

## **"Greedy/hungry" Infants**

### ***Observational study on the impact of a change in dietary care***

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**"Greedy" infants are defined subjectively, either they ingest too much daily milk or cry due to excessive hunger when the ingested volumes are limited. At present, few studies have focused on these infants. Due to excessive meal volumes and/or the early addition of infant cereals intended to satisfy their appetite and, as a result, an excessive weight gain during the first months, this population of infants may develop into overweight adults.**

**In this study, the change in the casein to whey proteins ratio, quantity of lactose and lipid fraction in the composition of the formula is a modifying factor of gastric evacuation that can be used to control satiety without increasing the volume or energy density of meals for these children. Greater objectivity on weight and growth is necessary. In the meantime, this study reveals greater comfort in feeding for infants and their parents.**

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#### **STUDY SUMMARY**

The purpose of the study was to describe the characteristics of "greedy" infants aged 5 months or younger and evaluate the impact of introducing specific infant formula (Novalac Satiety®) on their clinical development (weight, number of bottle feeds, volume of milk ingested, regurgitations) and on the satisfaction of their parents.

#### **A STUDY INVOLVING 252 PAEDIATRICIANS**

A longitudinal, prospective, multi-centre, cohort follow-up study was carried out with the help of 252 private practice paediatricians from all across France between May and September 2002.

**Of the 2,251 infants included in the study, 2,008 met the inclusion criteria. The reasons for excluding infants from the study were age, over 5 months (n = 128) and a quantity of missing information that exceeded 50% (n = 35).**

Of the 2,088 infants included and analysed, 1,871 (89.6%) were seen by the participating paediatricians 1 month later.

**According to the Paediatricians, at the time of inclusion these children were never satiated (82.9%) and cried frequently (75.1%). They drank volumes of formula deemed too high (74.2%) and almost half of them had already experienced a milk change since birth.**

The following **information** was **filled in** on the infant data form: age and sex, birth weight, gestational age, height and weight of parents, existence of excessive daily milk volumes, ingestion of infant cereals, previous milk change(s), infant perceived as not being satiated, crying, stools (quantification and aspect), regurgitations (based on the 7 grades Vandenplas (1) codification), late regurgitations, weight of infant (at birth and one month before inclusion).

- **The average age** of the infants was 9 weeks; there was a majority of boys (61.0%).
- **The average birth weight** of the "greedy" infants was normal (approximately 3.3 kg for girls and 3.4 kg for boys) as was their average weight one month prior to inclusion. However, their average weight at inclusion was higher than the standard Sempé and Pédrón weight curve (Table 1), sometimes justifying the Paediatrician's decision to change milks. As for the family characteristics of the infants at the time of inclusion, their fathers had an average age

of 30 and a Body Mass Index (BMI) of 24.3 and their mothers had an average age of 28 and a BMI of 22.3 (according to the WHO classification their parents were on average not overweight) (2).

- **The volume of milk consumed was excessive** according to paediatricians for 1,550 infants (74.2% of the infants included, or 78.8% of the 1,966 infants for which the data was available). This average volume increased with the infant's age, contrary to the average number of bottle feeds per day (6.6 to 4.9 bottle feeds for infants aged 1 and 5 months, respectively).

Table 1 – Weight of Infants (in g).

Age group at inclusion	Boy					Girl				
	1 <sup>st</sup> month	2 <sup>nd</sup> month	3 <sup>rd</sup> month	4 <sup>th</sup> month	5 <sup>th</sup> month	1 <sup>st</sup> month	2 <sup>nd</sup> month	3 <sup>rd</sup> month	4 <sup>th</sup> month	5 <sup>th</sup> month
<b>At birth</b>										
Total Number	93	398	347	220	121	78	245	213	143	78
Average	3379	3408	3387	3404	3450	3344	3314	3315	3280	3259
Standard Deviation	514	454	504	493	509	488	447	456	495	463
Median	3400	3400	3390	3400	3400	3380	3290	3250	3300	3240
<b>1 month prior to Novalac Satiety</b>										
Total Number	65	370	337	225	121	52	227	203	144	75
Average	3521	3673	4439	5300	6069	3385	3511	4223	4969	5650
Standard Deviation	552	656	697	840	802	520	592	652	790	1052
Median	3500	3585	4470	5300	6100	3400	3410	4220	5005	5900
<b>At the introduction of Novalac Satiety</b>										
Total Number	98	409	351	228	123	79	254	217	150	78
Average	3990	4579	5480	6203	7030	3851	4369	5114	5878	6708
Standard Deviation	714	631	736	878	835	595	604	751	805	1047
Median	3900	4570	5500	6200	7000	3800	4350	5200	5910	6800
<b>After 1 month with Novalac Satiety</b>										
Total Number	82	380	334	210	114	71	235	206	143	76
Average	4925	5480	6247	6963	7546	4735	5202	5901	6595	7276
Standard Deviation	754	675	771	866	735	617	600	754	807	1027
Median	4865	5405	6300	6950	7600	4600	5210	5950	6600	7390

- Over half the infants included had **one bottle feed at night**, but that proportion decreased as the infants' age increased. Thus, 69.5% of the infants included in their 2<sup>nd</sup> month of life had one bottle feed at night compared to 37.5% of infants included in their 5<sup>th</sup> month of life.
- 304 infants included (14.6%) had already taken infant **cereals** since their birth and that proportion increased as the infants' age at inclusion increased (1.6%, 5.9%, 13.0%, 27.3% and 35.6% in infants aged 1, 2, 3, 4 and 5 months respectively).  
**The introduction of cereals into the diet** had been done most often during the infant's 2<sup>nd</sup> or 3<sup>rd</sup> month of life and paediatricians deemed it too early in 69.7% of cases but too excessive in only 11.8% of cases.
- 40.4% of infants had no **regurgitations at inclusion** (n = 1,051) and approximately 1/3 suffered from grade over 1 of severity of regurgitations according to the Vandenplas codification. Late regurgitations, however, only affected 1/5 of the infants included (n = 453).

- 62.5% of infants included (n = 1,305) had already **experienced a formula change since their birth** and 56.6% of them had only experienced one formula change before inclusion in the study, with disparities according to the infants' age. Thus,  $\frac{3}{4}$  of the infants included in their 1<sup>st</sup> month of life, and having already experienced a milk change, had only changed once, while almost half the infants included in their 5<sup>th</sup> month of life had already changed twice.
- On average, the infants included had 2.8 **bowel movements** per day and almost half of them had formed stools, less than a third of the infants had soft or liquid stools.
- **In total**,  $\frac{3}{4}$  of the infants included (n = 1,568) cried frequently and paediatricians considered in the end that 82.9% of the infants included (n = 1,731) were never satiated.

## RESULTS

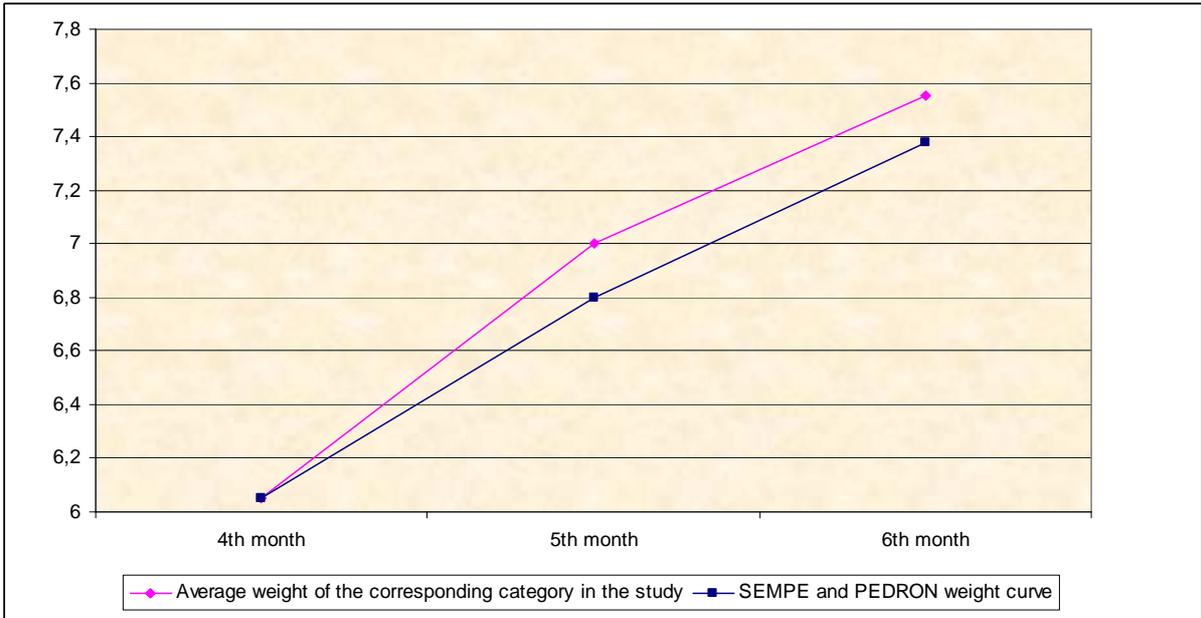
During the follow-up consultation (approximately 1 month after inclusion), the paediatrician noted the following information on the data form: volume of milk ingested over 24 hrs, regurgitations (if any), the infant's weight and the parents' degree of satisfaction.

**One month following the recommended milk change**, the following observations were made:

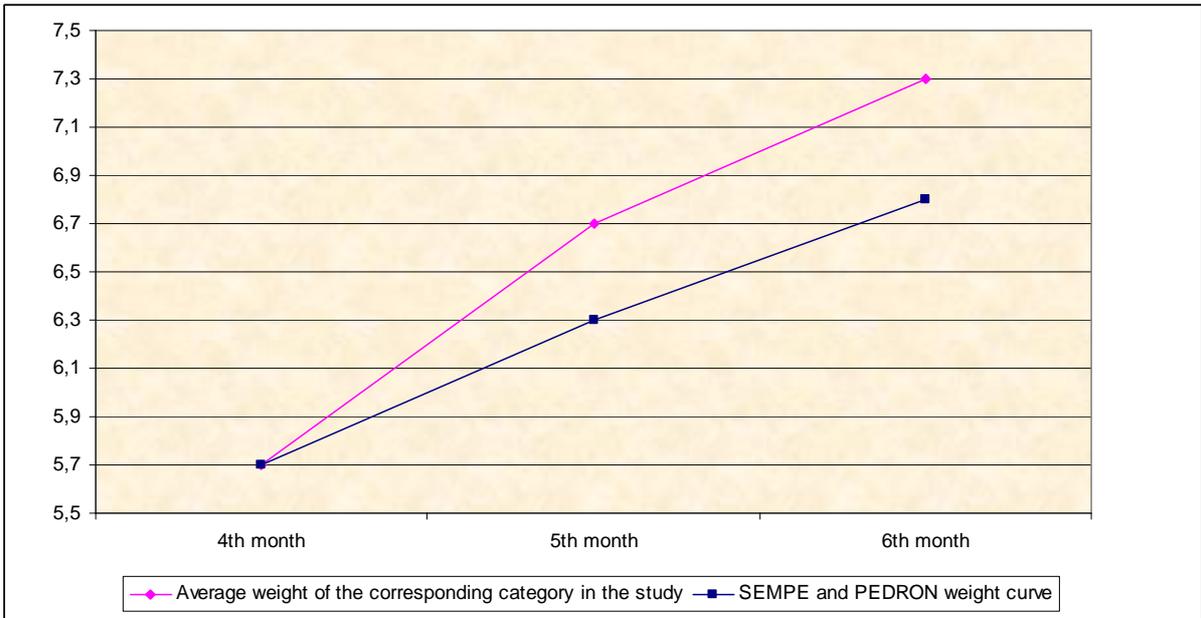
- the gap between the weight curves of the infants studied and the standard curves was narrowed (fig. 1),
- an average decrease of 89 ml in the daily milk volume,
- and a decrease in the number of infants suffering from regurgitations (from 60% to 39%).

In 88.4% of cases, the parents of the observed infants were very satisfied or satisfied 1 month following the change in their child's diet. The infants whose parents were not satisfied (4%) were distinguished by the presence of more frequent late regurgitations and soft stools at inclusion, suggesting a possible underlying pathology.

- **The volume of daily milk** ingested by the infants 1 week after the introduction of the specially designed infant formula was 807 ml on average, with an average decrease of 89 ml compared to at inclusion.
- After 1 week of feeding with the specific infant formula, **the average number of feeding bottle** was 5 per day, which, compared to inclusion, means an average daily decrease of 0.8 feeding bottle, with few disparities based on the age of the infants.
- One month after the introduction of specially designed formula, the proportion of infants who didn't **regurgitate** (grade 0 according to the Vandenplas codification) went from 40.5% to 61.3%. Infants with a regurgitation score over grade 1 now only represented 7.3% of the infants observed after 1 month instead of 26.6% before the diet change.



Boys



Girls

Figure 1: Evolution of the weight curves of infants included in their 5<sup>th</sup> month of life.

- Weight of newborn boys (Tab. 1).** Within the month following the introduction of the specific formula, if the progress of the weight remained positive, it seemed to be in relation to the age of the infant at the time of inclusion. Thus, the older the infant was at the time of inclusion, the slower their weight increased during the month following the milk change (+23.8%, + 19.9%, +14.9%, +12.6% and + 8.0% for infants aged 1, 2, 3, 4 and 5 months respectively). In total, after establishing a diet involving an infant formula specifically designed for 'greedy' infants, those same infants gained weight less quickly, with the exception of the younger infants (in their first month of life), and their weight curves become more like the standard Sempé and Pédrón curves.

- **Weight of newborn girls (Tab. 1)** The progress of weight gain in girls was very close to that of the boys. The older the infant was at the time of inclusion, the slower their weight increased within the month following the introduction of the new infant formula (+22.7%, +19.6%, +16%, +12.6% and + 8.9% for infants aged 1, 2, 3, 4 and 5 months respectively).
- **In total, 88% of parents (n = 1,678) said they were satisfied** 1 month after the new infant formula (Novalac Satiety ®) was introduced into their child’s diet (40.2% of parents were “very satisfied” and 40.0% were “satisfied”); 8.8% were moderately satisfied and only 4.3% of parents were not satisfied with this change (6.7% missing responses).  
**The infants of parents who were “very satisfied”** with the milk change were distinguished by the following characteristics at the time of inclusion: they cried much easier than most of the infants and were less often satiated despite a greater volume of milk and more bottle feeds ingested on a daily basis before the change in diet. After 1 month of feeding with the infant formula more of them did not have regurgitations (grade 0 in the Vandenplas codification).  
**The infants of “satisfied” parents** had, at the time of inclusion, fewer late regurgitations (75.7% compared to 72.3% for the overall population) and they had a higher incidence of formed stools (49.3% compared to 46.6%). The quantity of bottle feedings and stools was less significant in these infants than in the others. One month after the diet change, the children of “satisfied” parents most often had grade 1 regurgitations.

**Table 2: Characteristics of Novalac Satiety Infant formula**

Average Analysis	Novalac 1 <sup>st</sup> age		Novalac 2 <sup>nd</sup> age	
	p 100 g	p 100 ml	p 100 g	p 100 ml
<b>Energy content</b>				
kcal	516.2	67.1	501.2	65.2
kJ	2157.7	280.5	2095	272.4
Proteins (g)	12.1	1.6	15.1	2
Lipids (g)	27.4	3.7	24.8	3.2
Linolenic acid (g)	5.2	0.7	4.7	0.6
Alpha-linolenic (g)	530	68.9	470	61.1
Carbohydrates (g)	55.3	7.2	54.4	7.1
Choline (mg)	60	7.8	64	8.3
Taurine (mg)	44	5.7	-	-
L-carnitine (mg)	8	1	-	-

**Among “moderately satisfied” parents,** the BMI of the mother was slightly higher than the average BMI of all the mothers of the children included and they had fewer brothers and sisters than the others. They were most often boys (68.8% compared to 60.3%), they had more frequently experienced 3 milk changes before they were included in the study (10.6% compared to 4.6% for the whole group). After one month of feeding with the specific infant formula, 35.3% of them suffered from grade 1 regurgitations (compared to ¼ for the whole group). Furthermore, their daily milk volume remained higher after the milk change (849 ml compared to 807 for the whole group).

**For the “unsatisfied parents”,** a high proportion of the infants (36.6%) had late regurgitations; they had a higher incidence of soft stools and their daily milk volume was below average before the change in diet in relation to a below average weight at inclusion. These infants also had more frequent grade 2 regurgitations after the diet change (19.5% compared to 4.5% for the entire group). Lastly, and just as at inclusion, these infants weighed less than the average.

## DISCUSSION

**One month following the milk change, the daily milk volume decreased for all the infants regardless of age** (89 ml on average) and this was all the more true the older the infants were at inclusion. At the same time the number of bottle feedings also decreased by 12% approximately for all age groups. Furthermore, regurgitations also decreased significantly.

The introduction of specific infant formula (Novalac Satiety® which has been specifically designed to provide infants with a feeling of satiation, without increasing the ration of calories) (Tab. 2) into the diet of “greedy” infants was conveyed by a **slowdown in weight gain** for all age groups, regardless

of the sex of the infants. This slowdown was significant enough for the drop induced throughout that month to bring the weight curve of children over one month closer to that of the values of the standard weight curve.

The decrease in regurgitations and the reduction of the volume of milk consumed on a daily basis probably explain why 80% of the parents of the "greedy" infants observed were "satisfied or very satisfied" one month after their children started being fed the specific infant formula. The infants of "unsatisfied" parents had, in particular, more frequent than average late regurgitations, they had a higher incidence of soft stools; they weighed less at the time of inclusion and ingested a lower volume of milk, suggesting the possibility of underlying pathologies, including the possibility of an allergy to cow's milk proteins.

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