Comparison of nasogastric and intravenous methods of rehydration in pediatric patients with acute dehydration

Nager A L, Wang V J

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study compared the administration of rapid nasogastric hydration (RNG) with standard oral rehydration solution and rapid intravenous hydration (RIV) with normal saline, in the treatment of young children suffering with uncomplicated, acute moderate dehydration.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children aged 3 to 36 months who had acute complaints of vomiting and/or had diarrhoea, and who were determined (using certain criteria) to be dehydrated. This was presumed to result from gastroenteritis. These children were unable to tolerate oral fluids sufficiently to overcome their dehydration. Patients were excluded if they were severely dehydrated (>10%), had intractable vomiting or shock, suspected intussusception, appendicitis, malrotation, recent trauma, meningitis or congestive heart failure, or if evidence of these diagnoses appeared as the study progressed. Patients were also excluded if they had what was defined as a significant chronic disease (e.g. lung disease, renal insufficiency, and heart failure).

Setting
The setting was an institution. The economic study was carried out in Los Angeles, USA.

Dates to which data relate
The effectiveness data were collected between October 1997 and March 1999. Although not explicitly reported, it is assumed that prices of the different arms of treatment were collected at the same time.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were performed. These demonstrated that, when 44 participants were
enrolled in each of the groups, a difference in failure rates of 20% or more would reveal an 80% chance of being detected, at an alpha of 0.05 (one-sided level of significance). A convenience sample was selected from the 475 patients who presented to the ED with uncomplicated dehydration. Of the 96 patients that met the study criteria, one withdrew when found to have intussusception, three were excluded during the study period as they had severe, intractable vomiting, and two were excluded due to severe dehydration. The remaining 90 patients were distributed among the RNG (n=46) and RIV (n =44) groups.

Study design
This was a prospective, randomised controlled study that was carried out in a single centre. No details were provided on the unit or method of randomisation. The patients randomised to RNG hydration underwent placement of a flexible, silastic, 5 French feeding tube, after the application of Cetacaine spray/gel to the nose and throat. These patients received a continuous nasogastric infusion of 50 mL/kg of Pedialyte over a 3-hour period. The patients randomised to the RIV arm received a continuous infusion of 50 mL/kg of normal saline IV over a 3-hour period, after placement of a 22- or 24- gauge IV catheter. The patients were discharged or hospitalised for 24 hours. A chart review was undertaken for the hospitalised patients, while a telephone follow-up with standard questionnaires was conducted approximately 24 hours after discharge. All of the patients were discharged and the follow-up rate was 90% for both groups. There was no mention of any blinding.

Analysis of effectiveness
The basis for the analysis of the clinical study (intention to treat or treatment completers only) was not stated, but was implied to have been intention to treat. The primary outcomes were the safety, efficacy and tolerance of the rehydration process, and the durability of the treatment effect within 24 hours of discharge. To assess these outcomes, the per case failure rate of the technology (complications), fluid therapy complications, pulse levels and other vital signs (temperature, respiratory rate, blood pressure), were measured. Complications were related to tube/catheter placement, emesis for RNG, multiple attempts at placement, extravasation of IV fluids into the subcutaneous tissue, and inadvertent dispersion.

The patients were weighed and tested for hypoglycaemia, and laboratory studies of blood and urine samples were carried out before and after treatment. The groups were similar in terms of gender, ethnic self identification, number and duration of symptoms, episodes of vomiting or diarrhoea, absence or presence of tearing or abnormal capillary refill time, and their ultimate diagnoses (92% were attributable to viral gastroenteritis). However, the study groups differed in respect to their mean age, which was 13 months in the RNG group versus 16 months in the RIV group, (p=0.02).

Effectiveness results
In terms of efficacy and patient tolerance, tube placement failed in 2 patients (4.3% mean per case failure) in the RNG group, whereas catheterisation failed frequently in the RIV group and required 27 additional attempts (61.4% mean per case failure rate), (p<0.001).

There were no statistically significant differences in other vital signs, either before, during or after therapy.

For most of the laboratory tests studied there were statistically significant, but clinically insignificant, differences between the study groups.

In terms of the durability of the treatment effect, all of the patients were discharged from hospital. There was no statistically significant difference between the two groups as well as those that returned to the ED.

Clinical conclusions
RNG hydration may be safely and effectively used in children suffering from moderate dehydration caused by the acute symptoms of vomiting and/or diarrhoea, which is presumed to result from gastroenteritis. RNG is as efficacious as RIV and is associated with fewer complications.
Measure of benefits used in the economic analysis
There was no summary measure of benefit. The study was, therefore, a cost-consequences analysis.

Direct costs
No discounting was carried out as the costs were for one day. The resource quantities and the unit prices were not reported separately. The costs were reported as averages per patient and also as totals. The costs were estimated from actual data. The aggregate and per patient costs for laboratories, supplies and nursing time were assessed from the hospital’s usual charge basis for both treatment arms. The study was based on a provider perspective. The date when the quantity of resources was measured was not explicitly stated, and neither was the price year. The authors included all the costs of the treatment arms, even those that were considered to be similar such as necessary laboratory charges, supplies and nursing time.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
The indirect costs were not considered since the study adopted a provider perspective.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was undertaken.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
Only point estimates were reported. The total applicable cost per case was $642.64 for the RIV group and $525.90 for the RGN. This represented a cost-saving of $116.74 (18.2%) over the RIV group.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
Administering oral replacement therapy by rapid nasogastric hydration (RNG) in the emergency department (ED) was well tolerated. It was associated with no greater failure rates than oral replacement therapy generally, nor with a greater failure rate than rapid intravenous hydration (RIV). The authors considered urine specific gravity to be the best indicator of dehydration. Based on their findings, the authors concluded that RNG may provide, overall, a higher quality of rehydration than RIV in the same setting. In addition, both methods succeeded in reducing the need for hospitalisation with acceptable outcomes. The authors also concluded that the use of RNG results in significant cost-savings in comparison with RIV and standard IV therapy. Most routine laboratory testing is of little value in these patients and should be avoided, except when clinically indicated.
**CRD COMMENTARY - Selection of comparators**

The comparator was justified on the grounds that it was the standard practise. You should consider whether this is a widely used health technology your own setting.

**Validity of estimate of measure of effectiveness**

The study used a prospective, randomised controlled design, which was appropriate for the study question. The study sample was a convenience sample reflecting the specific indications for inclusion in the trial. There was no significant difference in most baseline characteristics. However, the patient groups were shown to have some significant difference with respect to age. There was no evidence of blinding.

**Validity of estimate of measure of benefit**

There was no summary measure of benefits (see comments under 'Validity of estimate of measure of effectiveness').

**Validity of estimate of costs**

All the categories of cost relevant to the provider perspective appear to have been included in the analysis. Since all the costs were incurred during less than two years, discounting was not necessary. No statistical or sensitivity analyses were carried out for either the quantities or the costs.

**Other issues**

The authors made appropriate comparisons of their effectiveness findings with those from other studies. The issue of generalisability to other settings was not addressed, but the authors reported a number of limitations to their study. This included the fact that determining the weights of the patients was problematic since they were young children. The authors acknowledged the fact that the ultimate diagnosis was not uniform and justified their choice to carry out specific tests. They also indicated that the results may have been influenced by the solutes that participants were given. Also, not all of the patients were contacted in the follow-up questionnaire and, as the authors acknowledged, the patients could have sought additional treatment elsewhere. The authors did not present their results selectively and their conclusions reflect the scope of the analysis.

**Implications of the study**

The authors found that most routine laboratory testing was of little value and recommended that it should be avoided, except when clearly clinically indicated. The authors recommend that RNG may be used in place of RIV in the ED or possibly in an alternative "well-equipped" outpatient setting. Further investigations might consider obtaining a non-stick baseline weight (such as from a well-child visit) and a post-treatment weight when the child is symptom free and well hydrated, along with recorded losses, in order to assess dehydration and clinical improvement more accurately.

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