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11-1-2008

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Recommended Citation

St Peter, S. D., Tsao, K., Sharp, S. W., Holcomb, G. W., Ostlie, D. J. Predictors of emesis and time to goal intake after pyloromyotomy: analysis from a prospective trial. *Journal of pediatric surgery* 43, 2038-2041 (2008).

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Published in final edited form as:

J Pediatr Surg. 2008 November ; 43(11): 2038–2041. doi:10.1016/j.jpedsurg.2008.04.008.

Predictors of emesis and time to goal intake after pyloromyotomy: analysis from a prospective trial

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Abstract

Background—Emesis after pyloromyotomy for pyloric stenosis is a common clinical phenomenon and the limiting factor in time to goal feeds. The amount of emesis that can be expected after myotomy is unknown. No data have been published that equip caregivers with the ability to understand which patients are more likely to have emesis and take longer to advance to goal feeds after pyloromyotomy. Therefore, we performed analysis of prospective data obtained from a randomized trial to determine if outcome can be predicted from preoperative or intraoperative variables.

Methods—The dataset was prospectively collected from a randomized trial comparing open to laparoscopic pyloromyotomy in 200 patients. All patients had serum electrolytes and sonographic pyloric measurement recorded upon presentation. The postoperative feeding schedule and criteria for stopping feeds was controlled by a standard computer entry order set. In this study, we used Pearson's correlation to evaluate the influence of patient variables, presenting electrolytes, and intraoperative variables against 2 outcome variables (postoperative emesis and time to goal feeds). Significance is defined as a $P \leq .01$.

Results—In patient demographics, only weight on admission held a significant correlation to the number of episodes of postoperative emesis, which was an inverse correlation. Of the electrolytes on admission, chloride, potassium, and anion gap correlated significantly with number of emesis and time to goal feeds. There was an inverse correlation for potassium and chloride, whereas it was direct with anion gap. Significance was not detected in the correlation to outcomes for operative or sonographic variables.

Conclusions—The degree of hypochloremic, hypokalemic, metabolic alkalosis on presentation strongly correlates to the number of episodes of postoperative emesis and time to goal feeds in patients undergoing pyloromyotomy for pyloric stenosis. Furthermore, the corresponding duration of dehydration and failure to thrive appears to correlate with outcomes as there was a significant inverse correlation with weight on admission to the number of episodes of postoperative emesis and time to goal feeds.

Keywords

Feeding regimen; Pyloromyotomy; Emesis; Predictors

Emesis after pyloromyotomy for pyloric stenosis is a common clinical phenomenon and the limiting factor in time to goal feeds. Many attempts have been made to attenuate

postoperative emesis with manipulation of the feeding schedule after pyloromyotomy. However, there are no data published to date that offer insight to which patients are more likely to have problematic emesis after the operation and which patients are more likely to tolerate feeds without delay. Therefore, we performed analysis of prospective dataset obtained from a randomized trial to determine if outcome can be predicted from demographic, presenting electrolyte, radiographic, or operative variables.

1. Methods

Approval was obtained from the Children's Mercy Hospital (Kansas City, Mo) internal review board before enrolling patients in this study. From April 2003 to March 2006, 200 patients were enrolled in the study. The study population consisted of infants diagnosed with pyloric stenosis by ultrasound using standard institutional sonographic criteria. All patients had serum electrolytes and sonographic pyloric measurement recorded on presentation per protocol. The postoperative feeding schedule and criteria for stopping feeds was controlled by a standard computer entry order set. The feeding schedule began 2 hours after the operation and was advanced sequentially with 2 feedings of electrolyte solution given 2 hours apart followed by 2 feedings of 1/2 strength formula or breast milk given 2 hours apart followed by 2 feedings of full strength formula or breast milk given 2 hours apart followed by ad libitum feeds or the previously used home feeding regimen. Patients with 2 emesis episodes at a given level on the feeding schedule were held at that level until they tolerated the feeds. More than 2 emesis episodes resulted in a "setback" and cessation of feeding for 6 hours with subsequent reinstatement of oral intake at the previous level.

Patients were randomized to the open or laparoscopic operation. The remainder of the study design for the prospective trial leading to this dataset including the results has been previously reported [1].

In this study, we used Pearson's correlation to evaluate the influence of demographic, presenting electrolyte, radiographic, and operative variables on 2 outcome variables (postoperative emesis and time to goal feeds). Time to goal feeds was defined as the time the first ad libitum feed was given, not the time of discharge. Strength of correlation was tested for significance with a P value for each correlation score. Significance is defined as a $P \leq .01$. To assure validity of the outcome variable of time to goal feeds, we tested all variables against time to initial feeds to assure the feeds were started in a similar time for all patients independent of the tested variables.

2. Results

In this population of 200 patients, mean age and weight of the population was 5.3 ± 2.3 weeks and 4.0 ± 0.8 kg, respectively. Mean operating time was 19.5 ± 7.3 minutes. Mean number of emesis was 2.2 ± 2.7 , and time to goal feeds was 20.2 ± 13.3 hours. Emesis occurred at least once in 128 patients or 64% of the population. The remaining demographic and results by group are reported [1].

Correlation scores between the tested variables and outcomes are listed with P values in Table 1. A significant correlation to the number of episodes of postoperative emesis was seen with chloride, potassium, and anion gap. This was an inverse correlation for chloride and potassium, whereas there was direct correlation with anion gap. These 3 variables also held significant correlation with time to goal feeds. In addition, weight on admission held significant inverse correlation to postoperative emesis and time to goal feeds. Strong significance was not detected in the correlation to outcomes for age, sex, sodium, bicarbonate, pyloric thickness, pyloric length, operative approach, or operating time.

There was no correlation with any variable and time to initial feed. The strongest correlation with any variable and time to initial feed was sex ($P = .13$), whereas the P value for the remaining variables was at least .43.

Correlation to the presence or absence of emesis (emesis = 1, no emesis = 0) showed similar trends but were not as strong as for the number of episodes of emesis and time to goal feeds. Weight on admission held a marginal inverse correlation to the presence of emesis that was not significant ($P = .06$). Potassium level on admission did as well ($P = .03$). Chloride and bicarbonate held significant correlation with presence of emesis with P values of .005 and .002, respectively. This correlation was inverse for chloride and direct for bicarbonate. The remaining variables had no significant correlation.

3. Discussion

Emesis after pyloromyotomy is the most common postoperative issue for patients with pyloric stenosis. Within the literature, considerable attention has been given to the feeding regimen after pyloromyotomy in attempt to attenuate this problem [2–10]. Several groups have advocated ad libitum feeding after without standardized steps of feeding advancement [2–5]. These advocates have shown that emesis will occur regardless of the regimen and thus simply allowing the infant to attempt feeding when awake and alert is simple and possibly more efficient [2–4]. Most recently, retrospective analysis found ad libitum feeding compared to a standardized advancing regimen revealed no difference in number of episodes of emesis [2]. Although the authors concluded significantly shorter time to goal feeds with the ad libitum feeds, this was not clinically meaningful as the means were separated by 4 hours. Previously, authors have suggested from retrospective data that a prolonged interval before initiating feeds results in fewer patients who vomit [6]. However, the fasting interval was 12 hours, which is obviously excessive given the fact that goal feeds can be reached within 20 hours as has been shown by several institutions who initiate early feeds [1–3]. Other authors have reported that feeding sooner than a prolonged interval may result in more emesis but that this does not affect time to recovery [7]. The major issue with these feeding regimen studies is that they are retrospective that may not only influence data points such as emesis but will also invariably be influenced by comparisons between surgeons or periods of time.

There are currently no data to illuminate which patients are more likely to have problematic emesis after the operation. If that population can be defined, then a study can be conducted on feeding regimen that uses only patients who are likely to show a difference and exclude those patients who were not likely to vomit regardless of feeding schedule and thus blur differences that may exist.

This prospective dataset of a homogenous population whose postoperative management was controlled and equal allows us to address the question at hand—are there any features on presentation with pyloric stenosis that will predict outcome?

In the results of the prospective study, we found that time to goal feeds was not different between approaches ($P = .43$); therefore, there is no benefit in dividing this population in half to have 2 separate measurements with half the detection power in each [1]. The operative approach did hold a correlation that reached traditional significance in number of episodes of emesis ($P = .04$) as reported in the trial [1]. However, with no difference in time to goal feeds the approach does not appear to influence the presence of pathologic or prolonged emesis. Operative approach is certainly the only parameter of the operative variables that appears to have any affect on emesis after the operation.

The reason this study uses a smaller α in the determination of significance is 2-fold. The first is that there were more than 20 total comparisons, so it would be imprudent to accept a 1 in 20 chance ($\alpha = .05$) of declaring a significant finding where there is not one. It is therefore prudent to move the significance level such that the fraction determining chance of a type 1 error has a denominator greater than the total number of tests run. The second reason is that we are not making direct comparisons between 2 groups to see if they are different but simply identifying the strength of correlation. In this dataset, several variables were on a different level of magnitude from those variables around the 0.05 range. All data are expressed in Table 1 for individual interpretation.

Data resulting from regression statistics should be viewed with the caution that correlation does not imply causation. A high correlation between 2 variables does not represent adequate evidence that changing one variable has resulted, or may result, from changes of other variables. In this case, variables with disparately stronger correlation than the others uniformly represent markers for the same phenomenon, which is the degree of physiologic perturbation created from chronic emesis. The severity of hypokalemic, hypochloremic, metabolic alkalosis was highly predictive of more severe postoperative emesis. This syndrome is not a depiction of severity of acute dehydration but the duration of emesis, as these electrolyte shifts progress with time from renal compensation. Along the same line, lower weight on admission was highly predictive of both more emesis and longer time to goal feeds when age held only a marginally inverse correlation with emesis and no correlation with time to goal feeds. After resuscitation, the new weight held marginal inverse correlation to both outcomes, which is consistent with the length of illness predicting recovery after pyloromyotomy. Altogether, those patients with longer and more complete obstruction have more severe electrolyte derangement, present with lower weight, and it is this population that will have more emesis after pyloromyotomy resulting in a prolonged time to goal feeds. The actual cause may be gastric muscle memory from chronic emesis, or it may be an unmeasured variable such as the degree of gastritis that should be linear with length of emesis.

The predictive values of the variables associated with dehydration are not as strong for the presence or absence of emesis because emesis is such a common event. We therefore suggest that the degree of perturbation in the variables consequent to dehydration predict more emesis episodes, which will influence the time to goal feeds more so than which patients will have emesis.

An important limitation of this model that requires illumination to put the data in context is strength of influence. The association between variables of chronic dehydration and postoperative emesis in this study is undeniable; however, the strength of influence is not clarified. The square of a given R score (R^2) is termed the coefficient of determination, which roughly estimates the percentage of variability seen in emesis that can be accounted for by a single electrolyte. Using this, the degree of influence would seem small for each individual variable. The low P values seen for each variable of dehydration are the result of a high degree of consistency, not necessarily a high degree of magnitude. However, because each individual parameter is likely not causal but the effect of a separate, common cause, the cumulative influence of these variables deserves consideration. An example to address the clinical effect in a tangible manner is that the mean number of emesis in patients with a gap less than 13 was 1.97 compared to 3.26 in patients with a gap of 13 or greater. These are the numbers are being used to design a trial on patients with severe electrolyte derangement to definitively show if feeding regimen or fasting interval influences amount of emesis after pyloromyotomy.

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Table 1

Correlation between all measured parameters and the outcome measures

Parameter	Episodes of emesis		Time to goal feeds	
	Correlation (R score)	P	Correlation (R score)	P
Age	-0.13	.06	-0.05	.48
Sex (male = 1, female = 0)	-0.004	.95	-0.01	.19
Admission weight	-0.22	.002	-0.19	.008
Operation weight	-0.17	.04	-0.15	.06
Sodium	0.05	.49	0.04	.58
Bicarbonate	0.13	.07	0.14	.05
Potassium	-0.22	.002	-0.23	<.001
Chloride	-0.20	.004	-0.17	.01
Anion gap	0.24	.001	0.17	.01
Pyloric length	0.01	.26	-0.001	.99
Pyloric thickness	-0.11	.12	-0.11	.12
Operative time	0.08	.25	0.04	.55
Operative approach (laparoscopic = 1, open = 0)	-0.14	.04	-0.06	.39