

DIAGNOSTICS AND TREATMENT OF NEONATAL NECROTISING ENTEROCOLITIS IN LATVIA

Ilze Meldere^{1,3,#}, Liene Rucka¹, Santa Smilga¹, Zane Ābola^{2,3},
 and Aigars Pētersons^{2,3}

¹ Rīga Stradiņš University, Department of Pediatrics, 16 Dzirciema Str., Rīga, LV-1007, LATVIA

² Rīga Stradiņš University, Department of Pediatric Surgery, 16 Dzirciema Str., Rīga, LV-1007, LATVIA

³ Children's Clinical University Hospital, 45 Vienības Ave., Rīga, LV-1045, LATVIA

Corresponding author, ilze.meldere@rsu.lv

Contributed by Aigars Pētersons

Necrotising enterocolitis (NEC) is one of the leading causes of neonatal morbidity, mortality and surgical emergencies. As the survival rate of extremely low birth weight (ELBW) infants is rising, so is the risk of NEC. The aim of this study was to compare diagnostics parameters like clinical and radiological findings and laboratory indicators and the treatment and outcome of NEC patients from 2000 till 2007 (Group 1) and from 2008 till 2016 (Group 2) treated in Neonatology Clinic (NC) of Children's Clinical University Hospital (CCUH). In the retrospective study, 277 newborns were divided among Group I and Group II – 105 and 172 patients, respectively. There were no statistically significant differences between both study groups in mean gestational age and birth weight. In both groups the first signs of NEC appeared on average eight days after birth. Differences in the diagnostic method used in both groups were not statistically significant; specific radiological findings were seen in approximately 1/3 of the cases. There were statistically significant differences in the management of NEC and patient mortality. Conservative therapy was applied in 70.0% of patients in both study groups. Over time, peritoneal drainage (PPD) as the sole surgical treatment decreased by 6.4%, but PPD with following enterostomy decreased by 8.9%. In Group 2 mortality of NEC patients decreased by 17.4%. Mortality among surgically treated NEC patients decreased as well, by 9.0%.

Key words: neonate, preterm infant, necrotising enterocolitis, surgical management, mortality.

INTRODUCTION

Neonatal necrotising enterocolitis (NEC) is a disease that affects the gastrointestinal tract of neonates and is characterised by focal or diffuse intestinal necrosis. In 90% of cases NEC affects preterm infants, particularly those with extremely low birth weight (ELBW), i.e. weight under 1000 grams, and very low birth weight (VLBW), i.e., 1000–1500 grams (Hall *et al.*, 2013). The incidence of NEC varies from 1 to 3 in 1000 live births and NEC affects 1 to 5% of infants in neonatal intensive care units (NICU) (Maheshwari *et al.*, 2011). The incidence of NEC continues to increase due to more ELBW and VLBW infants being born, as more preterm infants are treated in the NICU and new technologies are being introduced. Risk factors such as immaturity of intestines due to prematurity, initiation of enteral feedings and

bacterial infection play a significant role in the pathogenesis of NEC.

The diagnostics of NEC is based on clinical examination, and radiological and laboratory findings. In 1978, Dr. Martin Bell described three clinical stages of NEC, and the Bell's staging criteria have been modified various times. The criteria distinguish initial, proven, and surgical NEC. The stage of NEC depends on various clinical signs. The typical local signs of NEC are abdominal distention, abdominal wall oedema and erythema, ascites, and increased gastric residuals with or without bile, emesis, occult or grossly bloody stools. Systemic signs include lethargy, apnea, signs of septic shock, but laboratory findings show thrombocytopenia, elevated inflammatory markers (i.e. leukocytosis or leukopenia, elevated C reactive protein level,

interleukin 6), metabolic acidosis and electrolyte imbalance. Radiography (i.e. abdominal ultrasound and abdominal X-ray) plays a significant role in the diagnostics of NEC. Pathognomonic radiological findings of NEC are intestinal pneumatosis (intramural gas due to the production of gas from bacterial fermentation in the intestinal wall), fixed bowel loops, signs of ileus and pneumoperitoneum. Free fluid in the abdominal and pleural cavity, pneumoperitoneum and mass lesions can be visualised by ultrasonography.

There are two treatment options: medical or nonsurgical treatment and surgical treatment performed with additional medical treatment. Medical management includes *nil per os*, complete bowel rest and gastric decompression, broad-spectrum antibiotics, correction of hypovolemia and acid-base imbalance, blood transfusions in case of thrombocytopenia and/or anaemia and total parenteral feeding. Absolute indications for surgical management are pneumoperitoneum and peritonitis. The surgical approach depends on the infant's health condition, the staging of NEC and intraoperative findings. Laparotomy with resection of necrotic bowel with anastomosis or creation of enterostomy are known as the traditional surgical approaches. Primary peritoneal drainage (PPD), which can be followed or not by enterostomy in ELBW infants, can be used as an alternative approach (Downard *et al.*, 2012).

NEC is a devastating disease in the neonatal period due to its various clinical findings, aggressive and possibly fulminant course. It is one of the most common causes of neonatal morbidity, mortality and surgical emergencies (Gephard *et al.*, 2013).

The aim of this study was to compare diagnostics parameters like clinical and radiological findings and laboratory indicators and the treatment and outcome of NEC patients from 2000 till 2007 and from 2008 till 2016.

MATERIALS AND METHODS

The Ethical Committee of Children's Clinical University Hospital approved the study protocol, which was created in accordance with the Patient Data Protection Regulation.

A retrospective study was performed from January 2000 to December 2016, which included 277 patients from the Neonatology Clinic (NC) of the Children's Clinical University Hospitals' (CCUH) diagnosed with NEC according to International Classification of Diseases 10th revision (ICD-10). All the medical records with code P77 (Necrotising enterocolitis of newborn) were analysed (ICD-10, 2016). Patients were divided into two groups: Group 1 – patients hospitalised in CCUH NC from January 2000 to December 2007 (n = 105), and Group 2 – patients hospitalised from January 2008 to December 2016 (n = 172). Assessed parameters were compared between the two groups including sex, birth weight, weeks of gestation. The clinical stages of NEC of both groups were compared according to Bell's Staging Cri-

teria taking into account the diagnostic parameters. The following diagnostic clinical findings were assessed; general and local abdominal symptoms, radiological ultrasound and X-ray findings and laboratory labels (number of leukocytes and trombocytes, C reactive protein and interleukin 6 levels, pH and baseline excess (BE) levels of blood gases. The applied therapies (medical or surgical) were compared for both groups. Four surgical methods used in both groups were evaluated and compared: PPD, PPD and following enterostomy, bowel resection with the enterostomy and bowel resection with creation of primary anastomoses. In both study groups mortality was assessed and compared by birth weight and treatment management. Data were collected using Microsoft Excel 2013 and analysed with STATA/IC v.12.5. The Kruskal-Wallis H and Student T test was applied.

RESULTS

The sex distribution was similar — 137 (49.5%) male and 140 (50.5%) female newborns. NEC was more common in ELBW and very low birth weight (VLBW) infants in both groups — 33 (32.4%) ELBW infants in Group 1 and 71 (41.3%) in Group 2, and 34 (32.4%) VLBW infants in Group 1 and 50 (29.1 %) — in Group 2. No statistically significant difference in mean weeks of gestation was found between Group 1 and Group 2, i.e. 29.7 (SD = 4.4) and 32.7 (SD = 4.4) weeks of gestation. The first typical signs of NEC (feeding intolerance, gastric retention, abdominal enlargement, bloody stools and general signs of sepsis) were observed in the second week of life and the mean age at the time of diagnostic was 8.7 (SD = 8.07) and 7.8 (SD = 9.01) days in Group 1 and Group 2, respectively. The distribution of three stages according to Bell's Staging Criteria did not differ between the two groups: in Group 1 — 51.4%, 23.8% and 24.8%, in Group 2 — 48.3 %, 27.8% and 23.9% (Table 1). Specific radiological findings suggesting NEC were seen in 34.3% of cases in Group 1 and 34.5% — in Group 2. As expected, 68.6% patients in Group 1 and 72.7% in Group 2 received medical management. Surgical management of NEC differed significantly in both groups. Primary peritoneal drainage (PPD) as the sole surgery was used relatively less in Group II: PPD as the sole surgical manipulation in NEC decreased by 6.4%, and the use of a multi-staged operation with PPD and a following enterostomy decreased by 8.9% between the two time periods. Almost equal percentage of patients underwent intestinal resection and enterostomy formation in Group 1 and Group 2, i.e. 13.3% and 13.4%, but intestinal resection and creation of primary anastomosis was chosen only in Group 2 in 2.3% of cases (Fig. 1). A statistically significant difference was found in mortality between the two groups. The overall mortality was 44.8% in Group 1 and 27.3% in Group 2. The distribution of dead newborns by birth weight between groups did not differ significantly. In both study groups the highest mortality was in ELBW neonates, i.e., 53.2% and 57.5% in the two groups, respectively Fig. 2 and Fig. 3). There was a 9.0% decrease of mortality between the two time periods in

DESCRIPTION OF THE POPULATION

		Group 1 (n = 105)	Group 2 (n = 172)	p value
Male		50 (47.5%)	87 (52.4%)	NS
Female		55 (50.6%)	85 (49.4%)	NS
Weeks of gestation (SD)		29.7 (+/- 4.4)	32.7 (+/- 4.4)	NS
Birth weight, grams (SD)		2,1 (+/- 1.0)	1.9 (+/- 1.0)	NS
First clinical signs of NEC, days of life (SD)		8.7 (+/- 8.1)	7.8 (+/- 9.0)	NS
X-ray and US abdominal findings	No imaging done, %	37.1	32.8	NS
	Nonspecific, %	28.6	31.7	
	Intestinal pneumatosis, %	16.2	19.3	
	Pneumoperitoneum, %	18.1	15.2	
Bell's staging	I, %	51.4	48.3	NS
	II, %	23.8	27.3	
	III, %	24.8	23.8	
Mortality		47 (44.8%)	47 (27.3%)	0.003

SD, standard deviation; NEC, necrotising enterocolitis; NS, not significant

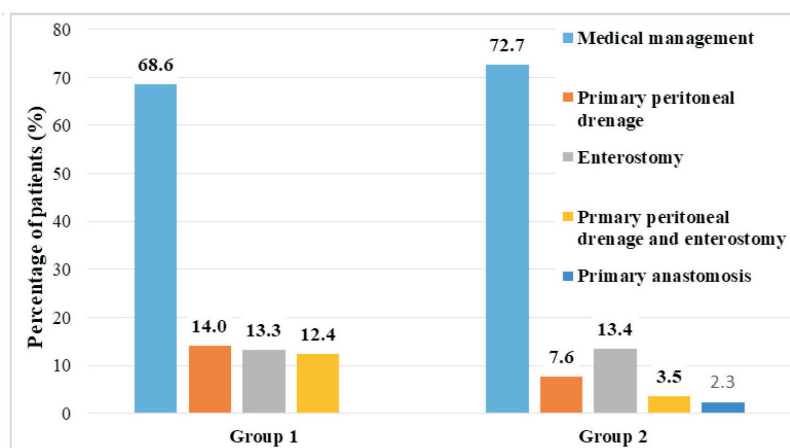


Fig. 1. Treatment used in cases of necrotising enterocolitis in both study groups ($p = 0.005$).

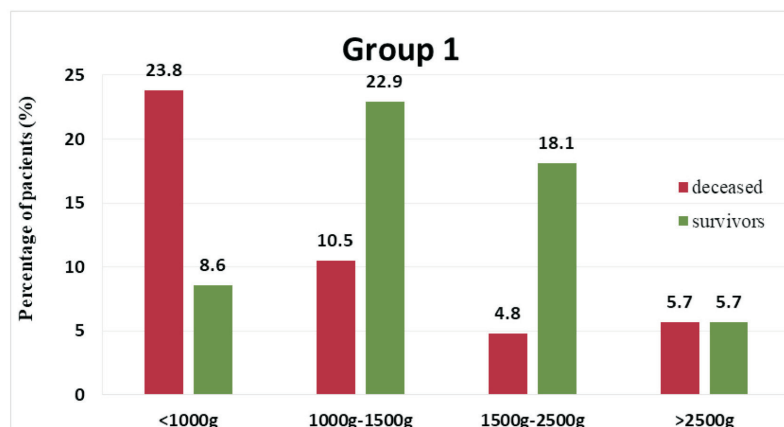


Fig. 2. Mortality and survival of patients with necrotising enterocolitis in Group 1 depending on their birth weight ($p < 0.001$).

the group of patients treated surgically — the rate of mortality in Group 1 was 20%, but in Group 2 — 11%. There is a very variable patient mortality over the years (Fig. 4).

DISCUSSION

There are approximately 20 000 live births each year in Latvia, the number of births in the last 17 years has not

changed significantly. In this time period there were 361 798 live births in Latvia and about 6% of them were premature births. The incidence of NEC in Latvia has been variable, i.e. from 0.2 to 1.6 per 1000 live births (Fig. 5), which is equivalent to data from other countries — 0.76 to 0.98 per 1000 live births in North America, 0.5 to 5 per 1000 live births in United Kingdom, and 1.8 per 1000 live births in Canada (Shnabl 2008; Hall, 2013; Gillfilan 2017). Each

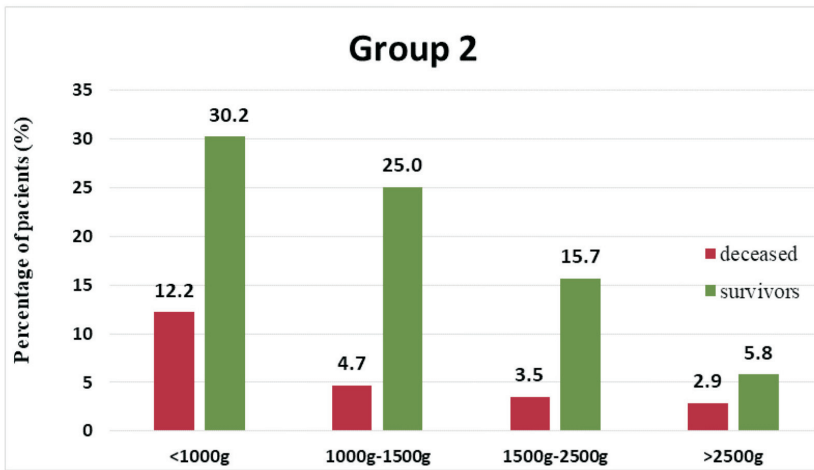


Fig. 3. Mortality and survival of patients with necrotising enterocolitis in Group 2 depending on their birth weight ($p = 0.058$).

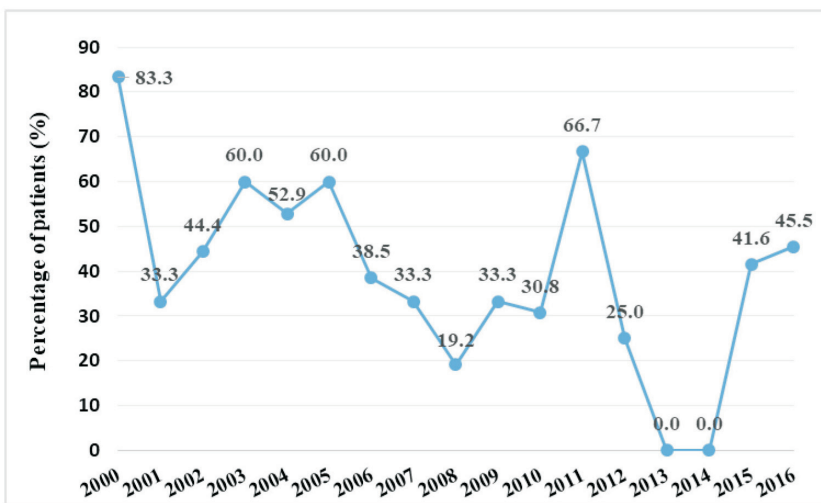


Fig. 4. The mortality (%) of newborns with necrotising enterocolitis.

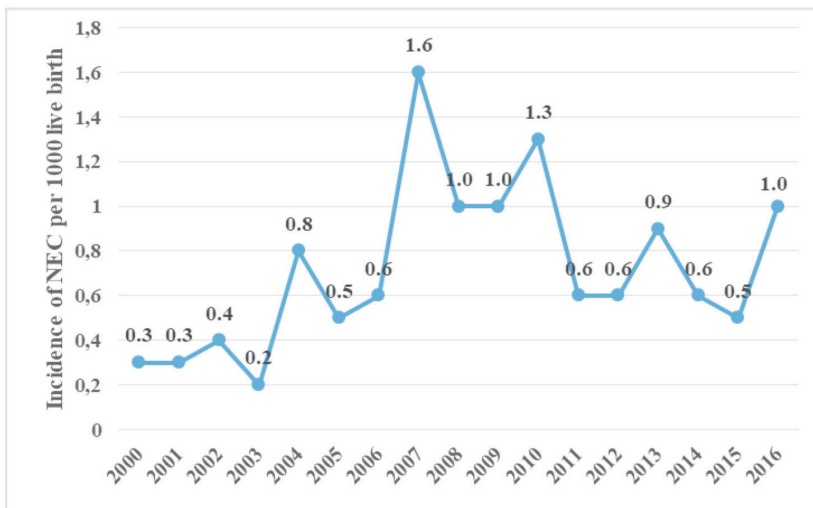


Fig. 5. The overall incidence of necrotising enterocolitis in Latvia.

year there are 5 to 39 new cases of NEC in CCUH NC. In Latvia all NEC patients from regional perinatal centres are transported to CCUH according to guidelines for the treatment and care of newborn with NEC. During the time period from January 2000 to December 2016, there were 19 240 patients in CCUH NC and 1.4% of these patients were diagnosed with NEC, which is similar as in NICUs in other countries, i.e. 2 to 5% (Gupta and Paria, 2016). The variable incidence of NEC during these years suggests that there might be diagnostic problems or the diagnosis of NEC

might have different interpretations due to lack of specific markers of NEC.

In the past few years, there have been a lot of discussions regarding the definition of NEC. It has been noted that the lack of specific criteria results in misleading statistics of NEC in different NICUs, and therefore when using the Bell's Staging Criteria, all the risk factors should be taken in consideration (Gupta and Paria 2016; Gephard *et al.*, 2017; Neu et Pammi, 2017). In most of the cases in premature in-

fants the onset of NEC is in the second or third week of life (Maheshwari *et al.*, 2011), although in 25% of cases the onset can be even after the age of one month (Clark and Munchi, 2014). In this study most of the patients developed first clinical signs of NEC after the first week of life, when the risk factors associated with pathogenesis of NEC, i.e. immaturity of intestines due to prematurity, initiation of enteral feedings, the type of enteral feedings, bacterial colonisation of the gastrointestinal tract and possible bacterial infection are manifested (Guner *et al.*, 2008). The interaction of risk factors leads to increased intestinal wall permeability, increased epithelial cell apoptosis of intestinal mucosa and activation of inflammatory marker cascade.

Although NEC usually affects premature infants, it can also affect infants born in term. Approximately 11% of all the NEC patients in CCUH NC were term infants with a birth weight of more than 2500 grams, which was similar to data in the literature. There are several risk factors of NEC for term infants, such as asphyxia during labour, respiratory distress, anaesthesia used during caesarean section, various prenatal factors and other underlying conditions, e.g. congenital heart disease, which causes hypoperfusion and hypoxia in gastrointestinal tract (Gephard *et al.*, 2013; Gordon *et al.*, 2017; Maheshwari *et al.*, 2017).

As our retrospective study showed, in most cases (65.0%) NEC was diagnosed based on clinical findings. This may lead to misinterpretation, especially in the first stage of NEC, when some of the clinical symptoms may be considered as normal signs of the development of a premature infant, e.g., increased gastric residuals due to decreased motility of intestines, abdominal distention and meteorism due to feeding intolerance or the use of continuous positive airway pressure or bloody stools due to viral infection. This might be the reason for NEC hyperdiagnosis suggested by changing statistics — increasing NEC incidence, increasing the percentage medically treated NEC, reducing the percentage of surgically treated NEC, as well as reducing mortality. This means that in the clinical practice, more accurate and specific NEC criteria are required. Specific radiological findings of NEC in both of our study groups were found in 35.0% of cases, which is less common than described in other studies — where in 60.5% of cases not only pneumoperitoneum but also various other specific signs of NEC have been found (Coursey *et al.*, 2009), making the diagnosis of NEC still based on clinical findings. Literature data shows that intestinal pneumatosis can be assessed by ultrasound earlier than by X-ray imaging and that the sensitivity of ultrasound is higher by 6.25% (Shebria *et al.*, 2012; Eaton, 2017). There were no statistically significant difference between X-ray and ultrasound diagnostic methods between the two study groups. Our study showed that radiologically diagnosed pneumoperitoneum was reduced by 3.0% in Group 2, which confirms the decline in the perforative NEC forms.

The study showed that approximately 60% of the patients with NEC in Latvia received solely medical management. The only absolute indication of surgical treatment in case of

NEC is intestinal perforation. In both groups in CCUH NC surgical management was received by 26 to 29% of patients, similar as in clinics in United States of America, United Kingdom, Taiwan, where surgical management was done in 20 to 40 to 60% of cases (Shnabl *et al.*, 2008; Young *et al.*, 2009; Wu *et al.*, 2011; Clark et Munshi, 2014). The surgical approach includes PPD, multiple stage surgeries with PPD and a following enterostomy, laparotomy with resection of ischemic bowel and creation of primary enterostomy and resection of ischemic bowel with primary anastomosis creation. The resection of ischemic bowel with primary anastomosis was first mentioned in 1979 by Kiesewetter *et al.* (1979) and lately this approach has been used more often due to the possibility of avoiding complications of enterostomy (e.g. prolapse, necrosis, strictures), feeding difficulties and metabolic disturbances (Hall *et al.*, 2009). The surgical method depends on intraoperative findings — whether the necrosis of intestines is focal, multifocal or panintestinal (Hall *et al.*, 2013). The statistically significant difference between the two groups can be explained by the decreased usage of PPD in all birth weight groups and the usage of primary anastomosis in surgical management since 2008.

Various studies show no significant difference in mortality, days spent in hospital or late outcome in critically ill ELBW infants based on surgical approach (Raval and Moss, 2014). The mortality rate in CCUH due to NEC has decreased by 17.4%, although the overall mortality still is high (27.3%), as in USA and UK where the mortality rate differs in various NICUs and makes up 20 to 50% of cases (Maheshwari *et al.*, 2011; Gephard *et al.*, 2012). The decrease in mortality could be attributed to the reduction of perforated form in the second group. It is known that in cases of NEC the mortality is inversely proportional to the birth weight — mortality increases if the birth weight is below 1000 grams (Hull *et al.*, 2014). Up to 42% of patients with NEC in CCUH were ELBW infants, and therefore the high mortality in this group of patients was associated with life-threatening underlying conditions of extremely premature infants, e.g. stage III and IV intraventricular haemorrhages, respiratory distress syndrome, hypoxic multiorgan failure, acute renal failure, disseminated intravascular coagulopathy, sepsis etc. The mortality of surgically treated NEC patients in the time period has decreased from 20% to 11% and it is lower than in the United States of America and the United Kingdom, where the mortality is 30% and 20%, respectively (Hull *et al.*, 2014; Eaton, 2017), which is associated with the critical condition of ELBW and VLBW infants in case of intestinal perforation.

CONCLUSIONS

1. The incidence of NEC in Latvia is similar to the incidence of NEC in other countries.
2. The distribution of three stages according to Bell's Staging Criteria did not differ between the study groups ($p = 0.64$).

3. Intestinal perforations decreased by 3.0% comparatively in the NEC patients second group, although there are no statistically significant differences between radiological NEC findings between the study groups ($p = 0.703$).
4. The use of PPD, both as the sole surgical manipulation and as a multi-stage operation, was reduced in the second study group ($p = 0.005$).
5. In the second group the mortality due to NEC decreased for both medical and surgically treated infants ($p = 0.003$).
6. In both study groups the highest mortality rate was among ELBW newborns, but there was no statistically significant difference in the mortality of patients with NEC in the different weight groups between the two patient groups ($p = 0.97$).

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NEKROTISKĀ ENTEROKOLĪTA DIAGNOSTIKA UN ĀRSTĒŠANA JAUNDZIMUŠAJIEM LATVIJĀ

Nekrotiskais enterokolīts (NEK) ir viens no biežākajiem saslīkstības, mirstības un neatliekamās ķirurģiskās palīdzības sniegšanas iemesliem neonatālajā periodā. Palielinoties ļoti zema svāra priekšlaikus dzimušo bērnu izdzīvošanai, NEK risks turpina pieaugt. Darba mērķis bija salīdzināt NEK pacientu klīniskās un radioloģiskās pazīmes, ārstēšanas taktiku un rezultātus divos laika periodos — 2000.–2007. g. (I grupa) un 2008.–2016. g. (II grupa), kuri ārstējušies Bērnu klīniskās universitātes slimnīcas Neonatoloģijas klīnikā. Retrospektīvajā pētījumā tika iekļauti 277 jaundzimušie ar diagnozi NEK, 105 — I grupā un 172 — II grupā. Abās pētījuma grupās nebija statistiski ticamu atšķirību NEK pacientu vidējam gestācijas vecumam un sadalījumam pēc dzimšanas svāra. NEK pirmās pazīmes abās pētījuma grupās parādījās vidēji astoņas dienas pēc dzimšanas. Pielietotajām diagnostikas metodēm statistiski nozīmīgu atšķirību abās grupās nebija — aptuveni 1/3 gadījumu tika konstatēta NEK specifiska radioloģiska atradne. Statistiski ticama atšķirība starp abām pētījuma grupām tika novērota pielietotajā terapijā un mirstībā. Konservatīva terapija abās pētījuma grupās tika pielietota 70% gadījumu. Laika gaitā samazinājās primāras peritoneālas drenāžas (PPD) veikšana: par 6,4% — kā vienīgā ķirurģiskā manipulācija un par 8,9% — PPD pielietošana ar sekojošu enterostomas izveidošanu vairāketapu operācijas ietvaros. II pētījuma grupā mirstība no NEK bija samazinājusies par 17,43%. Ķirurģiski ārstēto mirušo pacientu skaits II grupā samazinājās par 9%.