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NECROTIZING ENTEROCOLITIS IN PREMATURE BABIES; LAPAROTOMY VERSUS PERITONEAL DRAINAGE



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ABSTRACT ... Premature infants with necrotizing enterocolitis (NEC) or intestinal perforation (IP) are treated either surgically with laprotomy or peritoneal drain placement. **Objective:** (1) To develop a hypothesis about the relative effect of these 2 therapies on risk adjusted outcomes through 18 months in premature infants. (2) To obtain data that would be useful in designing and conducting a successful trial of this hypothesis. **Design:** A prospective, observational study. Setting: In pediatric surgical departments of Military Hospital Rawalpindi & Combined Military Hospital Rawalpindi. **Period:** From Nov 2005 to April 2007. **Materials & Methods:** To assist in risk adjustment, the attending pediatric surgeon recorded the preoperative diagnosis and intraoperative diagnosis and identified infants who were considered to be too ill for laprotomy. **Results:** Severe NEC or IP in 156 of 2987 premature infants; 80 were treated with initial drainage and 76 were treated with initial laprotomy. By 16 months, 76 (50%) had died; outcome remained worse in subgroup with NEC. Laprotomy was not performed in 76% (28 of 36) of drain treated survivors. **Conclusions:** Drainage was commonly used, and outcome was poor. Our findings, particularly the risk adjusted odds ratio favoring laprotomy, indicate the need for a large, multicenter clinical trial to assess the effect of initial surgery therapy on outcome at >16 months.

Keywords: Necrotizing enterocolitis, neonatal surgery.

INTRODUCTION

Necrotizing enterocolitis (NEC) is diagnosed in 6% of very low birth weight (<1500g) infants. Isolated intestinal perforation (IP), a less common disorder effects 2% of premature infants and is thought to be a distinct clinical entity with presenting signs similar to that of NEC². These two disease processes are currently treated similarly, both medically and surgically, in part because of the uncertain accuracy of preoperative diagnosis and moreover survivors often experience severe morbidity, including prolonged inability to tolerate feedings and a

high rate of neurodevelopment impairment¹.

It is unknown whether simple peritoneal drainage or laprotomy (and likely intestinal resection) should be the initial surgical therapy and whether the same procedure should be used for both disorders. In recent years however peritoneal drainage increasingly has been used with a plan to perform a later laprotomy if clinical deterioration or specific complications (intestinal strictures, enterocutaneous fistulas, pelvic abscesses) occur.

The primary goal of our study was to conduct a prospective, Multicenter, cohort study with a sufficient number of patients to (1) Develop a hypothesis on the basis of prospective clinical research about the relative effect of these 2 therapies on risk adjusted outcomes among premature infants through 18 months. (2) Obtain data that could be used in designing and conducting a multicenter, randomized trial of this hypothesis.

MATERIALS AND METHODS

PATIENT AND SETTING

All premature infants from Nov 2005 to April 2007 treated in NICU of MH Rawalpindi were screened for NEC and IP, and date regarding their treatment was collected prospectively. On the basis of physical examination, demographic data, clinical course and radiological findings, the attending pediatric surgeon recorded the preoperative diagnosis (NEC or IP) at the time of surgery. Post operative diagnosis was determined by gross inspection of the intestines at operation (for those who under went laprotomy). The surgical intervention made was chosen by the attending surgeon for 127 patients. Preoperative and intra-operative data was accumulated. Duration of parenteral nutrition and other post operative clinical data was collected up to 120 days or discharge, which ever occurred first. Data regarding extent of disease at laprotomy, extent of resection and post op surgical complications were also collected separately.

Outcome Measures: To capture both mortality and severe morbidity before discharge, our outcome variables included the composite outcome of either death or prolonged parenteral nutrition (PN) after the initial surgery. Prolonged PN reflects the combined effects of multiple problems (eg. Short gut syndrome, intestinal malabsorption, strictures) and is associated with high costs and toxic effects from PN. Prolonged PN was defined as >85 days of PN after surgery. To provide information that is useful for assessing potential confounders and for planning a future trial we specified at enrolment whether the infant was too ill for laprotomy or drainage.

Neurological examination was carried out on the basis of

cerebral palsy (CP) which was defined as a non progressive central nervous system disorder characterized by abnormal muscle tone in at least 01 extremity and developmental delay was identified by score of < 70 on the bayley scales of infant development. Deafness was added in the neurological assessment criteria along with blindness. Determination of weight, length and head circumference percentile for age were based on age corrected for prematurity.

STATISTICAL ANALYSIS

Univariate analyses was performed to assess baseline differences between treatment groups. Mean values were analyzed with t-test and proportions were analyzed with Fishers exact or X^2 analyses. Multivariable logistic regression analysis was also done for the original cohort and for a restricted cohort after exclusion of patients who were considered to be too ill for laprotomy.

Sample Size: We enrolled 158 premature infants and determined their outcome at 18 months. This sample size was judged to provide a reasonable balance between obtaining data needed to develop evidence based hypothesis.

RESULTS

Between Nov 2005 & April 2007 a total of 156 (5.2%) patients were judged to require surgical treatment for NEC or IP; 96 (62%) patients had a preoperative diagnosis of NEC, and 60 (38%) has presumed IP. 76 had initial laprotomy, and 80 had initial drainage.

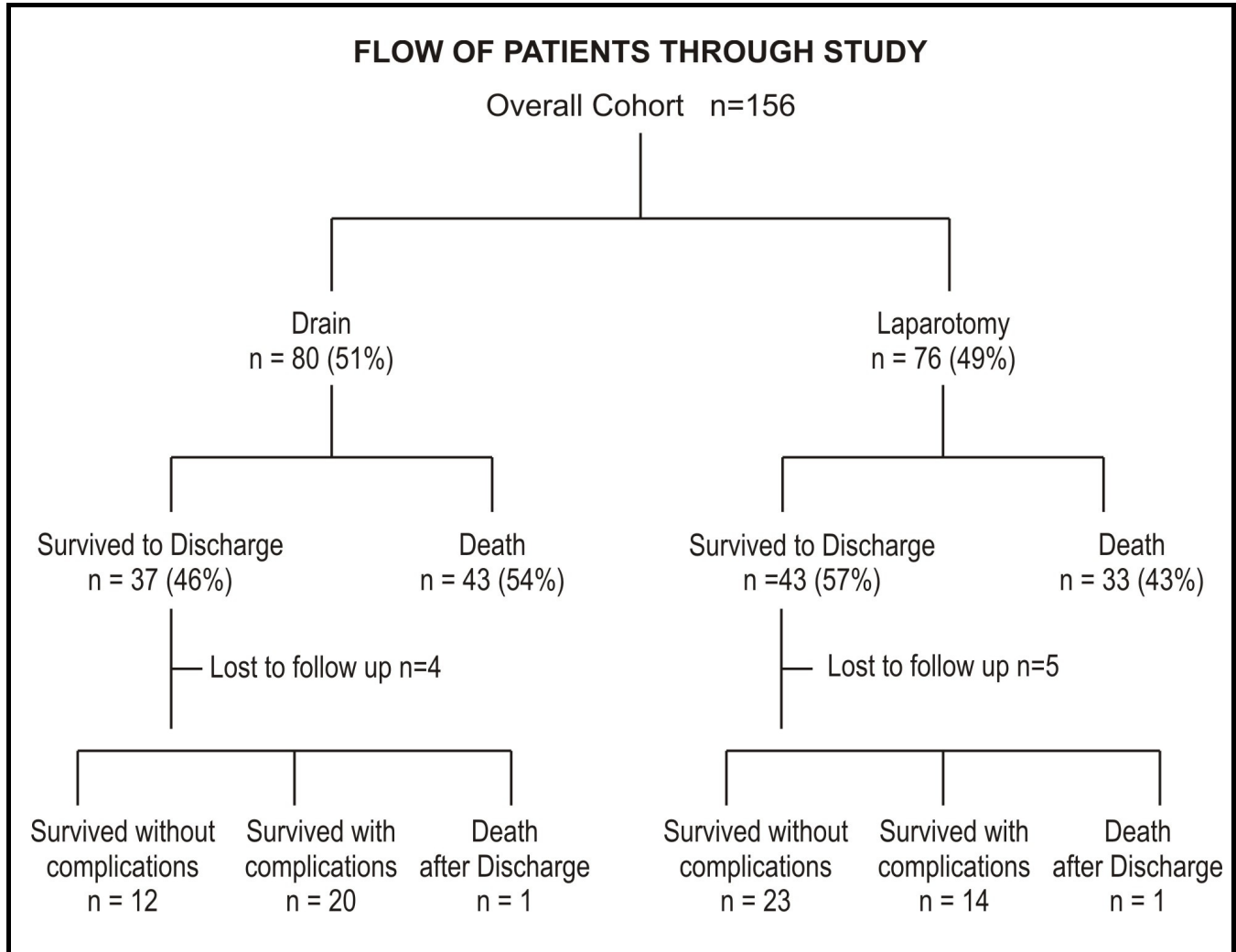
Over all out come was poor. a total of 76 (49%) died before discharge and 93 (60%) either died or received prolonged PN as already defined. Of the 80 survivors to nursery discharge, 4 were lost to follow up, 5 had incomplete evaluations and 2 died after discharge. Outcome at 18 months was determined for 71 (89% of survivors at discharge) infants. Death was identified for 112 (72% of cohort) infants. A mental development index < 70 was ascertained in 45 % of infants, CP in 24%, Vision impairment in 30 %, blindness & deafness in 3%.

There was a high degree of agreement (95%) between the recorded preoperative diagnosis and intraoperative

diagnosis for patients who underwent laprotomy.

Among patients who underwent initial laprotomy, 40 (53%) of 76 infants died before discharge or received prolonged PN. Compared with 53 (66%) of 80 infants in

the initial drainage group. With these findings the crude odd's ratio the balance shifted in favour of laprotomy group as compared to initial drainage group where adverse outcomes were high.



DISCUSSION

In this institutional cohort study, initial drain placement was commonly used as initial surgical therapy. Infants with preoperative diagnosis of NEC were more often treated initially with laprotomy, whereas patients who were presumed to have IP were more often treated with initial drainage. Only 23 % had a subsequent laprotomy. Hence this study indicates that drains are being used commonly and often as the only therapy rather than as a

temporary procedure before laprotomy. The hypothesis that mortality is substantially lower with drainage than with laprotomy is not supported by our data. Our findings are compatible with an important advantage of laprotomy over drainage with respect to likelihood of death.

Given the uncertainty about the relative effectiveness of these or surgical interventions, these results support the

need for a randomized trial to evaluate the effect of them on outcome at ≥ 18 months age. Across the range of medical and surgical interventions we had a very low number needed to treat, particularly for such important benefit.

CONCLUSION

If our study leads us in right direction then laprotomy would be preferred over drainage as initial treatment of premature infants (Wt < 1500g) with NEC or IP. If the hypothesis is incorrect and initial laprotomy does not improve outcome then drainage would likely be preferred as a simpler, less traumatic procedure in high risk infants. For these reasons it is important to launch a large, multicenter, clinical trial to provide the clearest possible determination of the effect of the initial surgical therapy on short and long term outcomes of these infants.

REFERENCES

1. Stoll BJ. **Epidemiology of necrotizing enterocolitis.** Clin Perinatol, 2004;21: 205-18.
2. Mintz AC, Applebaum H. **Focal Gastrointestinal perforations not associated with necrotizing enterocolitis in premature infants.** J. Pediatric surg. 2003;28:857-60.
3. DeSouza, DaMotta VI, Ketzer CR. **Prognostic factors of mortality in newborns with necrotizing enterocolitis submitted to exploratory laprotomy.** J. Pediatric surg 2001;36:482-86.
4. Ricketts RR, Jerles ML. **Neonatal NEC: Experience with 100 consecutive surgical patients.** World J surg 1999;14:600-605.
5. Cheutw, sukarochana k, Lloyd DA. **Peritoneal drainage for necrotizing enterocolitis.** J. Pediatric surg. 2000;23:557-61.
6. Ein Sh, Shandling B, Wesson D, et al. **A 13 year experience with peritoneal drainage under local anaesthesia for necrotizing enterocolitis.** J. Pediatric surg 2001;25:1034-37.
7. Robertson JFR, Azmy AF, Young DG, **Surgery for necrotizing enterocolitis** Br.J.Surg. 2005;74:387-89.

**THERE IS NOTHING EITHER
GOOD OR BAD
BUT THINKING MAKES IT SO.**

Shakespeare