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Staged abdominal repair compares favorably with conventional operative therapy for intra-abdominal infections when adjusting for prognostic factors with a logistic model

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Abstract. Staged abdominal repair (STAR) is a newly developed operative approach for the treatment of diffuse peritonitis. It demands a commitment at the first laparotomy for multiple relaparotomies scheduled at 24-h intervals. STAR reverses the pathophysiological impact of increased intra-abdominal pressure on pulmonary, renal, cardiovascular, and liver function and peritoneal blood flow. If required, prosthetic devices may be used to bridge any fascial gap and to accommodate the edematous peritoneum and distended bowels. This minimizes fistula formation and deters abdominal fascial retraction, while permitting definitive abdominal fascial closure without evisceration and hernia formation. Since prospective controlled studies are difficult to perform and are therefore not available, we provide another model to test improvement in outcome following STAR. We stratified 95 patients treated by STAR according to the APACHE-II score and compared this series with 260 patients with intra-abdominal infections treated by conventional operative management (NON-STAR) and entered into a prospective multicenter observation study. Pearson chi-square analysis revealed no significant difference ($P = 0.624$) between mortality of STAR (24.2%) and NON-STAR (21.8%). The Mann-Whitney U-Test, however, showed a significant difference ($P < 0.001$) between the APACHE-II scores of STAR and NON-STAR, indicating that there might be a difference in mortality when comparing patients at equal mortality risk. To adjust for the significant differences in prognostic factors, we used a logistic model with APACHE-II scores as dependent variables and introduced a therapeutic categorical variable pair (STAR and NON-STAR) to examine the difference of their respective contribution to the event rate. A significant difference in the mortality was confirmed in favor of STAR ($P = 0.0179$), and the logistic equation is given by [Log p/1-p = –4.14 + (0.193* APACHE-II) + (0.4121* OPERATION)], where OPERATION is +1 for NON-STAR patients and –1 for STAR patients. We conclude that STAR is superior to conventional operative therapy for advanced suppurative peritonitis.

Key words: Intra-abdominal infection – Staged abdominal repair (STAR) – Standard operation – Logistic regression – APACHE-II score

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Introduction

Staged abdominal repair (STAR) is a newly developed [51] operative approach to the treatment of advanced suppurative peritonitis. It combines the advantages of planned relaparotomies [28, 48] and the technique of leaving the abdomen open [42, 45, 52]. Of all patients operated on for intra-abdominal infections, about 10–15% qualify for this new technique [50]. Most hospitals treat no more than approximately 90 patients annually for peritonitis [53]. Of these, only 8–12 patients would be available for a prospective randomized trial to demonstrate superiority of one particular operative technique. Consequently, a fair comparison of methods is impossible for any single institution, and while multicenter studies are difficult to perform, there is plenty of anecdotal literature concerning the success of newer operations for advanced peritonitis [2, 3, 5, 9, 13–16, 20, 22, 24, 25, 27, 28, 33–35, 37, 38, 40, 44, 45, 47–49, 51, 55].

Several authors recommend using the APACHE-II score [32] for severity of disease stratification of intra-abdominal infections [4, 11, 12, 36, 39]. Only few studies, however, use such prognostic factors to stratify patients in therapeutic trials of intra-abdominal infections [44, 46, 51]. To our knowledge, no study testing operative methods uses statistical tests to adjust for prognostic factors when comparing an experimental patient population with a standard [41].

Therefore, the aim of the present study was to compare STAR with NON-STAR and to supplant anecdotal reports with tested data in anticipation of a full, prospective randomized trial. We compared mortalities of patients treated with STAR for advanced intra-abdominal infections and those who did not receive STAR. We had studied the STAR patients prospectively and had stratified them according to APACHE-II. The NON-STAR patients wer also prospectively studied in a concurrent, multi-institutional, observational study and stratified according to APACHE-II. To adjust for prognostic factors in assessing both the magnitude and the significance of treatment effects on mortality, we modified the multiple logistic model of S. J. Pocock [41].

Materials and methods

We compared 95 patients treated for suppurative peritonitis with STAR with 260 patients receiving conventional operative management other than STAR and defined as NON-STAR.

NON-STAR group

The outcome following conventional operative management of intra-abdominal infections was assessed in a multicenter observation study. The departments of surgery of eight university hospitals and four large general hospitals entered patients into this study during a period of nine months in 1987.

All patients operated on for intra-abdominal infections at each participating institution had to be included in the study to reduce selection bias. Early mortality, pregnancy, minor status, or other risks frequently used to exclude the critically ill were no exceptions from this rule. Treatment at each participating institution remained unequivocally unaffected by the study. The study center needed to be informed by phone as soon as each initial operation was completed to ensure that all operated patients were entered into the study. This information, recorded into a log book, included demographic data, time of operation, and procedure performed. Also, each institution was asked to check for discrepancies among their respective populations by comparing the patients entered into the study center log book with the total number of patients recorded at each respective institution.

A completed case report from for each registered patient was required 8 weeks after study entry. This case report form included patient demographic data preserving anonymity, data required for computation of the scoring systems, and additional information similar to that required for the STAR patients. Data were checked for completeness and then analyzed statistically utilizing SPSS/PC. Statistical Package for the Social Sciences.

STAR group

STAR, by definition, comprises multiple operative interventions planned either before or during, but not after the first procedure (index operation). At the time of the index operation the commitment is made to return to the abdomen to re-explore, irrigate, débride, resect, repair, and verify integrity of sutures and anastomoses until those disease processes indicating STAR at the first operation are resolved. The abdomen is then closed. Prosthetic devices for temporary abdominal closure are used to bridge fascial gaps caused by peritoneal edema associated with inflammation of the peritoneum and vital resuscitation. These devices, besides facilitating re-exploration, were also used to alleviate impairment of pulmonary, renal, cardiovascular, hepatic and gastrointestinal function induced by abdominal compartment syndrome. The STAR group represents our own experience with STAR and comprises patients different from those of the conventional study group.

Indication for STAR

Staged abdominal repair was performed in patients with advanced suppurative peritonitis under one of the following conditions:

1. The patient's condition had deteriorated to a point which precluded definitive repair at the initial operation (septic shock, and hemodynamic instability)
2. Excessive peritoneal edema (abdominal compartment syndrome) prevented reapproximation of the fascial edges without undue tension.
3. It was impossible to close an intestinal leak or otherwise eliminate the source of infection.
4. Débridement was incomplete, and remaining significant areas of necrotic tissue were a major concern for fostering further bacterial growth.
5. It was difficult to estimate the margins of bowel ischemia requiring resection, and a second look seemed appropriate.

Initially, only very sick patients presenting with multisystem organ failure (MOF) [7, 18, 31] and believed to have a very poor prognosis were included. Later, with experience, these indications became relaxed and patients with local problems which were not considered to be manageable by a single operation were included.

Data assessment was prospective, although in some cases charts were reviewed for completion of information. Data collected included demographic information, risk factors, presence of multiorgan failure, duration of symptoms, origin of infection, etiology, physiologic data for APACHE-II assessment, procedures performed, complications observed during operations, postoperative complications, number of blood transfusions, bacteriology from various sites during the index and subsequent STARs and follow-up bacteriology, mortality and cause of death confirmed at autopsy, and more. The data collected were entered into dBase IV database and analyzed and compared with those of patients undergoing a standard procedure utilizing SPSS/PC Statistical Package for the Social Sciences.

Operative technique for STAR

The operation starts with a standard midline or transverse incision. The infectious focus is removed or closed, purulent exudate is removed and necrotic tissue is débrided, and the abdominal cavity is irrigated with up to 10 l Ringer's lactate solution. If required, the bowel is resected, followed by either immediate anastomosis or temporary blind-loop formation with staplers. Definitive repair is deferred to subsequent laparotomies. If bleeding is a problem, packing until the next operation is a therapeutic option. Drains are not used routinely. The abdomen may then be closed using a device for temporary abdominal closure. Use of artificial burr or Marlex with a zipper or Ethizip [17, 31, 54] permits abdominal closure without causing pathologically elevated intra-abdominal pressure, often seen in peritonitis with massive peritoneal edema [6, 8, 10, 21, 23, 30, 43]. These devices also facilitate reopening at subsequent relaparotomies.

Reopening is possible in the intensive care unit for quick diagnosis of bowel perfusion or to control bleeding. STAR, however, is preferably performed in the operating room as formal re-exploration at 24-h intervals. More definitive repair can be accomplished following the first STAR, and previous repairs are inspected and corrected if necessary. New leaks may be repaired, and ongoing tissue necroses may be débrided. The peritoneal cavity may be irrigated with Ringer's lactate if necessary.

As peritoneal edema decreases, usually during the third and fourth STAR, the devices for temporary abdominal closure are trimmed or replaced to reduce the abdominal wound gap and to re-approximate fascia. When satisfactory healing is observed, peritoneal fluid is clear, and the fascia can be sutured without undue tension, the devices can be removed and the abdomen closed definitively.

Prior to each STAR, a potent antimicrobial or combination, active against endotoxin-producing enterobacteriaceae and obligate anaerobes, is administered intravenously. Most of our patients received 2 g cefotaxime sodium plus 500 mg metronidazole each every 12 h or 1 g imipenem/cilastatin every 8 h. Irrigation fluid never contained antibiotics.

Statistical analysis

For description of the two patient populations, simple descriptive statistics were used such as count and proportion, mean, standard deviation, median, minimum, and maximum. To test the difference in qualitative variables and mortality between STAR patients and NON-STAR patients, Pearson chi-square analysis was used. The Mann-Whitney U-Wilcoxon Rank Sum W Test was performed to test the difference of the ordered qualitative prognostic factor, APACHE-II score between STAR and NON-STAR. Significance level was $P < 0.05$.

To achieve statistical adjustment for significant differences in prognostic factors between the two groups, we used a multiple logistic model where P depended on the prognostic variables APACHE-II score (x_1) and Operation (x_2) as category variables for STAR (= −1) and NON-STAR (= +1). The corresponding logistic coefficients were estimated by the maximum likelihood method. The dependent variable was mortality and the logs odd for mortality is defined as Log (p/1-p). We used the statistical program SPSS 6.1 for Windows to calculate and plot probabilities.

Results

NON-STAR group

In the conventional operative therapy NON-STAR study group, 274 patients were registered at the study center; 271 had complete patient record forms, and 260 had standard operations and were analyzed and compared with 95 patients who underwent STAR. The mean age was 55.6, standard deviation (SD) 20.2, median 56 (13–97) years; that of survivors 52, and of nonsurvivors 69 years. The disease had been present for a median of 17 h (1–480) when the operation was begun. The group has been described elsewhere in more detail [31].

Mortality, sex distribution, type of peritonitis, intra-abdominal spread of disease, presence of MOF, and number of operations of both groups are compared in Table 1, and mortality of various subgroups is compared in Table 2. Table 3 and Fig. 1 allow for comparison of APACHE-II scores of various subgroups.

STAR group

The mean age of the 95 STAR patients was 57.6, SD 17.9, median 60 (15–90) years; that of survivors 54, and of nonsurvivors 67 years. The disease had been present for a me-

Table 1. Comparison of STAR and NON-STAR patients

Criterion Patients observed	STAR		NON-STAR		Significance
	Total 95 *n*	(%)	Total 260 *n*	(%)	
Mortality					
Overall	24	25	54	21	ns
Men	48	51	137	53	ns
Indication for operation					
Postoperative peritonitis	41	43	24	9	s
Diffuse peritonitis	83	87	156	60	s
Localized peritonitis/abscess	12	13	104	40	s
MOF present at first operation	61	64	40	15	s
Cardiovascular failure	25	26	51	20	ns
Pulmonary failure	43	45	26	10	s
Renal failure	17	18	7	3	s
Hepatic failure	4	4	17	7	ns
Number of laparatomies	529		325		
Operations per patient	5.57		1.25		

ns, Not significant; *s*, significant

Table 2. Comparison of outcome criteria of STAR and NON-STAR

Criterion	STAR		NON-STAR		Significance
	n	(%)	*n*	(%)	
Total mortality	24	25	54	21	ns
Died due to peritonitis	21	22	44	17	ns
Mortality of patients with MOF	19	31	24	60	s
Mortality of patients without MOF	5	15	30	14	ns

ns, Not significant; *s*, significant

Table 3. APACHE-II scores in various subgroups of STAR and NON-STAR patients

APACHE-II scores	STAR Mean	STAR SD	STAR Median	NON-STAR Mean	NON-STAR SD	NON-STAR Median
At first operation	15.9	7.1	16	10.5	7.5	9
Survivors	14.9	5.4	15	8.3	6.1	7
Nonsurvivors	20.8	8.2	21	18.8	6.1	19
Post-op peritonitis	16.2	7.9	15	14.6	7.4	15
Patients with MOF	16.5	6.6	16	16.9	8.3	8
Patients without MOF	15.2	7.9	13	9.3*	6.7	8

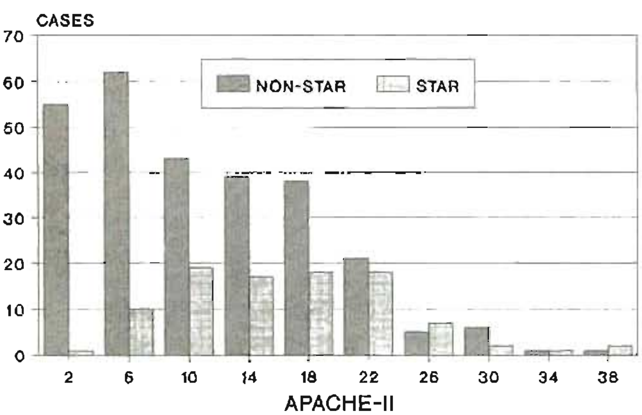

Fig. 1. Distribution of APACHE-II scores in the NON-STAR group and the STAR group

dian of 96 h (6–504) when the operation was begun. Qualitative variables of the STAR group are compared with those of the NON-STAR group in Tables 1 and 2, with respective APACHE-II scores in Table 3.

Besides débridement and intraoperative irrigation, leaks were closed by simple suture in 22% of the patients, a primary anastomosis was sutured in 44%, and bowel was exteriorized by colostomy formation in one third, often as Hartmann's procedure (n = 14). In 11% the bowel ends were stapled or simply sutured during the index operation (STAR-1) and the anastomosis was sutured during STAR-2 or STAR-3. Subsequent to STAR-1, additional intra-abdominal pathologies were often identified and treated. Unexpected necrotic bowel wall adjacent to colostomy or suture lines was seen in 13% of cases. Continued or newly developed intestinal or biliary leaks were noted in 16% of cases, bleeding in 15%, and abscesses in 8% of all cases. Two patients who suffered ongoing septic shock developed necrosis of the entire bowel. In these cases diagnosis was facilitated by bedside opening of the temporary abdominal closure device, obviating further resuscitation.

A variety of additional problems were managed, including 41 pulmonary infections, four myocardial infarctions, six cardiac failures, 11 liver failures, and 37 renal failures, of which 15 required hemofiltration or hemodialysis for an average of 21 (SD 16) days. The number of blood transfusions required was low, with less than 1 unit per patient. Fistula formation was observed in four cases. Persisting enterocutaneous fistulae were not seen. Four percent required reoperations for bowel obstruction. In three patients abscesses developed after the last STAR. Sixty-three patients had epidural analgesia for an average of 11 (SD 7) (3–31) days without complications. All patients were ventilator dependent for a median of 10 (1–131) days and stayed in the hospital for a median of 34 (1–183) days. Five patients died during STAR, and wound infections were seen in 12 of 90 patients (13%) following final closure, fascial dehiscence in 7 (8%).

Results of statistical analysis

Pearson chi-square analysis revealed no significant difference (P = 0.624) between mortality of STAR (24.2%) and NON-STAR (21.8%). The Mann-Whitney U-Test, however, showed a significant difference ($P < 0.001$) (U = 7582.0, W = 22723.0, Z = –5.9675, and 2-tailed P = .0000) between STAR and NON-STAR of the prognostic factor APACHE-II score, indicating that there might be a difference in mortality when comparing patients at equal mortality risk.

To achieve statistical adjustment for significant differences of prognostic factors between the two groups we used a multiple logistic model where P depended on the prognostic variables APACHE-II score (x_1) and Operation (x_2) as categorical variables for STAR (= –1) and NON-STAR (= +1). The corresponding logistic coefficients were estimated by the maximum likelihood method. The dependent variable was mortality and the logs odds for mortality is defined as Log (p/1-p). Logistic regression confirmed that after adjusting for significant differences of the prognostic factors in APACHE-II scores there is a significant difference in the mortality between STAR and NON-STAR (P = 0.0179) (Table 4). The logistic equation is given by

[Log p/1-p = –4.144 + (0.193* APACHE-II)
+ (0.4121* OPERATION)]
where OPERATION = +1 for NON-STAR patients
and = –1 for STAR patients

Figure 2 is the graphic display of this formula.

Table 4. Multiple logistic model to compare STAR with NON-STAR operations for intra-abdominal infections, with mortality as dependent variable

Factor ($_f$)	Numerical variable (x_i)	Logistic coefficient (c_i)		t-value
Operation	NON-STAR = 1, STAR = –1	0.412	0.174	0.0179
APACHE-II	Score from 0 to 48	0.193	0.024	0.0000
Constant term c_0		–4.144	0.434	0.0000

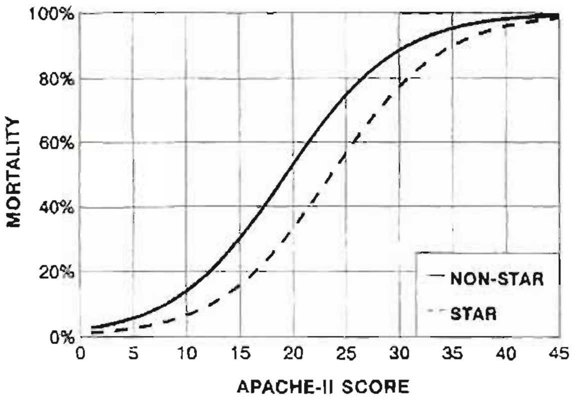

Fig. 2. Mortality of intra-abdominal infections for conventional operative management (*NON-STAR*) and staged abdominal repair (*STAR*), and adjusted for APACHE-II scores. The mortality curves calculated using a logistic model yielded a significant difference at $P = 0.0179$, and the logistic equation is given by Log p/1-p = –4.144 + (0.193* APACHE-II) + (0.4121* OPERATION) where OPERATION = +1 for NON-STAR patients and = –1 for STAR patients

Discussion

Successful therapy of intra-abdominal infection requires that four principles be followed (Table 5). The first two principles, namely closure or elimination of the infectious source and evacuation of toxic infectious material, were defined by Kirschner in 1926 [29] and became basic principles of standard operative management. The latter two principles, namely timely verfication and correction of the primary repair and abdominal purge and prevention of the abdominal compartment syndrome, have been introduced by STAR as additional principles.

Due to the lack of prospective randomized trials, it has not been possible to prove differences between standard operative management and STAR by direct comparison. Comparing results of the experimental treatment in well-defined patient populations with the results achieved concurrently in many representative hospitals with standard management may gauge the experimental therapy to allow for appreciation of new therapies until the ultimate proof is provided.

A detailed description of the two patient populations is basically not required to support the aim of the study, demonstrating differences between conventional operative management of peritonitis and STAR, since all risk factors are well caught within the APACHE-II system [4, 11, 12, 36, 39]. Nevertheless, we wanted to provide information which would allow for better understanding of the severity of the disease process. STAR patients had a median APACHE-II score of 16 and were significantly sicker than NON-STAR patients, whose APACHE-II score was only 9. There were more patients with MOF in the STAR group (64%) than in the NON-STAR group (15%), and even when comparing patients without MOF, STAR patients had a prognosis (APACHE-II of 13) inferior to that of the NON-STAR patients (APACHE-II of 8). The fact that a selection bias may have remained in the conventional group does not reduce its usefulness for comparison purposes, since disproportions in severity are accounted for when stratifying patients according to the APACHE-II severity of disease classification system [19, 26]. Inaccuracies in this system may be evenly distributed within the two study populations investigated here. Nevertheless, an error in both directions is possible within the APACHE-II system and, theoretically, all patients studied here could have been incorrectly classified by APACHE-II, which has a predictive accuracy between 81.5 and 84.8%, depending on the sensitivity and specificity level chosen.

The methodological error introduced by the APACHE-II stratification appears to be acceptable when compared with problems seen in prospective controlled trials where homogeneity among patients of the compared groups is insufficiently tested because the number of patients is not large enough to exclude alpha-type error.

Direct comparison of the study populations suggests that patients treated by STAR have a higher mortality: 24.2% versus 21.8% for those treated by conventional therapy. Statistical analysis, however, reveals no significant difference ($P = 0.624$). It is obvious that such comparison is inappropriate because the selection of patients had been highly biased, only patients at high risk for dying having been entered into the STAR study. This difference is reflected when comparing the prognostic APACHE-II scores of both patient populations. The difference is significant at a level of $P < 0.001$, indicating that patients of the NON-STAR group had a better prognosis and that there might be a difference in mortality when comparing patients at equal mortality risk. To achieve statistical adjustment for significant differences in prognostic factors between the two groups, we used a multiple logistic model with mortality as the dependent variable. This method represents the most statistically manageable way of relating probabilities to explanatory variables [41]. While logistic regression models are normally used to allocate diagnostic variables to their respective contribution to the event rate for prediction purpose, we are introducing a therapeutic/interventional categorical variable pair (STAR and NON-STAR) into the logistic model to examine the difference in their respective contribution to the event rate. The logistic regression analysis yielded a different formula for each operation and gave a significant difference ($P = 0.018$) for corresponding event rates. The graph (Fig. 2) of the logistic equation clearly shows the difference between the two treatment regimens. It also explains why the direct comparison of means is not powerful enough to catch differences in the extreme APACHE-II scores, since either the difference is too narrow or the number of patients is not large enough. Comparison with a larger number of patients in either group would be helpful.

Table 5. Principles of operative management of intra-abdominal infections

1. Halt delivery of infectious material (Repair)
2. Evacuate pus and adjuvants (Purge)
3. Verify and correct repair (1) and purge (2) (Control)
4. Treat abdominal compartment syndrome (Decompress)

Since the APACHE-II score used in the logistic regression captures mortality risk factors other than operations reasonably well, we may assume that the difference between the two operative methods is real. The caveat is that STAR was performed solely by one group of surgeons, who may have been particularly dedicated. The presumption that STAR will perform as well in other hands remains unproven. Supporting evidence, however, comes from a similar comparison of standard versus the open abdomen technique, which had been performed by a similarly dedicated group of surgeons [44]. No significant difference was found between standard operative management and the open abdomen technique.

Perhaps STAR fares better because the hemodynamic instability is recognized and only essential elements, e.g., control of visceral perforation, hemorrhage, are performed initially and more demanding procedures are delayed until the patient's general condition improves. Shorter operation and anesthesia time, with early entry into the ICU, may permit a more timely resuscitative effort to control pathophysiologic consequences of septic shock such as deranged hemodynamics, coagulapathy, hypothermia, and acidosis. With the patient's stability, controlled local management now can include more detailed definitive repair and allow for early detection of complications such as new intestinal leaks.

With the abdomen closed, intra-abdominal complications are difficult to identify in spite of advanced technology. Symptoms of such complications usually present late when the disease process has matured, and the corrective efforts may come too late [1]. Also, definitive procedures during septic shock may aggravate bleeding and shock, and anastomoses may fail when performed during shock.

Another benefit of STAR may be that it prevents the negative implications of intra-abdominal compartment syndrome without increasing the risk for bowel fistulae. Increased intra-abdominal pressure developing after the abdomen has been closed or as the direct result of closing widely separated fascial edges can compromise cardiopulmonary, renal, and GI tract and liver function [6, 8, 10, 21, 23, 30, 43] and contribute to the patient's morbidity and mortality if not recognized following conventional operation. It is evident that the prosthetic devices used with STAR enable fascial approximation without tension and permit closure without increased intra-abdominal pressure. Postoperative increased intra-abdominal pressure can be monitored and corrected easily by adjusting the prosthetic closure.

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