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Original article**Surgical treatment for necrotizing enterocolitis; a new score to extreme surveillance.****Miriam García*¹, Sonia Pértega², Cristina González², Isabel Casal¹.**

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Surgical treatment for necrotizing enterocolitis; a new score to extreme surveillance.**BACKGROUND:**

The time to perform a surgical intervention in necrotizing enterocolitis remains a challenge for the paediatric surgeon. We design a novel score system to predict infants in high risk for the development of surgical necrotizing enterocolitis.

METHODS:

A total of 124 consecutively patients diagnosed of NEC at the University Hospital of A Coruña, Spain were included in the study.

Associations were analyzed by bivariate and multivariate analysis. We applied multivariate logistic regression modeling to identify factors that could provide accurate risk of surgical NEC.

We include not only analytical and radiological parameters or physical examination, we analyze prenatal, sociodemographic, perinatal and peripartum variables that condition the presence of predispose factors which could determine the debut of this entity and in its progression.

RESULTS:

Patients requiring surgical treatment have presented an antecedent of respiratory distress (worsening of the ventilatory requirements) in the perinatal period, they present higher values of glycemia at diagnosis of the illness, debut with coagulopathy and have in laboratory findings marked neutrophilia.

CONCLUSIONS:

Our score system obtained by combining several parameters could detect infants at risk of developing severe necrotizing enterocolitis improving the morbidity and mortality associated with delay in the surgical treatment.

KEYWORDS:

-Necrotizing enterocolitis

-Surgery

-Score

-Treatment

INTRODUCTION:

Necrotizing enterocolitis (NEC) remains an elusive disease, between infants with NEC, some of them are controlled with medical therapy while others required surgical intervention to remove necrotic bowel. The factors that influence the progression of the disease remain largely unknown (1).

Surgical treatment in necrotizing enterocolitis is reserved for those patients with intestinal gangrene and should ideally be performed once intestinal vascular involvement is established, but before perforation occurs.

However, this "ideal" moment is obscured by clinical variability and this period between ischemia and necrosis often presents scant and variable symptomatology.

In 1975, O'Neill proposed the presence of pneumoperitoneum as an absolute criterion of surgery. However, pneumoperitoneum and therefore intestinal perforation is a late indicator of surgical treatment in necrotizing enterocolitis. Later repeated attempts to identify analytical parameters that would reliably identify patients at risk to progress to severe disease and guide surgical treatment have been unsuccessful. Several scores have been developed in recent years to predict outcomes but in the vast majority, agreement between the predictive outcomes and the need of surgical treatment was poor (2) (3).

In necrotizing enterocolitis there are no indicators of imminent perforation, but clinical deterioration of the patient despite medical treatment, the presence of a fixed loop gut in serial radiographs or the presence of a palpable mass or abdominal tenderness or erythema have been considered in recent years indicators of intestinal necrosis and therefore indicators of surgical intervention (4). However, these manifestations also occur in many cases once the perforation is established in the absence of pneumoperitoneum and therefore they can also be late indicators. In the other hand many patients with intestinal

gangrene don't present these indicators. For these reasons and for the variability of the clinical evolution of this entity and the variability of the professionals involved in the therapeutic management of these patients make very difficult to take decisions at certain moments of the clinical evolution of the disease.

This fact has been previously reported in the literature in numerous publications, highlighting some of them as important decision-making factor the team responsible for taking decisions, and interpersonal variability (5).

The aim of this review is to determine predictive characteristics including all the variables that could be associated with the need of surgical treatment. These includes sociodemographic variables, neonatal, analytical, clinical, radiological and management that may be able to predict infants with high risk of surgical requirements. We developed a simple scoring system to guide the pediatric surgeon to decide when a surgical intervention is required.

MATERIAL AND METHODS

Our study aims to evaluate which parameters have in common the patients that required surgical treatment in our Hospital. For this reason, we have carried out a retrospective study and with the collected data we have performed a multivariate logistic regression analysis.

A total of 124 patients were consecutively included in the study who were diagnosed of NEC at the University Hospital Complex in A Coruña, Spain between 2003 and 2015.

A diagnosis of NEC was made based on clinical, radiological and/or histopathological evidence of stage II, III or IV NEC according to Bell's modified criteria (8) in infants within 28 days of birth.

Our Center is considered a tertiary center for the management of these patients. We have a NICU with no restriction on ventilator support and perform major surgery and cardiac surgery in neonates. Our referential area includes a population of 103764 births in the period of study.

A retrospective review of the patients' medical records was carried out.

The following epidemiological data were collected from the patients include in the study: sex, mothers's age and gestational characteristics as type of gestation (spontaneous, or obtained by different assisted reproductive techniques including intrauterine insemination, in vitro fertilization, or intracytoplasmic sperm injection), type of pregnancy (single or multiple), gestational age at delivery, and gestational age at birth.

We also register the presence of antenatal antecedents such as: the presence of oligoamnios or the administration of corticosteroids.

Perinatal history was also collected, as type of amniotic fluid, the type of birth, and the need for instrumental delivery. We registered also weight at birth and the punctuation in the Apgar test at one- and five-minutes post birth.

We collected which drugs were administered or the treatment required as the need for surfactant administration, transfusion, antibiotics, mechanical ventilation, inotropic drugs, enteral nutrition and the presence of umbilical catheters.

Furthermore, clinical variables were also collected as the presence of increased gastric residuals (defined as the presence of gastric stasis larger than 2ml/kg or > 50% of previous feeding volume). Gastric residual volume is considered a surrogate parameter of gastrointestinal dysfunction during the progression of enteral feeding in the early phase of critical illness and beyond and we collected it due his importance in necrotizing enterocolitis.

We also collect the presence of abdominal distension, abdominal wall discoloration, tenderness and/ or abdominal pain. The criteria used for the diagnosis of abdominal pain was the presence of signs of pain during abdominal exploration (considering direct signs as discomfort during exploration, crying, or painful gesture or indirect signs as tachycardia or hypertension)

We collected different bloody parameters during the course of the disease (serum pH, CPR, leucocytes count, neutrophils, glucose levels, creatinine, total of proteins and serum albumin.... among other relevant parameters), and the presence of coagulopathy. We registered the presence of coagulopathy as an increase in the normal values of the TP (prothrombin time) or TPTA (activated partial thromboplastin time) in the blood analysis.

Radiological findings were obtained from the abdominal X-rays including the presence of dilated intestinal loops, pneumatosis intestinalis, fixed bowel loop, portal venous gas, and intraabdominal free air.

Data concerning perinatal therapeutic management and subsequent events: mortality, perforation and stenosis in patients with necrotizing enterocolitis during the follow up were also collected.

We compared all these factors in patients who required surgical treatment vs those who presented good evolution with only medical care.

Medical treatment was investigated reviewing of the patient's medical records during their admission in the critical care intensive unit. We review all the medications required for their support as the need of supplementary oxygen, mechanical ventilation, treatment with inotropes, blood transfusion, antibiotics and the presence of umbilical catheters.

We excluded patients who did not meet criteria for inclusion in the study; those who were referred from other centers without baseline data for diagnosis of NEC, those with intraoperative finding of focal intestinal perforation or those who did not sign the informed consent.

This sample size $n = 124$ makes it possible to estimate the parameters of interest with a confidence interval CI of 95% ($\alpha = 0.05$) and a precision of $\pm 8.9\%$. A descriptive study was made of the included variables. The quantitative variables were expressed as mean \pm standard deviation (SD), while the qualitative variables were expressed as an absolute n value and the percentage, with estimation of the 95% confidence interval. Comparisons for quantitative variables were made using Student's t-test or the Mann-Whitney U test, depending on which was appropriate after checking for normality using the Kolmogorov-

Smirnov test. Associations between qualitative variables were analyzed using Pearson's chi-squared test.

After bivariate analysis, multivariate logistic regression modeling was performed to identify risk factors associated independently with surgical treatment.

This study was carried out according to the principles laid down in the Declaration of Helsinki and ensuring compliance with Spanish Decree 29/2009, which regulates the use of and access to electronic medical records. Informed consent of the parents and approval from the regional Clinical Research Ethics Committee was obtained Code 2014/504).

RESULTS

A total of 124 consecutive patients diagnosed with NEC were included in the study.

We excluded a total of 7 patients (2 patients presented intraoperative finding of focal intestinal perforation and 5 referred from other centers without baseline data for diagnosis of necrotizing enterocolitis).

-General characteristics of the patients:

There were 77 males (62,1%) and 47 females (37,9%).

Median birth weight was 1873,8±807,9 grams and median gestational age at birth was 33±4,2 weeks. Median postnatal age at onset was 10,1±9,2 days.

77 patients were treated conservatively (62,1%) and surgical treatment occurred in 47 patients (37,9%). 14 (11,3%) of the patients required bowel resections of more than 15 cm.

The mortality rate is 11,3 %.

-Differences between medical and surgical patients:

The sociodemographic, gestational, prenatal and peripartum characteristics according to the type of treatment required are shown in Table 1.

Multiple pregnancy, artificial gestation and instrumented delivery increase the chances of requiring surgical treatment. Apgar values at minute one and five post birth, were lower in surgical patients 6,9±2,1 vs 7,3±1,7.

Patients with NEC requiring surgical treatment presented an early debut of the disease. Mean age of onset was $10,4 \pm 8,2$ days in the medical group vs $9,6 \pm 10,5$ days in the surgical group.

Related to the medical treatment, patients who needed blood transfusion during the admission had an increased risk of requiring surgical intervention (OR= 2.6, CI= 0.99, 6,7) and this was statistically significant in the bivariate analysis ($p= 0.04$).

The requirements for mechanical ventilation, number of hours of it, inotropic drugs or the presence of umbilical catheters did not increase the risk for surgical intervention. The administration of enteral nutrition is a protective factor to avoid surgical exploration in our cases of series (OR= 0.46 CI= 0,12, 1.8).

The analytical parameters throughout the follow-up according to the final need for medical or surgical treatment are shown in Table 2.

Survival rate was significantly lower in patients requiring surgery 76,6% vs 96,1% in the medical group (OR= 7.54 IC= 1.979, 28.706).

-Statistical analysis:

This study aims to assess which parameters have in common the patients that required surgical treatment in our hospital, for this we performed a multivariate logistic regression analysis.

-Bloody parameters:

The bivariate analysis between the different parameters studied and the need for medical or surgical treatment shows that there are statistically significant differences in the variables glycemia (crude OR 1.02, CI = 1.014, 1.038), serum creatinine (OR = 17.3, IC

= 2.78, 107.43), serum albumin (crude OR = 0.37, CI = 0.197, 0.713), platelets (crude OR = 1, CI = 1.0, 1.0), neutrophils (crude OR = 1, 02; 1.0; 1.045) and serum pH (crude OR = 0.02, IC = 0.00, 0.525).

Patients who have required surgical treatment have the highest creatinine and blood glucose levels, lowest serum albumin levels and lowest platelets at diagnosis. We also found that in patients requiring surgical intervention the neutrophil count is higher and the serum pH is lower.

After adjusting for statistically significant and clinically relevant variables (glycemia, serum creatinine, serum albumin, platelets, CRP and neutrophils) in the multiple regression model, we observed that the variables associated with a higher probability of requiring surgical treatment are glycemia, creatinine and the level of serum albumin at the diagnosis of the disease.

The higher values of creatinine and glycemia increase the risk of surgical treatment and the values of serum albumin at the highest diagnosis decrease it.

-Clinical manifestations:

In the bivariate analysis, the clinical manifestations related to the need for surgical treatment have been abdominal pain, and the presence of coagulopathy at diagnosis.

After adjusting for a multivariate model considering significant and clinically relevant variables: presence of gastric residue, abdominal erythema, abdominal tenderness, abdominal pain, presence of coagulopathy.

We register these parameters at the time of diagnosis and objectify that, the variables that are associated with surgical treatment, are the presence of abdominal pain during abdominal exploration and coagulopathy in the blood tests.

-Radiological variables:

In the bivariate analysis, the radiological variables associated with surgical treatment are the presence of a fixed loop at diagnosis and the presence of portal venous gas.

-Final multivariate logistic regression model:

Finally, a logistic regression model is carried out combining different clinically relevant and statistically significant variables obtained in the analysis performed by blocks previously. Thus, by combining these parameters we will obtain independent predictors of surgical requirements in our sample of patients.

In our series, we have observed that the variables with independent effect to predict the surgical decision after taking into account sociodemographic, gestational, prenatal, perinatal, analytical, clinical and physical exploration and radiological variables are the presence of perinatal respiratory distress in the neonatal period, the values of glycemia and neutrophils and the presence of coagulopathy at diagnosis of the disease.

-Score system:

The score system was developed given a punctuation to these factors we have identified as potential markers of risk for surgical requirement:

- 0 point for a level of neutrophils less than 70% and glycemia levels less than 60 mg/dL
- 1 point for the presence of respiratory distress, coagulopathy, and levels of glycemia between 60-120 mg/dL
- 2 points for levels of neutrophils > 70%
- 3 points for levels of glycemia > 120 mg/dL

ROC curves were drawn for the prediction or requiring surgical treatment based in the score (Figure 1).

Area under the curve is 0.829 (95 % CI 0.743-0.915). Sensitivity and specificity for predicting surgical requirement by the score was 81.8% and 76.7% respectively (Table 4).

The optimal cutoff value was 2.5.

DISCUSSION:

Necrotizing enterocolitis is the most frequent surgical emergency in the neonatal period.

This disease is a severe life-threatening condition involving the gastrointestinal tract of the newborn.

Diagnosis of NEC

The percentage of surgical treatment required by patients with NEC ranges from 20-50% in the majority of published studies (6)(7) and is consistent with the 38% presented in our series.

Necrotizing enterocolitis is a challenge for the pediatric surgeon. The factors involved in the debut of progression of the illness remains certainly unknown.

To combat this devastating disease several proposed risk reduction strategies have been presented in the last decades. Prevention strategies as prophylactic enteral probiotics administration, have experience a great development in recent years. This is based on the fact that, the administration of probiotics among premature infants modify the balance of the gut microbiome in favor of non-pathogenic bacteria and this could change the fate of the disease; but evidence is still lacking and additional clinical trials are needed to evaluate both safety and efficacy of the use of probiotic agents to prevent NEC (8,9).

Once the disease is established, the factors involved in the progression of the condition persist, despite the multiple studies carried out, without clarifying. Classically patients undergoing surgical intervention for the treatment of NEC are considered to have a higher risk of perforation or perforation is established. Just the presence of pneumoperitoneum (free intraperitoneal air on abdominal radiography) is universally accepted as an absolute indication for surgical treatment and is not always present when necrosis and gangrene or

inclusive intestinal perforation occurs. For this reason, the presence of free abdominal air, is a late indicator by definition.

Necrotizing enterocolitis is a disease that can involve variables quantities of bowel and the extent of the intestinal loss is a strong determinant of long-term outcomes. For these reason there are reports in which an anticipation in the surgical treatment before perforation occurs, show and improvement in survival rates and a decrease in the intestine loss (10)(11).

In relation to the surgical indication, we consider that currently no isolated parameter except pneumoperitoneum has been shown as a reliable indicator that allows correlating clinical and radiological findings with therapeutic indication and prognosis (12).

Surgeon's decision to operate or not, is an individually decision, based in most cases of the traditional approach of the center or in the personal experience more than objective criteria.

This uncertainty for clinical decision making has inspired a variety of algorithms including scores, most of them considering only a combination of clinical parameters and laboratory test in the hope to facilitate therapeutic decision (12).

That is why in recent years there have been studies that propose clinical indexes combining different parameters. These clinical indexes aim to guide the patient's therapy by combining objective and subjective parameters.

For these reasons it is important to include in theses indexes not only analytical parameters, physical examination and (1, 12-15) thus, this is the first study which have added prenatal, sociodemographic, perinatal and peripartum variables that condition the presence of predispose factors that could determine the debut of this entity and in its

progression.

We obtained after performed a multivariate logistic regression analysis taking into account all this variable parameters, that patients requiring surgical treatment have presented an antecedent of respiratory distress in the perinatal period, analytically, they present higher values of glycemia at diagnosis, they debut with coagulopathy and present in laboratory findings marked neutrophilia.

The limitations of this study are the fact that, is not a multicenter study and this could lead a bias at the time of the surgical decision.

Applying this simple score among centers could objectify decision making and minimize the personal inferences of each surgeon.

Future randomized controlled trials would be useful to identify risk factors for the debut and progression of this elusive illness minimizing the risk of bias.

Further attempts at prevention and treatment of this disease are needed to decrease the still high impact of this devastating disease.

CONCLUSIONS:

Despite risk factors for progressive NEC despite elusive, we consider that anticipation in the surgical management of these infants before perforation or an extensive grade of gangrene is present would improve outcomes in terms of survival. Our score of risk could detect the ischemic bowel before gangrene and before perforation. Our patients may benefit from an earlier operation and improve the morbidity and mortality associated with necrotizing enterocolitis.

In the absence of pneumoperitoneum, the challenge faced by pediatric surgeons is to be able to reliably identify those infants who would benefit from surgery while minimizing the risk of the operation itself. Identifying infants with severe intestinal ischemia or necrosis due to NEC and performing a resection of the necrotic bowel would likely be beneficial and may improve outcomes.

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Table 1. Demographic, gestational, prenatal and peripartum characteristics according to type of treatment required.

Treatment required

	Medical		Surgery		OR crude (95% CI)	OR adjusted (95% CI)
	n (%)	media±DT	n (%)	media±DT		
Demographic						
Sex					0,76 (0,36;1,6)	
Male	46 (59,7%)		31 (40,2%)		1	
Female	31 (66%)		16 (34%)			
Mother's age (years)		31,6±6,4		32,5±5,8	1,02 (0,96;1,08)	1,02 (0,95;1,09)
Gestational						
Type of pregnancy						
Single	67 (65,7%)		35 (34,3%)		1	1
Multiple	10 (45,5%)		12 (54,5%)		2,3 (0,9;5,84)	1,81; (0,6;5,4)
Type of gestation						
Spontaneous	68 (65,4%)		36 (34,6%)		1	1
Artificial	9 (45%)		11 (55%)		2,3 (0,88; 6,1)	1,71 (0,5;5,2)
Gestational age (weeks)		33,3±3,8		32,6±4,8	0,97 (0,88;1,05)	0,9 (0,8;1,15)
Age at diagnosis (days)		10,4±8,2		9,6±10,5	0,98 (0,95; 1,03)	
Gestational information						
Streptococcus test						
No	17 (50%)		17 (50%)		1	
Yes	9 (81,8%)		2 (18,2%)		0,78 (0,52;1,15)	
NC	51 (64,5%)		28 (35,5%)			
Restrictive intrauterine growth						
No	62 (61,4%)		40 (38,6%)		1	
Yes	15 (65,2%)		7 (34,8%)		0,85 (0,33;2,19)	
Low weight for gestational age						
No	62 (60,7%)		40 (39,3%)		1	
Yes	15 (68,1%)		7 (31,8%)		0,72 (0,27;1,93)	
Oligoamnios						
No	65 (62,5%)		39 (37,5%)		1	
Yes	12 (60%)		8 (40%)		1,11 (0,42; 2,96)	
Treatment						
Corticoids						
No	47 (63,5%)		27 (36,5%)		1	
Yes	30 (60%)		20 (40%)		1,16 (0,5;2,4)	
Perinatal history						
Amniotic fluid						
Clear	70 (63%)		41 (36,9%)		1	
Dark	7 (53,8%)		6 (46,2%)		1,46 (0,46;4,65)	
Type of birth						
Vaginal	44 (60,3%)		29 (39,7%)		1	
Caesarean section	33 (64,7%)		18 (35,3%)		0,83 (0,39;1,74)	
Instrumental delivery						
No	75 (64,6%)		41 (35,3%)			1
Yes	2 (25%)		6 (75%)		5,5 (1,6;28,4)	14,2 (2,1-98,5)
Weight at birth (gr)		1940±816,1		1766,6±791	1 (0,99;1)	1 (0,9-1,0)
Apgar 1`		7,3±1,7		6,9±2,1	0,93 (0,77;1,12)	1,0 (0,8-1,3)
Apgar 5`		8,4±1,4		8,2±1,8	0,94 (0,74;1,18)	

Table 2: Analytical variables according to type of treatment. Univariate and multivariate analysis of logistic regression.

<i>Analytical parameters</i>	Type of treatment		n	Media±DT	P	OR crude	95% CI	OR adjusted	95%CI
	Medical	Surgery							
<i>General parameters</i>									
Glycemia (mg/dL)	71	82.859±29,89	37	139,89±71,99	0,000	1,02	1,014;1,038		
Creatinin (mg/dL)	68	0,54±0,22	38	0,78±0,48;	0,002	17,3	2,78;107,43	13793,9	7,1-26597794,1
Na (mEq/L)	72	137,52±3,9	41	135,78±5,9	0,091	0,93	0,86;1,01		
Hematocrit (%)	74	41,84±8,82	45	42,93±10,43	0,57	1,01	0,97;105		
Hemoglobin (g/dL)	72	14,36±2,89	44	14,51±3,76	0,81	1,01	0,90;114		
K+ (mEq/L)	70	4,92±0,83	40	4,98±0,81	0,68	1,1	0,69;1,78		
Total proteins (mg/dL)	66	4,8±0,76	32	4,2±0,78;	0,003	0,37	0,197;0,713	0,13	0,025-0,68
Platelets (10x ⁹)	72	333793,05±168295,5	44	224340±153598;	0,001	1,0	1,0;1,0	1	1-1
<i>Infectious parameters</i>									
Leucocytes (10x ⁹)	73	10713,74±4817,26	44	8577,5±8031	0,08	1,0	1,0;1,0		
Neutrophils (%)	74	46,7±16,9;	45	59,8±46,7	0,045	1,02	1,0;1,045	1,02	0,97-1,08
Linfocits (%)	66	34,91±15,06	41	30,34±17,57	0,16	0,98	0,96;1,007		
Serum pH	65	7,36±0,08;	34	7,31±0,08;	0,028	0,02	0,00;0,525	2,5	0,00-2899001,4
<i>Acute phase reactants</i>									
PCR	47	1,79±3,90;	30	3,32±4,15;	0,123	1,1	0,974;1,241	1,12	0,82-1,53
Procalcitonin	5	4,14±4,10	5	4,07±4,47	0,98	0,99	0,72;1,37		

Table 3. Final model of multivariate logistic regression.

	B	Standard error	p	OR	95% CI (OR)	
Coagulopathy	1.456	.697	.037	4.289	1.094	16.805
Respiratory distress	2.540	.816	.002	12.679	2.560	62.794
Glycemia (mg/dL)	.014	.005	.010	1.014	1.003	1.024
Neutrophils (%)			.041			
<25%						
25%-70%	1.434	1.262	.256	4.194	.354	49.749
>70%	3.324	1.468	.024	27.784	1.563	493.775
Constant	-6.812	1.738	.000	.001		

Table 4. Score to predict surgical management.

VARIABLE	POINTS	TOTAL POINTS	ESTIMATED PROBABILITY OF SURGICAL TREATMENT
Respiratory distress	1	0	0,2%
Coagulopathy	1	1	0,8%
Neutrophils (%)		2	3,0%
<70	0	3	10,5%
>70	2	4	30,6%
Glycemia (mg/dL)		5	62,4%
<60	0	6	86,2%
60-90	1	7	95,9%
90-120	1		
>120	3		