

PROSPECTIVE OBSERVATIONAL STUDY ON ADULTS WITH ACUTE DIARRHOEA TREATED WITH GELATIN TANNATE®

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RATIONALE AND OBJECTIVES

The main treatment for acute diarrhoea is oral rehydration to replace fluid and electrolytes.

Gelatin Tannate is a safe and effective treatment, supplementary to rehydration, in adults and children and infants.

The **primary objective of this study** is to observe how the acute diarrhoea has progressed at 12 h in adults treated with Gelatin Tannate.

METHODS

Multicentre, prospective, observational study. The information for the study was gathered in Health Centres in Almería. The maximum patient inclusion time was 4 months (between March and June, 2006).

•**Primary endpoints of the study:** Number and characteristics of bowel movements, patient weight, presence of vomiting and presence of fever. The criteria for effectiveness in this analysis is improvement of the diarrhoea and associated symptoms at 12 hours.

•**Patient selection:**

Inclusion criteria: Three or more watery stools a day with onset within previous 72 hours.

Exclusion criteria: Patients with chronic diarrhoea, immunosuppression, weight 20% or more below standard, systemic disease or the taking of anti-diarrhoea agents and/or antibiotics prior to inclusion.

•**Statistical tests:** The McNemar and Wilcoxon non-parametric tests were used for the statistical analysis. The T-test for paired data was used in the parametric bivariate contrasts.

RESULTS

Data were obtained on a total of 64 patients. 54 patients met the inclusion criteria and none of the exclusion criteria and were considered for the statistical analysis.

•**Descriptive and comparative analysis of the population**

The gender distribution was equal (50%, N=44) with an average age of 33 (33.5; SD= 9.3; Median=31.2). Acute diarrhoea was the main problem in 39 of 54 patients (72.2%, N=39) and almost half of the patients' (44.4%, N=24) general condition was affected (ECOG=1).

Table 1 shows the primary endpoints of the study at baseline and at 12 h. Figures 1-5 illustrate the main differences found.

| TABLE 1 | Baseline % (N total) | 12 hours % (N total) | p-value |
|---|-------------------------|-------------------------|---------|
| Number of bowel movements (≥ 4 bowel movements) | 85.2% (54) | 0.0% (45) | p<0.001 |
| Characteristics of the stools | (54) | (23) | N.A. |
| Watery | 100.0% | 0.0% | |
| Soft | 0.0% | 39.1% | |
| Normal | 0.0% | 60.9% | |
| Vomiting | 50.0% (54) | 2.3% (44) | p<0.001 |
| Dehydration | 9.6% (52) | 0.0% (3) | |
| Bloody diarrhoea | 15.4% (52) | 0.0% (45) | p=0.125 |
| No signs of peritonitis/sepsis | 100% (54) | 100% (51) | |
| | Mean \pm SD (N total) | Mean \pm SD (N total) | p-value |
| Temperature (°C) | 37.5 \pm 0.95 (54) | 36.4 \pm 0.31 (45) | p<0.001 |
| Weight (kg) | 70.8 \pm 9.9 (54) | 69.5 \pm 9.5 (41) | p=0.811 |

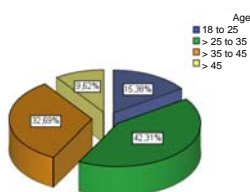


FIG. 1. DISTRIBUTION OF THE POPULATION BY AGE

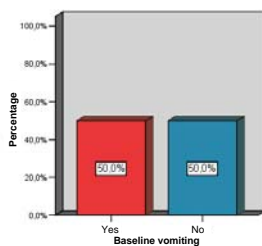


FIG. 3. PRESENCE OF VOMITING: BASELINE VS 12 H

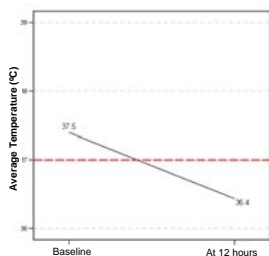
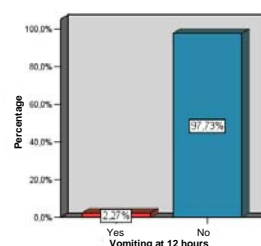


FIG. 2. TEMPERATURE: BASELINE VS 12 H

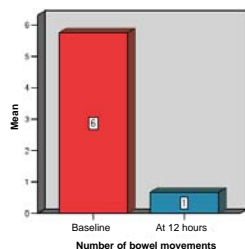


FIG. 4. NUMBER OF BOWEL MOVEMENTS: BASELINE VS 12 H

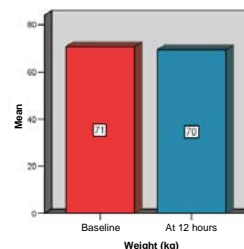


FIG. 5. PATIENT WEIGHT: BASELINE VS 12 H

CONCLUSIONS

•**The average number of bowel movements** reduced from 85.2% of patients (N=54) presenting more than four at baseline to none with more than four at 12 hours (N=45).

•**The consistency of the stools** progressed from being watery in 100% of the cases at baseline (N=54) to a soft consistency (39.1%) or normal (60.9%) at 12 hours (N=23). 15.4% of the patients (N=52) had **bloody diarrhoea** at baseline, but in all cases this had completely disappeared at 12 hours (N=45).

•In the first few hours after onset of the diarrhoea, 50% of the patients had **episodes of vomiting** (N= 54) while after 12 hours of treatment, only 2.3% of patients were continuing to vomit (N=44).

•**Body temperature reduced by 1.1°C** after 12 hours of treatment, passing back below the fever threshold to normal.

•**After 12 hours of treatment with oral rehydration and Gelatin Tannate, the diarrhoea in the adult patients had improved significantly.**