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Outcomes analysis after percutaneous abdominal drainage and exploratory laparotomy for necrotizing enterocolitis in 4,657 infants

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Abstract

Purpose—Necrotizing enterocolitis (NEC) is a common acquired gastrointestinal disease of infancy that is strongly correlated with prematurity. Both percutaneous abdominal drainage and

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laparotomy with resection of diseased bowel are surgical options for treatment of NEC. The objective of the present study is to compare outcomes of patients who were treated either with bowel resection/ostomy (BR/O), percutaneous drainage (PD) or Both procedures for NEC in a retrospective analysis.

Methods—A retrospective analysis was performed using data from the Agency for Healthcare Research and Quality, extracted from a combination of the Nationwide Inpatient Sample (NIS) and Kids' Inpatient Database (KID) from 1988 to 2005. Multiple logistic regression analyses were performed for in-hospital mortality associated with PD, BR/O or Both procedures for management of NEC. In addition, linear regression was performed for length of stay and total hospital charges. Odds ratios were calculated using the BR/O category as the reference group.

Results—There were 4,238 patients identified who underwent BR/O, 286 for PD, and 133 for Both procedures for NEC. Patients undergoing PD had a 5.7 times higher odds of death compared to patients treated with BR/O ($p < 0.05$) alone; patients receiving Both procedures did not have significantly higher odds of death compared to the BR/O group. Patients who underwent PD had a shorter length of stay (43 days; $p < 0.05$) and lower total hospital charges ($173,850; $p < 0.05$) in comparison to patients treated with BR/O. Length of stay and total hospital charges were greater in patients who received Both procedures, compared to those receiving BR/O alone, but this was not statistically significant.

Conclusion—In this nationwide sample of infants with NEC, outcomes for peritoneal drainage alone were poorer than those for bowel resection and enterostomy and for Both procedures. Increased overall mortality and shorter length of stay and hospital charges suggest higher early mortality associated with peritoneal drainage alone. Risk stratifying these groups using prematurity, birth weight, and number of concurrent diagnoses yielded equivocal results. A more detailed study will be needed to determine whether the patient populations that underwent initial laparotomy and bowel resection are substantially different from those that receive peritoneal drainage, or whether differences in outcome may be directly attributable to the type of procedure performed.

Keywords

Infant; Necrotizing enterocolitis; Surgical management; Percutaneous abdominal drainage; Laparotomy; Celiotomy; Bowel resection; Colectomy; Enterostomy; Outcomes; Mortality; Hospital charges; Length of stay; Population-based data; Nationwide Inpatient Sample; Kids' Inpatient Database

Introduction

Necrotizing enterocolitis (NEC) is the most common of serious acquired gastrointestinal diseases affecting neonates and occurs predominantly in premature infants. The frequency of NEC in neonatal intensive care unit admissions ranges from 1 to 5% [1]. It is one of the leading causes of death during the neonatal period with mortality rates ranging from 10 to 50% and is commonly associated with low birth weight and prematurity [2–6].

Although most cases of NEC are managed medically, greater than 30% of infants with NEC undergo surgical treatment [7, 8] such as bowel resection, with or without diverting enterostomy (BR/O), and percutaneous abdominal drainage (PD). BR/O has a complication rate as high as 68%, including both early events like local infection and sepsis, and late complications, such as small bowel stenosis and obstruction, incisional hernia, and dependence on parenteral nutrition [9]. PD is preferred by some surgeons as the primary procedure for patients who are too unstable to undergo a laparotomy [10–18]. In addition, unstable patients may initially undergo a PD as a temporizing measure with subsequent BR/O performed after clinical improvement [17, 18].

Outcomes described for BR/O and PD have been similar [10, 17, 19, 20], thus the preferred treatment methods for NEC is still undecided. In this retrospective analysis, we aim to compare the outcomes of patients who are treated through BR/O versus PD for NEC using population-based data from 1988 to 2005.

Methods

Databases

A retrospective analysis was performed using a combination of the Nationwide Inpatient Sample (NIS) (1988–1996, 1998, 1999, 2001, 2002, 2004, 2005) and the Kids' Inpatient Database (KID) (1997, 2000, 2003). Both the NIS and KID have been developed as part of the Healthcare Cost and Utilization Project (HCUP) of the Agency for Healthcare Research and Quality (AHRQ). The NIS is an all-payer database that currently compiles information on up to 8 million inpatient discharges from approximately 1,000 hospitals across the United States each year. Hospitals are selected to represent a 20% stratified sample of all community hospitals. Data from 759 to 1,054 hospitals located in 8–37 states were available in the data set under study [21]. The KID contains a sample of pediatric (age 20 or less) discharges from all community, non-rehabilitation hospitals from states which participate in HCUP. The KID samples patient discharges, rather than sampling at the hospital level like the NIS. Patient discharges are then weighted to obtain national estimates. The sampling algorithm involves systematic random sampling so that 10% of uncomplicated in-hospital births and 80% of complicated in-hospital births are selected, as well as other selected pediatric cases. The KID contains information from between 2,521 to 3,438 hospitals in 22–36 states over the period studied [22].

Information collected on patients from both databases included age at admission, gender, race, diagnosis and procedure information, insurance status, admission source (emergency department vs. non emergency department), mortality, length of stay (LOS), total hospital charges, as well as geographic location, urbanicity, and teaching status of the hospital.

The data use agreement from AHRQ and HCUP does not allow the reporting of information where the number of observations is less than or equal to 10 in order to help maintain patient confidentiality. Therefore, we have entered "≤10" in cases where there were 10 or fewer observations in any category. The *p* value for the comparison, however, was calculated using the exact number of observations obtained in the analysis.

Patient selection

Patients were initially selected from the NIS and KID databases if they had an International Classification of Diseases, Ninth Revision (ICD-9) diagnosis code corresponding to NEC (777.5) and an age at admission of less than 60 days. Those patients who underwent any type of surgical management for NEC were selected using the International Classification of Diseases, Clinical Modification (ICD-9-CM) procedure codes displayed in Table 1.

Within this population of patients who underwent surgical management of NEC, ICD-9 procedure codes were used to subdivide patients into three groups: those who underwent percutaneous abdominal drainage, those who underwent bowel resection or ostomy, and those who underwent Both procedures for management of NEC. The ICD-9 code used to identify those patients with NEC who underwent percutaneous abdominal drainage was 54.91. The ICD-9 codes used to identify those patients with NEC who underwent bowel resection or ostomy included those describing resection of the small intestine (45.61, 45.62), and colonic resection (45.7, 45.71, 45.72, 45.73, 45.74, 45.75, 45.76, 45.79, 45.8), or the placement of an enterostomy (46.0, 46.01, 46.03, 46.1, 46.10, 46.11, 46.13, 46.2, 46.2, 46.21, 46.23, 46.39, see Table 1 for a complete list of relevant descriptions). Patients who underwent Both procedures needed Both procedure codes (54.91 and the procedure codes used for BR/O); patients receiving simultaneous resection and drainage (Both procedure codes listed on the same day of hospital stay) and patients receiving drainage following resection (PD procedure code recorded on a later inpatient day) were re-assigned from the Both group to the BR/O group.

Data management and analysis

A descriptive analysis was performed using variables of gender, race, age in days at presentation, prematurity, low birth weight (less than 1,000 g), number of unique ICD-9 diagnosis codes, insurance status (uninsured or insured), geographic region (Northeast, Midwest, South or West), type of hospital (urban teaching, urban non-teaching or rural) and inpatient mortality. Summary statistics for LOS and inflation-adjusted total hospital charges were calculated. Total hospital charges were adjusted for inflation to reflect 2006 (year) dollars [23]. In the bivariate analysis, comparisons between the three groups (PD, BR/O, and Both procedures) were performed using Pearson's chi-square for categorical outcomes and the Kruskal–Wallis test for non-normally distributed continuous variables.

For analysis of outcomes associated with PD versus BR/O versus Both procedures for management of NEC, a multiple logistic regression was performed for in-hospital mortality and multiple linear regression analyses were performed for LOS and total hospital charges. The variables of gender, race, age in days, prematurity, low birth weight, insurance status, geographic region, type of hospital, admission source, and number of co-morbid conditions were controlled for in all multivariate analyses. The number of co-morbid conditions was assessed by counting the number of unique ICD-9 codes associated with each admission. Odds ratios were calculated using the BR/O category as the reference group.

Results

Demographic data

From the NIS and KID databases from 1988 to 2005, 4,238 patients were identified who underwent bowel resection or ostomy for NEC (BR/O), 286 patients who underwent percutaneous abdominal drainage for NEC (PD), and 133 who underwent Both PD and BR/O for NEC (Table 2). Within the group receiving Both procedures, 42% of records identified both operating days; among these, the mean interval between PD and subsequent BR/O was 30.3 days (median 10, SD 38.2). With respect to gender, there was no difference among the three groups ($p = 0.84$). The BR/O group was composed of 59.5% males and 40.5% females; the PD group was composed of 58.0% males and 42.0% females; and the Both group was composed of 60.9% males and 39.1% females (Table 2).

The difference in racial makeup among the 3 groups was statistically significant ($p = 0.03$), with a higher proportion of Hispanics in the Both and PD group (23.9% for Both vs. 22.3% for PD vs. 16.0% for BR/O) and a higher proportion of whites in the BR/O group (49.1% for BR/O vs. 43.5% for PD vs. 35.9% for Both). Not all states collected information on race, and there were 34.0% unknown in the BR/O group and 35.7% unknown in the PD group (Table 2). The infants in the BR/O group presented slightly older (5.3 days for BR/O vs. 4.7 days for PD vs. 3.6 for Both), but this difference was not statistically significant ($p = 0.14$, see Table 2). In addition, infants who received either Both procedures or PD were more likely to be either premature (85.7% for Both vs. 83.6% for PD vs. 61.8% for BR/O) or have a low birth weight (55.6% for Both vs. 63.6% for PD vs. 29.1% for BR/O); this difference was statistically significant in both instances ($p < 0.001$, see Table 2). Also significant was the difference between the number of co-morbid diagnoses recorded during each inpatient stay (7.4, 9.6, and 10.5 for BR/O, PD and Both groups, respectively, $p < 0.001$). The majority of patients (over 90%) from all 3 groups were insured with a higher percentage uninsured in the group that received Both treatments ($p = 0.05$, see Table 2).

Hospitalization characteristics

As shown in Table 3, the differences in geographic location were statistically significant among the 3 groups ($p < 0.001$). There was a larger overall representation of the South (28.9%) and West (29.2%). There were proportionately fewer patients in the Northeast who received PD or Both procedures. There were also fewer patients who received Both procedures in the South. Patients from the West were most likely to fall into the Both group.

With respect to the type of hospital, there was no statistically significant difference among the three groups. Urban, teaching hospitals were the most common in all groups (81.7% for BR/O, 85.5% for PD, and 84.9% for Both) (Table 3).

Outcomes

As depicted in Table 4, the in-hospital mortality for the PD group was substantially higher (60.5%) than the BR/O or Both groups (21.4 and 28.8% respectively). This difference was statistically significant with a p value of <0.001. The median LOS was significantly shorter for the PD group, but longest in the patients who received both treatments (47.7 days for PD

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vs. 79.5 days for BR/O vs. 88.6 days for Both; p value <0.001). The mean total hospital charges were also less for the PD group with the Both group incurring the most hospital charges ($353,366 for PD vs. $466,273 for BR/O vs. $543,241 for Both), which was also statistically significant ($p < 0.001$).

Table 5 displays the adjusted outcomes. The BR/O group was used as the reference group. For in-hospital mortality, the PD group had a 5.7 times higher odds of death compared to the BR/O group, and this was statistically significant with a p value of <0.05. The Both group had a trend toward higher odds of death compared to the BR/O group (OR 1.5) but this difference was not significant. The PD group had a LOS that was 43 days shorter than the BR/O group ($p < 0.05$), while the Both group had a 4.1 day increase in LOS relative to the BR/O group (not statistically significant). Total hospital charges were $173,850 less for the PD group in comparison to the BR/O group ($p < 0.05$), but the Both group incurred $16,178 more than the BR/O group (not statistically significant).

Discussion

The present study is the first to present population-based data to retrospectively compare outcomes for a large sample of infants managed with either percutaneous abdominal drainage, BR/O or both procedures for management of necrotizing enterocolitis. Utilizing a nationwide sample of data from 1988 to 2005, we found that patients undergoing BR/O have a lower mortality rate than patients who undergo PD or both procedures for treatment of NEC. The source data represent a sample from an average of 26 states representing 1,500 hospitals annually over the period studied. The association between the procedure performed and the noted outcomes persisted only for PD when multivariate analysis controlling for number of co-existing diagnoses, birth weight, and prematurity were performed. Given the findings of high mortality and decreased mean duration of hospital stay, it is likely that patients treated with PD suffer high rates of mortality early in the course of treatment.

Similar to our results, Blakely et al. [24] in a multicenter prospective cohort study saw outcomes that are more favorable in patients undergoing BR/O rather than PD. However, other studies have shown essentially equivalent results between the two interventions, including a multi-center randomized controlled trial that found no significant difference in survival at 1 or 6 months in patients undergoing either laparotomy or PD [25]. In another randomized controlled trial, Moss et al. [20] examined 117 patients without any difference in 90-day mortality between patients of the two arms. A meta-analysis examining published studies from 1978 to 1999 showed no significant difference in mortality rates in patients undergoing PD versus BR/O [26], but a later meta-analysis examining prospective studies from 2000 to 2008 revealed an excess mortality of 55% for patients undergoing PD [27].

The discrepancy between the retrospective outcomes reported here and the largest randomized trial by Moss, et al. [20] may be attributable to bias from patient selection, in that surgeons may have selected for a more gravely ill sub-population when considering PD. Further evidence supporting a surgeon selection bias includes low utilization of PD (less than 10% of the population sampled), smaller numbers of concurrent diagnoses for patients initially receiving BR/O, and low rate of laparotomy after PD (less than one-third). Such bias may also account for the higher mortality rate associated with PD in the present population-based study. The randomized trial by Moss et al. reported equivalent mortality following PD and BR/O in subgroup analyses of extremely premature and extremely acidotic infants, suggesting that both options for treatment are equivalent so long as the underlying disease severity is equivalent in both comparison groups. Previous studies, however, have shown that survival rates for NEC are inversely correlated with number of co-morbidities, with higher numbers of concurrent diagnoses associated with higher mortality following management with local drainage [31]. Despite the likely influence of clinician bias, multivariate analysis employed in the present study revealed a persistent association of peritoneal drainage with higher mortality.

A prognostic tool capable of stratifying or quantifying NEC patients' mortality risk would be useful to guide therapeutic decision-making and to better assess outcomes associated with particular interventions across varying presentations of the disease. Clinical tools such as the score for neonatal acute physiology-perinatal extension (SNAP-PE II) [28], trajectory of metabolic derangement [29], and radiological signs such as the presence of pneumatosis or portal venous gas have been advanced as criteria indicating one surgical procedure over another [8]. Future population-based studies that incorporate a reliable severity index for NEC should identify survival advantages that result from patient selection.

Limitations of this study include the unavailability of specific clinical details in the NIS or KID databases. Since these AHRQ-sponsored databases do not employ persistent patient identifiers, the present study cannot account for hospital-to-hospital transfers, and this has the potential to skew the resulting analysis. Most concerning in this regard would be patients who received a surgical procedure at one facility prior to transfer to a tertiary care center. Such patients, if included in the sample, would contribute to erroneously low length of stay estimates and could also reduce the reported numbers patients who received both types of surgical procedure. Omitted data include staging of NEC [30], which would permit further subset analyses incorporating severity of illness in these patients. Prematurity and birth weight data are extrapolated from diagnosis codes; the accuracy and precision of reporting varies within the sample and only 15 diagnoses are captured for each admission, which limits our capacity to control for the influence of these factors in the adjusted outcomes rates. Birth weight has been implicated in earlier studies as a possible independent indicator for PD in the management of perforated NEC [11, 19]. Gestational age is not reliably reported within the sample of NIS and KID data utilized in this study and we were therefore unable to control for severity of prematurity, independent of birth weight. Within the data set examined, dates of procedures performed during the inpatient stay are not uniformly provided. It is therefore possible that some patients designated as Both in our analysis received a percutaneous abdominal drainage procedure concurrently with or after laparotomy. Finally, the present study did not attempt to assess the contribution of concurrent intestinal anastomosis toward the outcomes studied.

In conclusion, patients who undergo PD for NEC suffer a higher overall mortality rate, but incur shorter length of stay and lower hospital charges; an effect likely attributable to increased early mortality in this group. Patients who undergo both PD and BR/O do not suffer a significantly higher mortality rate relative to BR/O, but they remain in the hospital longer. The combined observations may reflect clinical instability prior to "salvage" percutaneous drain placement, followed by relatively abrupt deterioration (and associated early mortality) or slow recovery (with subsequent laparotomy and bowel resection). An alternate interpretation may be advanced that the mortality differences are directly attributable to the surgical technique employed, a finding that has not been replicated in previous randomized trials. Further study is needed to better elucidate which factors influence clinical outcomes for infants with necrotizing enterocolitis.

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Table 1

ICD-9-CM procedure codes for surgical management of NEC

Code	Procedure	Code	Procedure
45.61	Multiple segmental resection of small intestine[a]	46.10	Colostomy, not otherwise specified[a]
45.62	Other partial resection of small intestine[a]	46.11	Temporary colostomy[a]
45.7	Partial excision of large intestine[a]	46.13	Other permanent colostomy[a]
45.71	Multiple segmental resection of large intestine[a]	46.2	Ileostomy[a]
45.72	Cecectomy[a]	46.20	Ileostomy, not otherwise specified[a]
45.73	Right hemicolectomy[a]	46.21	Temporary ileostomy[a]
45.74	Resection of transverse colon[a]	46.23	Other permanent ileostomy[a]
45.75	Left hemicolectomy[a]	46.39	Other enterostomy[a]
45.76	Sigmoidectomy[a]	54.1	Laparotomy
45.79	Other partial excision of large intestine[a]	54.11	Exploratory laparotomy
45.8	Total intra-abdominal colectomy[a]	54.19	Other laparotomy
46.0	Exteriorization of intestine[a]	54.5	Lysis of peritoneal adhesions
46.01	Exteriorization of small intestine[a]	54.59	Other lysis of peritoneal adhesions
46.03	Exteriorization of large intestine[a]	54.91	Percutaneous abdominal drainage[b]
46.1	Colostomy[a]		

International Classification of Diseases, Clinical Modification

[a]Procedure codes used to identify bowel resection or ostomy for NEC

[b]Procedure code used to identify percutaneous abdominal drainage for NEC

Table 2

Patient demographics

Characteristic	BR/O[a] (*N* = 4,238)	PD[b] (*N* = 286)	Both[c] (*N* = 133)	*p* value	Total (*N* = 4,657)
Gender, *N* (%)				0.84	
Female	1,716 (40.5)	120 (42.0)	52 (39.1)		1,888 (40.6)
Race[d], *N* (%)				0.03	
White	1,365 (49.1)	80 (43.5)	33 (35.9)		1,487 (48.4)
Black	720 (25.7)	45 (24.5)	24 (26.1)		789 (25.7)
Hispanic	448 (16.0)	41 (22.3)	22 (23.9)		511 (16.6)
Other	255 (9.1)	18 (9.8)	13 (14.1)		286 (9.3)
Age in days on admission mean (SD)	5.3 (10.5)	4.7 (9.2)	3.6 (8.0)	0.14	5.2 (10.4)
Underweight[e], *N* (%)	1,232 (29.1)	182 (63.6)	74 (55.6)	<0.001	1,488 (31.9)
Prematurity, *N* (%)	2,619 (61.8)	239 (83.6)	114 (85.7)	<0.001	2,972 (63.8)
Number of co-existing diagnoses, mean (SD)	7.4 (4.6)	9.6 (3.4)	10.5 (3.2)	<0.001	7.6 (4.5)
Insurance status, *N* (%)				0.05	
Uninsured	100 (2.5)	<10	8 (6.3)		114 (2.6)

[a]Patients undergoing laparotomy with bowel resection and enterostomy

[b]Patients undergoing percutaneous abdominal drainage alone

[c]Patients undergoing percutaneous abdominal drainage and laparotomy with bowel resection and enterostomy

[d]Not all states collected information on race (34.1% unknown for BR/O, 35.6% unknown for PD, 27.9% unknown for both)

[e]Birth weight <1,000 g

Table 3

Hospital characteristics

Characteristic	BR/O[a] (N = 4,238)	PD[b] (N = 286)	Both[c] (N = 133)	p value	Total (N = 4,657)
Geographic region, N (%)				<0.001	
Northeast	882 (20.8)	50 (17.5)	21 (15.8)		953 (20.5)
Midwest	884 (20.9)	79 (27.6)	35 (26.3)		998 (21.4)
South	1,249 (29.5)	76 (26.6)	22 (16.5)		1,347 (28.9)
West	1,223 (28.9)	81 (28.3)	55 (41.3)		1,359 (29.2)
Type of hospital, N (%)				0.35	
Urban, teaching	3,417 (81.7)	241 (85.5)	112 (84.9)		3,770 (82.1)
Urban, non-teaching	734 (17.7)	38 (13.5)	19 (14.4)		791 (17.2)

[a] Patients undergoing laparotomy with bowel resection and enterostomy

[b] Patients undergoing percutaneous drainage alone

[c] Patients undergoing percutaneous drainage and laparotomy with bowel resection and enterostomy

Table 4

Unadjusted outcomes

Outcome	BR/O (*N* = 4,238)	PD (*N* = 286)	Both (*N* = 133)	*p* value	Total (*N* = 4,657)
In-hospital mortality, *N* (%)	904 (21.4)	173 (60.5)	38 (28.8)	<0.001	1,115 (24.0)
LOS (days), mean (SD)	79.5 (60.5)	47.7 (45.7)	88.6 (64.7)	<0.001	77.8 (60.3)
Total hospital charges ($)[a], mean (SD)	466,273 (395,264)	353,366 (350,927)	543,241 (400,870)	<0.001	461,289 (393,895)

[a]Adjusted for inflation to 2006 dollars

Table 5

Adjusted outcomes

Outcome	PD vs. BR/O	Both vs. BR/O
In-hospital mortality: odds ratio (95% confidence interval)	5.7 (4.1, 7.9)	1.5 (0.9, 2.7)
Length of stay: days (95% confidence interval)	−43.1 (−50.4, −35.7)	4.1 (−11.8, 20.0)
Total hospital charges: US dollars[a] (95% confidence interval)	−173,850 (−236,935, −110,764)	16,178 (−92,254, 124,610)

Adjusted for gender, race, age in days, prematurity or low birth weight, insurance status, geographic region, type of hospital, number of co-existing diagnoses, and admission source

[a]Adjusted for inflation to 2006 dollars