



Study Toward Evidence-based Pediatric Surgery

Perforated Necrotizing Enterocolitis in the Premature Neonate

A Multicenter Study by Larry Moss, et. al.

Entrance Information: For Enrolled & Eligible Not Enrolled (ENE) Patients

INSTITUTION _____		MEDICAL RECORD NUMBER _____		
GENDER	<input type="radio"/> Boy <input type="radio"/> Girl	DATE OF BIRTH	____/____/____ (MM/DD/YYYY)	
ETHNICITY	<input type="radio"/> white, not of Hispanic origin <input type="radio"/> black, not of Hispanic origin <input type="radio"/> Asian or Pacific Islander <input type="radio"/> Hispanic	<input type="radio"/> American Indian or Alaskan Native <input type="radio"/> unknown <input type="radio"/> other		
MEDICAL HISTORY				
1. Enrolled?	<input type="radio"/> Yes- skip to Q 3 <input type="radio"/> No- go to Q 2			
2. Why was patient not enrolled?	<input type="radio"/> Parent refusal <input type="radio"/> Parent not informed of trial by surgeon choice <input type="radio"/> Surgeon uninformed about how to enroll patient <input type="radio"/> Managing physicians did not realize patient was eligible <input type="radio"/> Other _____			
<p>For Enrolled Patients: Please complete <u>Entrance Information Q 3 -28</u> only. For ENE Patients: Please complete <u>Entrance Information Q 3 -28</u>, and <u>Follow-up Information Q 1-2</u>.</p>				
3. Age (days)	_____			
4. Date of operation	____/____/____ (MM/DD/YYYY)			
5. Gestational age by exam at birth (weeks)	<input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26	<input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30	<input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 34	<input type="radio"/> 35 <input type="radio"/> 36 <input type="radio"/> 37 <input type="radio"/> 38
6. Corrected gestational age at operation (weeks)	<input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26	<input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30	<input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 34	<input type="radio"/> 35 <input type="radio"/> 36 <input type="radio"/> 37 <input type="radio"/> 38
7. Birth weight (gm)	_____			
8. Weight at operation (gm)	_____			
9. APGAR scores	1 Minute <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10			
	5 Minute <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10			

Entrance Information (cont.)

10. History of PDA	<input type="radio"/> Yes- go to _____ <input type="radio"/> No- go to Q 11	<input type="radio"/> Medically closed <input type="radio"/> Surgically closed <input type="radio"/> Spontaneously closed <input type="radio"/> Open																							
11. Cranial ultrasound results prior to operation	<input type="radio"/> Abnormal go to _____ <input type="radio"/> Normal- go to Q 12 <input type="radio"/> Not done- go to Q 12	<input type="radio"/> Gr I <input type="radio"/> Gr II <input type="radio"/> Gr III <input type="radio"/> Gr IV																							
MEDICATIONS																									
12. Surfactant total doses	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4																								
13. Steroids	<input type="radio"/> Yes- go to _____ <input type="radio"/> No- go to Q 14	<input type="radio"/> Hydrocortisone	Length of course (days): _____ Date of last dose ____/____/____ (MM/DD/YYYY)																						
		<input type="radio"/> Dexamethasone	Length of course (days): _____ Date of last dose ____/____/____ (MM/DD/YYYY)																						
		<input type="radio"/> Other _____	Length of course (days): _____ Date of last dose ____/____/____ (MM/DD/YYYY)																						
		14. Indomethacin	<input type="radio"/> Yes- go to _____ <input type="radio"/> No- go to Q 15	Number of doses _____ Date of last dose ____/____/____ (MM/DD/YYYY)																					
15. Vasopressors	<input type="radio"/> Yes- go to _____ <input type="radio"/> No- go to Q 16	<input type="radio"/> Dopamine <input type="radio"/> ≤ 5mcg <input type="radio"/> > 5mcg <input type="radio"/> Epinephrine <input type="radio"/> Other 1 _____ <input type="radio"/> Other 1 _____																							
16. Antibiotics prior to perforation	<input type="radio"/> Yes- go to _____ <input type="radio"/> No- go to Q 17	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 70%;">Antibiotic</th> <th style="width: 30%;">Duration (days)</th> </tr> </thead> <tbody> <tr><td><input type="radio"/> Ampicillin</td><td></td></tr> <tr><td><input type="radio"/> Gentamycin</td><td></td></tr> <tr><td><input type="radio"/> Vancomycin</td><td></td></tr> <tr><td><input type="radio"/> Cefotaxime</td><td></td></tr> <tr><td><input type="radio"/> Clindamycin</td><td></td></tr> <tr><td><input type="radio"/> Ceftazidime</td><td></td></tr> <tr><td><input type="radio"/> Metronidazole</td><td></td></tr> <tr><td><input type="radio"/> Other Antibiotic 1 Name: _____</td><td></td></tr> <tr><td><input type="radio"/> Other Antibiotic 2 Name: _____</td><td></td></tr> <tr><td><input type="radio"/> Other Antibiotic 3 Name: _____</td><td></td></tr> </tbody> </table>		Antibiotic	Duration (days)	<input type="radio"/> Ampicillin		<input type="radio"/> Gentamycin		<input type="radio"/> Vancomycin		<input type="radio"/> Cefotaxime		<input type="radio"/> Clindamycin		<input type="radio"/> Ceftazidime		<input type="radio"/> Metronidazole		<input type="radio"/> Other Antibiotic 1 Name: _____		<input type="radio"/> Other Antibiotic 2 Name: _____		<input type="radio"/> Other Antibiotic 3 Name: _____	
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<input type="radio"/> Other Antibiotic 2 Name: _____																									
<input type="radio"/> Other Antibiotic 3 Name: _____																									

Entrance Information (cont.)

TREATMENT			
17. Mechanical ventilation at time of perforation	CHOOSE ONLY ONE MODE OF MECHANICAL VENTILATION		
	<input type="radio"/> Room Air		
	<input type="radio"/> Supplemental O2 LPM: _____ FIO2(%): _____		
	<input type="radio"/> CPAP FIO2(%): _____ PEEP : _____		
	<input type="radio"/> CMV FIO2(%): _____ PIP: _____ PEEP: _____ RATE: _____		
<input type="radio"/> HFV FIO2(%): _____ PA: _____ AMP: _____			
18. Feedings	<input type="radio"/> Yes- go to → <input type="radio"/> No- go to Q 19	a. Number of days fed: _____ b. Quantity of feeds at perforation: _____ cc/kg/day c. Type of Feeds: <input type="radio"/> Breast Milk <input type="radio"/> Formula _____ <input type="radio"/> Mix	
19. Lines	<input type="radio"/> UAC	<input type="radio"/> Yes- go to → <input type="radio"/> No	<input type="radio"/> In past <input type="radio"/> At time of operation
	<input type="radio"/> UVC	<input type="radio"/> Yes- go to → <input type="radio"/> No	<input type="radio"/> In past <input type="radio"/> At time of operation
	<input type="radio"/> Other	<input type="radio"/> Yes- go to → <input type="radio"/> No- go to Q 20	<input type="radio"/> In past <input type="radio"/> At time of operation
20. Abdominal film at operation	<input type="radio"/> Yes- go to → <input type="radio"/> No- go to Q 21	<input type="radio"/> Free Air <input type="radio"/> Pneumatosis <input type="radio"/> Portal Venous Gas	
21. Diagnosis by	<input type="radio"/> X-ray <input type="radio"/> Paracentesis <input type="radio"/> Clinical Assessment		
22. Type of operation	<input type="radio"/> Peritoneal Drainage →		<input type="radio"/> Serous <input type="radio"/> Stool
	<input type="radio"/> Laparotomy →	<ul style="list-style-type: none"> • Number of areas of small bowel resected: _____ • Length of small bowel resected (cm): _____ • Number of areas of large bowel resected: _____ • Length of large bowel resected (cm): _____ • Ileocecal valve left: <input type="radio"/> Yes <input type="radio"/> No • Total length of resection (cm): _____ • Total length of bowel left (cm): _____ • Anatomy after operation: _____ 	
VITAL SIGNS BEFORE INCISION			
23. Vital signs before incision	Tmax (Celsius): _____ HR (bpm): _____ RR (bpm): _____ MAP (mmHg): _____ Cap Refill (sec): _____		
LABORATORY RESULTS (MOST RECENT BEFORE PERFORATION)			
24. ABG	<input type="radio"/> Yes- go to → <input type="radio"/> No- go to Q 25	pH: _____ PaO2: _____ PaCO2 : _____ Bicarb: _____ Base deficit: _____	
25. CBC	<input type="radio"/> Yes- go to → <input type="radio"/> No- go to Q 26	WBC (K/UL): _____ HCT (%): _____ PLTS (K/UL): _____ Segs (%): _____ Bands (%): _____	
26. C-reactive protein	<input type="radio"/> Yes- go to → <input type="radio"/> No- go to Q 27	CRP: _____ Time (HH:MM): _____ : _____ Date (MM/DD/YYYY): ___ / ___ / ___	
27. Blood culture	<input type="radio"/> Yes- go to → <input type="radio"/> No- go to Q 28	<input type="radio"/> Positive → <input type="radio"/> Negative	Organism: _____ Time (HH:MM): _____ : _____ Date (MM/DD/YYYY): ___ / ___ / ___
28. Coagulation panel	<input type="radio"/> Yes- go to → <input type="radio"/> No	INR: _____ PT (sec): _____ PTT (sec): _____ Fib (mg/dl): _____ Time (HH:MM): _____ : _____ Date (MM/DD/YYYY): ___ / ___ / ___	

If this is an Eligible, Not Enrolled Patient please complete the next page when the data are available.



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Follow-up Information for All Eligible, Not Enrolled Patients

To be completed ONLY after discharge or death

FOR ELIGIBLE, NOT ENROLLED PATIENTS ONLY

Please indicate the date of discharge or death and mail form to:

Bonnie Lang Silverman, PhD
Research Coordinator
Children's Surgery Research Center
Yale University School of Medicine
330 Cedar Street, FMB 207
PO Box 208062
New Haven, CT 06520-8062

Date submitted: ___/___/___ (MM/DD/YYYY)

INSTITUTION _____		MEDICAL RECORD NUMBER _____	
1. Date of discharge	___/___/___ (MM/DD/YYYY)		
2. Date of death	___/___/___ (MM/DD/YYYY)		