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TABLE I–*Factors Associated with Low Birth Weight.*

Factors		Number*	LBW	Percentage
Maternal age	≤ 18 yrs	57	41	71.9
	> 18 yrs	243	136	56
Maternal education	upto middle school	186	114	61.3
High school and Higher		114	63	55.3
Socioeconomic status	Lower	193	115	59.6
(Kuppu Swamy)	Middle	105	60	57.1
Higher		Sample Inadequate		
Sex	Male	210	112	53.3
Female		90	65	72.2
Gestational age	term	227	109	48
preterm		73	68	932
Iron-Folic acid supplementation	Yes	152	83	54.6
	No	148	94	63.5
Antenatal visits	≥3	108	64	59.3
	<3	83	51	61.4
	None	109	62	56.9

* out of 300 total cases.

Racecadotril in Acute Diarrhea

A recent editorial review [1] concisely yet comprehensively summarizes the main properties and advantages of racecadotril, the first purely intestinal antisecretory drug. Nevertheless, some points raised by the author need clarification.

The results of a study by Cezard, *et al*. were questioned because (1) "collection of stool uncontaminated by urine is difficult in girls", (2) a larger number of patients were withdrawn from the racecadotril group for trial deviation. In fact (*a*) this study was conducted in a University Hospital Center greatly experienced in infant stool collection, (*b*) both, boys and girls, were treated and the sex ratio was similar in the placebo group, (*c*) patient withdrawal had no statistical consequence since "intention-to-treat" and "per-protocol" analysis led to similar results.

The opinion that "There was no study to evaluate adverse effect - possibly rebound - after the drug has been discontinued" should be revised: in several studies, monitoring for adverse effects was conducted for 5-10 days whereas diarrhoea (and therefore treatment) lasted 2-3 days and no rebound or adverse effect were reported.

The concern about a multi center trial for

which "we are unable to locate a publication discussing the results"[1] can be addressed. The study was conducted by a multinational company distinct from the French company in which the drug was discovered and developed and its design allowed to assess safety rather than efficacy of racecadotril. Thus, whereas the former studies were performed in a limited number of centres in a single country, during a single period, *i.e.*, under conditions likely to ensure homogeneity in geographical and epidemiological terms, the study in question was performed in 24 centers from 16 different countries scattered in Latin America and Asia, each center providing a small number of cases. Hence, the design and the inherently difficult monitoring of the study led to a large number of missing data and heterogeneity of available ones. These drawbacks did not allow publication of the study in a decent journal. Nevertheless, the study was provided to health authorities and was considered as a safety study (excellent on this parameter).

As a conclusion, we would like to mention that a number of expert groups have recently underlined the interest of racecadotril in the management of acute diarrhea(2-5).

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Reply

We thank the authors for their response to our editorial. Our key concern remains mainly with regard to non-publication of medical trials, the imprecise assessment of effect size in clinical treats of relatively small sample size, and the concern related to sometimes the blurred line between investigations and business interests. There is potential for bias to influence even expert groups, when such groups are promoted and created by industry. We mean no disrespect to the investigators in question, but the issues we raised are those that have in the recent past, received attention in the best scientific journals.

Our condition remains that benefit of this drug for treatment of acute diarrhea has not been documented to an extent and in a manner that is required minimally to recommend its use.

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