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How to predict oral rehydration failure in children with gastroenteritis.

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Abbreviations.

AGE Acute gastroenteritis

CDS Clinical dehydration scale

CRT Capillary refill time

ED Emergency department

MTS Manchester triage system

ORS Oral rehydration solution

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Abstract

Objectives: Oral rehydration is the standard in most current guidelines for young children with acute gastroenteritis (AGE). Failure of oral rehydration can complicate the disease course, leading to morbidity due to severe dehydration. We aimed to identify prognostic factors of oral rehydration failure in children with AGE.

Methods: *Design* A prospective, observational study.

Setting Emergency department (ED), Erasmus Medical Centre, Rotterdam, The Netherlands, 2010- 2012.

Patients 802 previously healthy children, aged 1 month-5 years with AGE.

Outcome Failure of oral rehydration was defined by secondary rehydration by a nasogastric tube, or hospitalisation or revisit for dehydration within 72 hours after initial ED visit.

Results: We observed 167 (21%) failures of oral rehydration in a population of 802 children with AGE (median 1.03 years old, IQR 0.4-2.1; 60% male). In multivariate logistic regression analysis, independent predictors for failure of oral rehydration were a higher Manchester Triage Urgency (MTS) level, abnormal capillary refill time (CRT) and a higher clinical dehydration scale (CDS) score.

Conclusion: Early recognition of young children with AGE at risk of failure of oral rehydration therapy is important, as emphasized by the 21% therapy failure in our population. Associated with oral rehydration failure are higher MTS urgency level, abnormal CRT and a higher CDS score.

Key words: Acute Gastro-enteritis, Children, Emergency department

Abbreviations.

AGE Acute gastroenteritis

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What is known

- Oral rehydration is current standard in most guidelines for young children with acute gastroenteritis.
- Failure of oral rehydration can complicate the disease course, leading to morbidity due to severe dehydration and hypovolemic shock.

What this study adds

- The importance of early recognition of failure of oral rehydration is emphasized by the 21 % therapy failure in our western population.
- Special attention should be directed to patients with high Manchester Triage System urgency level, abnormal capillary refill time or higher clinical dehydration score.

Introduction

Acute gastroenteritis (AGE) frequently occurs in young children. The highest incidence occurs in children 1-4 years of age, with norovirus and rotavirus as the most common causes. Every year in Europe, among 23.6 million children under the age of five years, approximately 3.6 million rotavirus-related AGE episodes occur, leading to more than 87,000 children being hospitalized and almost 700,000 children visiting the outpatient clinic.(1) Oral rehydration using oral rehydration solution (ORS) is the standard therapy in the current European guidelines for young children with AGE. (2-4) In developed countries most patients have mild dehydration and the disease course is usually uncomplicated. However, even in mildly dehydrated children, treatment failure due to frequent vomiting and diarrhea, lack of sufficient intake or a combination of both, can complicate the disease course, with potential severe dehydration or even hypovolemic shock. Although rare, severe dehydration due to treatment failure explains why AGE is in the top 10 of diagnoses of malpractice claims in children.(5, 6) Early identification of children at risk for severe dehydration may reduce morbidity.

We aimed to identify prognostic factors of failure of oral rehydration in patients younger than 5 years of age with mild or moderate dehydration due to AGE, after attending the emergency department (ED).

Methods

Design

We conducted a prospective, observational study on AGE in children attending the ED. (7, 8) Ethical approval for this study was obtained by the institutional review board (IRB) of the Erasmus MC. Informed consent was required and obtained from all parents (MEC-2008-071; MEC- 2005-314).

Outcomes and definitions

The primary outcome was failure of oral rehydration, defined as: secondary nasogastric tube rehydration in children with mild or moderate dehydration (after persistent refusal of ORS or persistent vomiting during oral rehydration), a revisit with an intervention within 72 hours after the initial ED visit or (secondary) hospitalisation. According to our previous study, a revisit with intervention was defined as secondary oral or nasogastric rehydration treatment at ED, performance of diagnostic laboratory tests and/ or hospitalisation. (8)

As viral AGE is the most common cause of acute vomiting or diarrhea in healthy children under the age of 5 years, AGE was defined as acute infectious related vomiting and/or diarrhea in paediatric patients admitted to the ED, lasting less than 7 days, with a symptom-free period of two weeks before.(9, 10) Our definition was previously used (7) and only differs from ESPGHAN guideline (3) not including vomit and/ or stool frequency. Although frequency of evacuations was not part of the definition we think this selection reflects the ED population of children at risk for dehydration at the ED. Moreover, “change in stool consistency is more indicative of diarrhea than stool number, particularly in the first months of life.”. (3)

The clinical dehydration scale (CDS) is based on the items general appearance, mucous membranes, eyes and tears.(11) As these items were recorded in a dichotomised way, every item showed a normal (0 points) or an abnormal (2 points) value, added up to a total CDS (max 8 points).

A capillary refill time (CRT) of three seconds or more was defined as prolonged.(12)

Patients and setting

Previously healthy children 1 month- 5 years of age with acute vomiting and/ or diarrhea were consecutively included at the ED of the Sophia Children's Hospital. This is an innercity paediatric university hospital, with 7000 children attending the ED annually. About 35 % of the children presenting with infectious causes at the ED suffer from chronic co-morbidity.(13)

We included children, suspected of AGE based on the complaint of vomiting and/or diarrhea at presentation at the ED. (3)

We excluded children with chronic diarrhea (> 7 days), children suspected of a paediatric surgical disease or trauma and children with vomiting due to another infectious disease, such as urinary tract infection or pneumonia. Also excluded were children with complex chronic conditions, such as congenital heart disease, renal failure, metabolic disease and chronically ill children with complex needs.

Data collection

We collected data on age, gender, MTS urgency level, vital signs, data on vomiting and diarrhea, as well as data on referral, discharge and follow-up. Data were prospectively collected from a structured electronic patient record system from May 1st 2010 till Dec 1st 2012. (14)

In practice, the nurse assigned the child to a triage urgency level according to the Manchester Triage system (MTS)(15), indicating the patients appropriate maximum waiting time of respectively 120 minutes (level: non urgent), 90 minutes (level: standard), 30 minutes (level: urgent), 10 minutes (level: very urgent) or 0 minutes (level: emergent, indicating immediate treatment). Then, the nurse assessed the clinical condition of the child and registered signs and symptoms for dehydration.

All patients were evaluated and treated by the attending physician within the time frame allocated by the MTS. As the study was performed in a tertiary teaching hospital, the attending physician was a member of staff supervising a paediatric resident in all patients. In general, patients received ORS appropriate for the level of dehydration, according to the current protocol.(16) Children without clinical signs of dehydration were provided with ORS in order to inform parents on signs and symptoms of dehydration as well as at home-management, including on the preparation of ORS. In these patients other liquids (for example apple juice) were provided if ORS was refused. Patients with mild dehydration received 50 ml/kg during ED stay of about 120 minutes (median 133 minutes; IQR 94-179), patients with moderate to severe dehydration (without signs or symptoms indicating hypovolemic shock) ór persistent vomiting received (primarily) nasogastric tube rehydration 80 ml/kg ORS during 3-4 hours at the ED. Children with clinical signs of hypovolemic shock received appropriate treatment immediately, including intravenous fluid resuscitation. In these children, nasogastric tube rehydration and intravenous rehydration were considered appropriate treatment, they were not identified as treatment failure.

Telephonic follow-up after discharge was performed with standardised questionnaires three days after ED discharge and then every 24 hours until the patient was symptom-free.(8)

Statistical analysis

Based on international guidelines and reviews we focused our analyses on age, gender, MTS urgency, items of the CDS, heart rate, respiratory rate, CRT, frequent vomiting and diarrhea (Table 1) (3, 4, 18, 19). We used Chi square, Student's t test and logistic regression analysis as appropriate. Receiver operating characteristic (ROC) curves with 95% confidence interval

(95%CI) were calculated for failure- associated variables. A p-value <0.05 was considered statistically significant.

Observing missing data in mainly the CDS- related variables and data on frequency of vomiting and diarrhea (Table 2), we decided to impute these missing data in order to increase methodological validity, assuming they were missing at random. Missing data were imputed using a multiple imputation model including age, gender, MTS urgency level, vital signs, data on vomiting and diarrhea, and referral, discharge and information during follow-up. This imputation process resulted in ten databases, that were used for pooled analyses.(17) Imputation was performed by using the Design and Hmisc packages (AregImpute function) in R version 2.15.2. For the comparative analysis, the statistical Packages for the Social Sciences (SPSS) version 20.0 (Chicago, IL) was used.

Results

Of 7,061 paediatric patients visiting the ED, 1,995 had complaints of AGE. We excluded 1,080 children, predominantly because of age and co-morbidity. An additional 113 children who participated in an intervention study on standardised assessment and treatment of AGE were excluded as the intervention could influence our outcome parameter. (7)

The study population consisted of 802 children with vomiting/ diarrhea (age 1.03 years, IQR 0.4-2.1; 60% male) (Table 2). Oral rehydration therapy failed in 167 patients (21%). Twenty-nine percent of the patients with treatment failure were allocated to the MTS urgency level ‘emergent-very urgent’, compared with 12% in the non-failure category. Three quarter of children with complaints of AGE in our population were classified by 9 out of 50 MTS discriminators: fever discriminator in 25%, discriminator vomiting and diarrhea in 26%, level of

pain discriminator in 10% and the discriminator 'recent' problem in 13%. In the children with oral therapy failure, we observed age adjusted heart rate and respiratory rate above percentile 99% (18) in 342 (43%) respectively, compared with 317 (40%) in the children in the non-failure group (non-significant difference). CRT was prolonged in resp. 78 (9.7%) patients compared with 45 (7.1%) patients in the non-failure group. Highest scores of the CDS were more frequently observed in the failure group compared to the non-failures, with 1 or more abnormal dehydration score item in 21/168 patients (12.5%) in the failure group, compared with 27 /635 (4.3%) in the non-failure group. In order to be able to predict failure of oral rehydration, we calculated ROC values for these items, showing an ROC (95%CI) of resp. 0.63 (0.58-0.68) for MTS urgency, 0.58 (0.52-0.64) for CRT and 0.54 (0.49-0.59) for the CDS.

In multivariable analysis, higher MTS urgency level, prolonged CRT and the total CDS score remained significantly associated with failure of oral rehydration. (Table 3). The ROC (95%CI) for the final model, including MTS, CRT and CDS score combined was 0.68 (0.63-0.74).

The statistical analysis was performed on the imputed dataset, as well as on the original dataset, showing associations in the same direction.

Discussion

Therapy failure was observed in 167 (21%) of all patients. This emphasizes the importance of early recognition of failure of oral rehydration therapy also in western populations of children. According to several guidelines, important signs and symptoms in assessment and treatment of children with AGE are (young) age, (abnormal) vital signs, the CDS, urine output, frequency of vomiting and diarrhea and 'parents not able' (to manage rehydration therapy at home).

Complementary to former studies mostly addressing assessment and treatment of AGE, we focused on prognostic factors of oral rehydration. The strongest independent effects for rehydration failure were found for MTS, CRT and the total CDS score. The prognostic value of this final model (ROC area) was moderate, but substantially higher than the ROC areas of these separate items.

The MTS assigns patients to 5 urgency categories based on specific signs and symptoms (discriminators) in one of the 50 flowcharts representing complaints. Although the primary aim of the triage system is to differentiate the patients in need of (direct) care from those who can safely wait, in our study, the MTS triage system also identified the patients at risk of a complicated disease course.

Next, a prolonged CRT was observed in children with rehydration failure. In initial patient assessment, a prolonged CRT increases the risk of a serious illness. (19) Interpreted within the clinical context of temperature, CRT is also useful in the assessment of children with dehydration. (20) (21) In a recent meta-analysis, a prolonged CRT showed a high specificity of 89-94 % for identifying 5 % dehydration, with a wide range in sensitivity (0-94%). (12) ESPGHAN guideline 2014 described 3 best individual signs of assessment of dehydration being: CRT, abnormal skin turgor and abnormal respiratory pattern.(3) In our study, CRT showed a high specificity of 90% in particular (with substantial positive LR of 2.69 (CI95 % 2.43-2.99)), but low sensitivity of 27.2 % for failure of oral rehydration, with a negative likelihood ratio of 0.81 (CI95% 0.79-0.83). In contrast, MTS classification was characterized by a relative high sensitivity, but at the cost of a low specificity.

Last, oral children with rehydration failure showed a higher total CDS score in univariate and multivariate analysis, with an ROC curve 0.54 (CI95% 0.49-0.59). Former research on the

CDS in children with AGE at their initial ED visit showed a ROC curve 0.65 (95%CI 0.57-0.73) for hospitalization(22) compared with 0.54 (95%CI 0.49-0.59) for our definition of failure (secondary nasogastric rehydration, revisits with an intervention, hospitalization).

Strength and limitations

The strength of our study is that we performed a prospective study in a large group of previously healthy young children with AGE. We showed MTS urgency level, CRT and the CDS to be associated with oral rehydration failure. The number of children with failure of rehydration (n= 167) was sufficient for reliable evaluation of the set of potential prognostic factors for failure of rehydration. (Table 1).

Several limitations need to be addressed. We note that the CDS is a four-item, three-dimensional scale. Unfortunately, in our study, the four items were coded as dichotomous variables. Only 48 (6%) children had one or more abnormal items 38 (4.7%) patients only had one abnormal item, 9 (1.1%) patients had two abnormal items and only one patient (0.1%) had three abnormal items Although we collected dichotomised variables instead of the original 3 categories and using a different outcome definition, we showed comparable findings. Given the low number of abnormal classifications on the variables in the CDS we do not expect that dichotomization has affected our conclusions on prognostic value.

Next, we had to deal with missing values. We consider our data of sufficient quantity and quality after imputation of missing data according to a sophisticated imputation method, and outcome variables showed no missing data and were not imputed.

Clinical implications

In developed countries, severe dehydration due to AGE is rare. Although rehydration with ORS is common practice, we still observed a 21% rehydration failure in our mildly dehydrated study population. Recent studies support a more feasible approach with oral rehydration using diluted apple juice and other preferred fluids, added with ondansetron if indicated. (23) Furthermore, adequate parental instruction can make (home) oral rehydration therapy more successful, reducing oral therapy failure. (24)

Our findings should raise awareness that dehydration after ED visit still occurs, also in the developed countries. This necessitates the identification of a vulnerable patient group. Our model may contribute to this aim, as we saw that a child with a high MTS urgency level, an abnormal CRT and an abnormal CDS score at initial assessment, is more prone for therapy failure. These characteristics are available at initial presentation. If we are sure to inform parents adequate and make adequate appointments for revision (based on e.g. our observations) we may safely refrain from invasive interventions at the ED in low risk patients.

Conclusion

In our study on predominantly mildly dehydrated children, we observed a 21% failure of oral rehydration therapy. Associated with oral rehydration failure are high MTS urgency level, prolonged capillary refill time and an abnormal CDS score.

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Table 1 Risk factors according to guidelines.

	ESPGHAN 2014(3)	NICE 2009(4)	Bruel Lancet 2010(25)	NVK 2012(16)
Age	< 6 months <2 months hospital visit	<12 months (in particular <6)		< 6 months
Gender				
MTS Urgency level				
Vital signs				
Tachycardia		X		X
Abnormal breathing	X	X	X	X
Prolonged capillairy refill time	X	X	X	X
Pale/ mottled skin		X		X
Clinical signs and symptoms				
Clinical Dehydration Scale (11)	X			
General appearance/ altered mental state	X	X	X	X
Mucous membranes				
Tears				
Eyes				
Urine output	X	X		
Turgor	X			
Weight loss	X			
Vomiting during rehydration		X		X
Persistent vomiting	X	X >2/ 24 hours		X >4/ 24 hours
Diarrhea frequency	X	X >5/ 24 hours		X >8/24 hours
Other				
Etiology (ROTA/NORO +)	X			
Feeding/ stop breastfeeding		X		
Children with signs of malnutrition		X		
Co-morbidity	X	X		
Parents not able	X	X		

Table 2 Patient characteristics

	Available data ˚ N (%)	Failure ˚ N=167 (100)	Non- failure ˚ N= 635	P<0.05
Age (years)[a]	802 (100)	1.03 (0.4-2.1)	1.23 (0.5-2.5)	
Sex, male	802 (100)	100 (59.9)	352 (55.4)	
Referral	802 (100)			*
Self- referral		45 (26.8)	336 (53.0)	
Referred [#]		122 (73.1)	299 (47.0)	
MTS urgency	798 (99.5)			*
Emergent/ Very urgent		48 (28.6)	77 (12.1)	
Urgent		83 (49.7)	305 (48.0)	
Standard/ Non-urgent		36 (21.4)	249 (39.3)	
Clinical characteristics				
Heart rate (/ min) [^]	639 (79.7)	141(26)	132 (24)	*
Respiratory rate (/min) [^]	484 (60.3)	39(12)	34 (11)	*
Temperature (˚C) [a]	763 (95.1)	37.5 (37.0-38.6)	37.8 (35.4-41.0)	
Capillary refill time	609 (75.9)			*
Normal		97 (58.1)	434 (68.5)	
Prolonged		33 (19.8)	45(7.1)	
Missing		37 (22.2)	156 (24.6)	
Symptoms				
Vomiting frequency	478 (59.6)			
None		11 (6.6)	53 (8.3)	
≤4 times/ day		66 (39.5)	229 (36.1)	
> 4 times/ day		30 (18.0)	89 (14.0)	
Diarrhea frequency	406 (50.6)			
None		36 (59.9)	124 (19.5)	
≤ 8 times per day		45 (26.9)	186 (29.3)	
>8 times per day		3 (1.8)	12 (1.9)	

Clinical Dehydration Scale				
Consciousness	376 (46.9)			
Well		79 (47.3)	572 (90.2)	
Abnormal		2 (1.2)	1 (0.2)	
Mucous membranes	468 (58.4)			*
Moist		77 (46.1)	363 (57.2)	
Dry		13 (7.8)	15 (2.4)	
Eyes	294 (36.7)			
Normal		40 (24.0)	248 (39.1)	
Sunken		3 (1.8)	3 (0.5)	
Tears	420 (52.4)			*
Normal		61 (36.5)	337 (53.1)	
Decreased		10 (6.0)	12 (1.9)	
Dehydration scale total [a]	271 (33.8)	0.0 (0-0)	0.0 (0-0)	*
Score 0 (0 abnormal items)		148 (88.6)	609 (95.9)	
Score 2 (1 abnormal item)		13 (7.8)	22 (3.5)	
Score 4 (2 abnormal items)		5 (3.0)	4 (0.6)	
Score 6 (3 abnormal items)		1 (0.6)	0	
Score 8 (4 abnormal items)		0	0	
Failure of oral rehydration	802 (100)			
Nasogastric tube		2 (1.2)	NA	
Revisits		46 (27.5)	NA	
Hospitalisation		120 (71.9)	NA	

Absolute number (percentage)
[a] Median (IQR)
[^] Mean (SD)
[#] Others' include secondary care and after telephone contact

Table 3 Characteristics of patients with failure of oral rehydration treatment.

Variables		Univariable OR(95%CI)	P	Multivariable OR(95%CI)	P	ROC (95%CI)
Age (per year)		0.89 (0.78-1.02)	NS			
Gender (male)		1.20 (0.85-1.70)	NS			
MTS urgency						0.63 (0.58-0.68)
MTS Standard/ Non urgent		Ref				
MTS Urgent		1.89 (1.23- 2.89)	<0.05	1.83 (1.15-2.92)	<0.05	
MTS Emergent/ very urgent		4.32 (2.62- 7.14)	<0.05	3.97 (2.21-7.12)	<0.05	
Age- adjusted vital signs (18)						
Heart rate	≤ p25	Ref	NS			
	p25	0.64 (0.13-3.26)				
	p50	0.38 (0.06-2.22)				
	p75	1.29 (0.35-4.84)				
	p90	1.17 (0.37-3.69)				
	≥ *p99*	1.88 (0.61-5.78)				
Respiratory rate	≤ p25	Ref	NS			
	p25	4.2 (0.88-20.45)				
	p50	2.45 (0.74-8.0)				
	p75	2.66 (0.40-17.50)				
	p90	2.36 (0.71-7.88)				
	≥ *p99*	3.60 (1.24-10.39)				
Capillary refill time (CRT)						0.58 (0.52-0.64)
Normal		Ref				
Abnormal		3.21 (2.02- 5.09)	<0.05	2.26 (1.35- 3.78)	<0.05	
Vomiting						
None		Ref				
≤ *4 /day*		1.3 (0.82- 2.07)	NS			
>*4 / day*		NA				
Diarrhea						
None		Ref				
≤ *8 /day*		1.02 (0.45- 2.32)	NS			
>*8 / day*		NA				
Dehydration scale total		1.14(1.04-1.27)	<0.05	2.54 (1.30-4.98)	<0.05	0.54 (0.49-0.59)
Model MTS CRT CDS-total						0.68 (0.63-0.74)

[x] Only the category heart rate ≥ p99 showed a significant association.

Abbreviations: CI, confidence interval; OR, odds ratio; P, p-value; NS, not significant; NA, not applicable.