (Local Chapter)
6. Narciso S. Navarro - Asian Surgical Association
7. Arsenio C. Pascual - International College of Surgeons
8. Isaac David E. Ampil II - PCS Committee on Surgical Research
9. Raymund Erese - PCS Committee on Surgical Research

Operational Definitions

COLON - segment of bowel from the ileocecal valve to the sacral promontory

PRIMARY REPAIR - Either of the following:

(1) Debridement with simple closure of the perforation/s
(2) Resection of a segment of bowel containing the perforation/s followed by anastomosis

COLOSTOMY - Any of the following:

(1) Exteriorization of the injured colonic segment
(2) Resection of the injured colonic segment with end colostomy
(3) Primary repair of the injured colon with creation of a proximal stoma (ileostomy or colostomy)

NON-DESTRUCTIVE COLON WOUNDS - colonic injuries that did not require resection

DESTRUCTIVE COLON WOUNDS - any form of injury to the colon warranting resection

CLINICALLY DETECTABLE PERITONITIS - inflammation of the peritoneum or serosal surfaces as evidenced by congestion and edema; presence of fibrinous, purulent, or fibrino-purulent; and/or frank abscess/es formation.

STANDARD OF CARE - any intervention supported by at least level I evidence and approved by 75 per cent of the members of the panel

Summary of Guidelines

1. Can non-destructive penetrating colon injuries be repaired primarily?

GUIDELINE 1. For non-destructive colonic injuries, the standard of care is primary repair.

LEVEL I EVIDENCE
CATEGORY A RECOMMENDATION

2. What factors would make primary repair for non-destructive colon injuries a less likely option?

GUIDELINE 2. In non-destructive colonic injuries with clinically detectable peritonitis, colostomy is the primary option.

LEVEL III EVIDENCE
CATEGORY A RECOMMENDATION

3. Can destructive penetrating colon injuries be repaired primarily?

GUIDELINE 3. Destructive colon injuries can be repaired primarily.

LEVEL II EVIDENCE
CATEGORY A RECOMMENDATION

4. What factors would make primary repair for destructive colon injuries a less likely option?

GUIDELINE 4. In destructive colonic injuries, colos-tomy is the primary option in the presence of any of the following:

a. significant underlying medical illness
b. clinically detectable peritonitis

LEVEL III EVIDENCE CATEGORY A RECOMMENDATION

a. hemodynamic instability
b. significant associated intra-abdominal organ system injuries (>3)

LEVEL III EVIDENCE
CATEGORY B RECOMMENDATION

Guidelines

1. Can non-destructive penetrating colon injuries be repaired primarily?

GUIDELINE 1. For non-destructive colonic injuries, the standard of care is primary repair.

LEVEL I EVIDENCE
CATEGORY A RECOMMENDATION

There were 5 level I articles identified: 1 meta-analysis and 4 randomized controlled trials (RCT). Two RCTs were from the same institution.[5,6] The earlier study[5] was superseded by the latter,[6] which included 67 more patients. The former was considered duplicative and thus excluded.

The meta-analysis[4] showed a clear advantage of primary repair over colostomy with respect to post-operative complications. Odds ratio was 0.32 (0.13-0.77). Two of the 3 RCT's were evaluated in this meta-analysis.[7, 8] There were no suture line failures in the 71 patients who underwent primary repair.

The largest RCT[6] analyzed 176 patients, 81 of whom underwent colorrhaphy. There were no suture line failures. Two deaths occurred in this group, both non-colon related. One hundred forty three (143) patients had colostomies, with a single colon-related mortality. Morbidity rates for all RCT's are tabulated in Table 1. The results suggested that primary repair is at least as successful as colostomy, even when patients present with previously identified criteria for obligatory colostomy.

There was one RCT[3] that the Technical Working Group classified as level II evidence. Forty eight percent (129 cases) of the study subjects were not randomized, and the concealment of allocation was clearly inadequate.[4] There was one suture line failure in 67 primary repairs. The morbidity rates for this study were 47.8 percent for primary repair and 56.9 percent for colostomy (p=0.361). There was one death in each group, both non-colon related.

There were 41 level III articles, four of which were local publications.[9-12] Two articles[13-14] favored colostomy over primary repair with respect to postoperative complications. Three articles dealt exclusively with exteriorized repairs,[40,48,53] and were excluded from the analysis.

The local publications reported a leak rate of 0.8 per cent (3/372). There were 16 deaths (4.3%), all non-colon related. Sixty-eight patients had colostomies, with associated 10 per cent mortality. Overall morbidity rates were 17.2 and 19 percent for primary repair and colostomy, respectively.

The rest of the articles[19-39, 41-47,49-52,54-59,61-63] reported a total of 3191 cases of primary repair, with 35 suture line failures (1.09%). Seven deaths (0.2%) were attributable to these leaks. A total of 1619 colostomies were performed. Morbidity and mortality rates were 21.6 and 3.7 percent respectively. Some of the studies[34,49] reported increasing morbidities in cases where severe fecal contamination or peritonitis was noted.

2. What factors would make primary repair for non-destructive colon injuries a less likely option?

GUIDELINE 2. In non-destructive colonic injuries with clinically detectable peritonitis, colostomy is the primary option.

LEVEL III EVIDENCE
CATEGORY A RECOMMENDATION

Some of the retrospective studies[14,34,49] reported increasing leak rate in cases where peritonitis was present. However, there are no data comparing the leak rates in patients with to those without peritonitis. The definition of peritonitis also varied from study to study, making valid comparisons difficult to achieve.

3. Can destructive penetrating colon injuries be repaired primarily?

GUIDELINE 3. Destructive colon injuries can be repaired primarily.

LEVEL II EVIDENCE
CATEGORY A RECOMMENDATION

The level I articles[6-8] make a recommendation in favor of primary anastomosis for colon injuries requiring resection. However, in these studies, there were only 31 cases of resection anastomosis. There were no anastomotic leaks. Two patients died (7.1%) from non-colon related causes. The overall morbidity rates were 12.9 and 40.6 percent for resection-anastomosis and colostomy, respectively.

A recent prospective study by Demetriades and cohorts[15] analyzed 297 patients, 197 of whom underwent primary anastomosis. There were 13 suture line failures (6.6%); none resulting in death. The overall incidence of colon related abdominal complications was 24 percent (primary repair, 22%; diversion, 27%; p=0.373). Morbidity increased in the presence of severe fecal contamination, transfusion of $\geq$ 4 u blood within the first 24 hours and single agent prophylactic antibiotics. However, multivariate analysis, controlling for these confounding factors, showed no difference in outcome between primary anastomosis and colostomy (adjusted RR of 0.90: 95% CI 0.55-1.39; p = 0.64). The authors concluded that primary repair should be considered in such patients.

4. What factors would make primary repair for destructive colon injuries a less likely option?

GUIDELINE 4. In destructive colonic injuries, colostomy is the primary option in the presence of any of the following:

a. significant underlying medical illness
b. clinically detectable peritonitis

LEVEL III EVIDENCE
CATEGORY A RECOMMENDATION

c. hemodynamic instability
d. significant associated intra-abdominal organ system injuries (>3)

LEVEL III EVIDENCE
CATEGORY B RECOMMENDATION

In a prospective observational study, Cornwell and associates[16] analyzed 27 patients (25 primary repairs and 2 colostomies). There were 2 suture line failures and both were fatal (8%). The authors surmised that there is still place for colostomy in high-risk patients with destructive colon injuries.

In the level III studies[17-39, 41-47,49-52,54-59,61-63], 920 patients had resection anastomosis for destructive colon injuries. There were 34 anastomotic leaks (3.7%) with 4 colon-related mortalities (0.4%). The overall morbidity rates were 7.6 and 21.7 percent for primary anastomosis and colostomy, respectively. Most of the suture line failures were in those patients with associated significant intra-abdominal injuries and/or disease processes.

There are 2 level III studies that dealt exclusively with destructive colon injuries. Stewart[17] reported on 60 patients (43 managed by primary anastomosis and 17 by colostomy). Anastomotic leak rate was 14 percent (6/43).

There was a 33 percent leak for patients who had medical illness and those who received more than 6 units of blood. Septic morbidity rates were 37 and 29 percent respectively. They concluded that primary repair should not be performed in these subsets of patients. The study of Murray et al[18] included 140 patients (112 primary anastomosis and 28 diversions). Anastomotic leak rate was 8 percent (9/112). Univariate analysis identified Penetrating Abdominal Trauma Index (PATI) >25 and hypotension in the emergency room to be associated with increased risk of anastomotic dehiscence. Septic morbidity rates were 29.5 and 29 percent respectively. The author suggested that in such cases, a diversion procedure might be appropriate.

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