

Sensory Evaluation of Oral Nutritional Supplements for Clinical Practice – A Prospective, Randomized, Double-Blind Study

Avaliação Sensorial de Suplementos Nutricionais Oraís para a Prática Clínica - Um Estudo Prospectivo, Randomizado, Duplo-Cego

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ABSTRACT

Background & aims: Oral nutritional supplements (ONS) have been increasingly used by patients with difficulties to fulfill their energy/protein aims only by usual food intake. However, lack of adherence to ONS is common due to complains about palatability including flavor, texture and smell. As ONS differs in composition and palatability we aimed to assess the sensory perception in different ONS available for clinical use. **Methods:** In a double-blind approach, 201 healthy volunteers were randomly assigned into 3 groups, according the type of ONS tested (hypercaloric/normoproteic [HN], hypercaloric/hyperproteic [HH], and glucose control -specialized [DM]). All participants ingested randomly 20mL of each ONS from each specific group with an interval of 5 minutes between intakes. After each intake, they were asked to rank the taste, aroma, color and consistency of the ONS, according to a Likert scale. Furthermore, they were submitted to the Madrid scale questionnaire specific to assess the sensory perception of oral diets. Contrasts of the obtained scores for the criteria studied were tested in pairs between the supplements by the Tukey's test. **Results:** HN group – Overall, ONS-A was superior for aroma, taste, consistency and general sensory perception; while ONS-C was inferior for all studied criteria ($p < 0.05$). HH group - Overall, ONS-D was superior and ONS-C was inferior for all studied criteria ($p < 0.05$). DM group - Overall, ONS-C was significantly superior for all the criteria individually studied but not for general sensory perception, while ONS-B was significantly inferior for all the studied criteria ($p < 0.05$). **Conclusions:** There are differences in sensory order among the commercially available supplements for clinical use that may influence the adherence of patients to the nutritional treatment.

RESUMO

Introdução e objetivo: Suplementos nutricionais orais (ONS) têm sido cada vez mais utilizados por pacientes com dificuldades para atingir as necessidades energéticas / proteicas apenas pela ingestão habitual de alimentos. No entanto, a palatabilidade é uma das principais dificuldades para a falta de adesão ao ONS, que inclui sabor, textura e aroma. Tendo em vista a diferença de composição nutricional e sabor entre os ONSs, o presente estudo teve como objetivo avaliar a percepção sensorial de diferentes ONS disponíveis na prática clínica. **Métodos:** Em uma abordagem duplo-cega, 201 voluntários saudáveis foram aleatoriamente divididos em 3 grupos, de acordo com o tipo de ONS testado (hipercalórico / normoproteico [HN], hipercalórico / hiperproteico [HH] e especializado para diabetes melitus [DM]). Todos os participantes ingeriram aleatoriamente 20mL de cada ONS e de cada grupo específico com intervalo de 5 minutos entre as ingestões. Após cada ingestão, foi solicitado que eles classificassem os ONSs de acordo com sabor, aroma, cor e consistência por meio de uma escala Likert. Além disso, eles foram submetidos ao questionário específico da escala de Madrid para avaliar a percepção sensorial de dietas orais. As diferenças dos escores obtidos para os critérios estudados foram testados em pares entre os suplementos pelo teste de Tukey. **Resultados:** Em relação aos suplementos do grupo HN, o ONS-A foi superior quanto ao aroma, sabor, consistência e percepção sensorial geral; enquanto o ONS-C foi inferior para todos os critérios estudados ($p < 0,05$). Os suplementos do grupo HH, o ONS-D foi superior e o ONS-C foi inferior em todos os critérios estudados ($p < 0,05$). E os suplementos do grupo DM, o ONS-C foi significativamente superior para todos os critérios estudados individualmente, mas não para a percepção sensorial geral, enquanto o ONS-B foi significativamente inferior para todos os critérios estudados ($p < 0,05$). **Conclusões:** Existem diferenças na ordem sensorial entre os suplementos comercialmente disponíveis para uso clínico que podem influenciar a adesão dos pacientes ao tratamento nutricional.

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INTRODUCTION

Nutritional therapy (NT) aids in preventing malnutrition-associated adverse outcomes, such as infection, impaired wound healing, longer hospital stay, and mortality¹. Oral feeding should be the first-choice intervention for hospitalized patients, and oral nutritional supplementation (ONS) should be introduced when food intake meets less than 60-80% of their planned nutritional needs². Particularly, ONS intake may be of value for patients with preserved digestive tract who are losing weight or cannot ingest a sufficient amount of food due to anorexia, digestive symptoms, taste changes, hypermetabolism, malabsorption, hypercatabolism³.

ONS is often applied to complement intake of oral diet calories/protein, but sometimes they can also be required to provide complete nutritional requirements. The patient compliance to ONS is then crucial to maintain or improve their nutritional status. ONS has been shown to efficiently improve nutritional support in older adults and different patients populations with various health and eating-related problems. However, ONS acceptability and intake may be suboptimal in many patients^{4,5}. Several social and individual factors may interfere with adequate ONS intake, such as disease, age, food preferences, and explain ONS low adherence intake. One of the patients most common complaint, avoiding ONS intake, is related to unpleasant organoleptic perceptions in terms of flavor, texture and/or smell^{6,7}.

Sensory analyzes may assist the development and optimization of ONS, as well as the recognition of potential consumer preferences. Several ONS, with different organoleptic properties, are available for clinical practice and its composition may differ accordingly to the therapeutic target to be achieved. In this context, we hypothesized that the compliance of ONS may be related to sensory differences.

We tested the subjective perception of some ONS in an attempt to identify their strengths and weaknesses in terms of palatability, as one of the determinants factors for adherence to oral nutritional therapies.

METHODS

Ethical issues

The study protocol was approved by the Ethics Board Committee of the Real e Benemérita Associação Portuguesa de Beneficência. Written informed consent was obtained from each participant before trial participation.

Study design and subjects

This prospective, monocentric, double-blind, randomized

study enrolled 201 healthy subjects who volunteered to participate in its protocol between July 2014 and June 2015.

There were 201 women, average age was 29.7 ± 8.3 years old and BMI mean was 23.4 ± 3.9 Kg/m². Individuals were dietitians students at a clinical nutrition post-graduation course.

Random and double-blind procedures

Participants were randomized in 3 different groups, according to a computer generated randomized block list. These groups differed between them by the kind of 11 ONS, from different brands commercially available, to attend 3 kinds of nutritional support: hypercaloric / normoproteic supplements (HN group), hypercaloric / hyperproteic supplements (HH group); diabetes mellitus-specialized supplements (DM group), as shown in Table 1. Allocation was double-blind manner and concealment was maintained until statistical analysis. For this purpose, for each group, each one of the evaluated supplements received a specific code (A, B, C, or D) provided by an independent pharmacist. The latin square design was used in order to control more variations. Except for this independent pharmacist, participants, investigators and staff were kept blind to the ONS assignment.

ONSs were donated by distinct manufacturers without other financial contribution or any participation during the study.

Sensory analysis

All participants ingested 20mL of each ONS tested in their specific group alternated by 2 minutes water wash out

Tabela 1 – Characteristics of nutritional supplements and its distribution among the studied groups of volunteers

Group	Diet	Caloric density (kcal)	Proteins (%)	Fiber
HN	ONS-A	1.52	14.00	-
	ONS-B	1.50	16.70	-
	ONS-C	1.50	16.00	-
	ONS-D	1.50	15.00	-
HH	ONS-E	1.50	27.00	1.50
	ONS-F	1.20	21.00	-
	ONS-G	1.50	26.70	-
	ONS-H	1.50	27.00	-
DM	ONS-I	1.08	23.00	1.20
	ONS-J	0.93	20.00	0.80
	ONS-K	1.00	19.00	2.00

HN, hipercaloric / normoproteic supplements group; HH, hipercaloric / normoproteic supplements group; DM, diabetes mellitus-specialized supplements group

between intakes. Participants were asked to rank the taste, aroma, color and consistency of the ONS, according to a Likert scale ranging between very poor, poor, fair, good, and very good. Furthermore, they were asked to fulfill a questionnaire validated to assess the preferences of ONS, the Madrid scale⁸. This tool classified the appearance, odor, texture, taste, feeling of fullness, sweetness, aftertaste and overall impression criteria as pleasant, "neither good nor bad" and unpleasant. Values from 1 to 3 pre-established for each classification / criteria were added, so that the final value obtained varied from 0 to 100. The higher the final value obtained, the better the sensory perception of the ONS.

Sample size and statistical analysis

Sample size was calculated based on a previous pilot sample that included 179 independent volunteers⁹. Considering a 0.25 effect of the variables, 95% power, 5% significance level, and 0.5 correlation between the responses to the supplement taste, a sample size of 185 cases was estimated.

Contrasts of the obtained scores were tested in pairs between the supplements, according to Tukey's test¹⁰, using the software R 3.2.0 (R Core Team, 2015). Graphics were built with their confidence intervals for the mean scores, according to the supplements, using ggplot2 package. Significance level was set in 5%.

The statistician did not know about the brands and did the analysis only with the codes.

RESULTS

Data on HN group obtained by the Linkert scale is shown in Figure 1. Overall, the participants considered ONS-A superior to the other ONS, with significant better results for aroma and taste (vs. ONS-C and ONS-D) and for better consistency (ONS-C) ($p < 0.05$). For all the criteria studied, the ONS-C was significantly inferior to the by-criterion best ranked supplement. ONS-B was not significantly superior or inferior to any studied supplement. The Madrid scale confirmed these findings by showing a better sensory perception of ONS-A over the other studied ONS ($p < 0.05$). There was a worse sensory perception of ONS-C in relation to both ONS-A and ONS-B ($p < 0.05$).

Data on HH group obtained by the Linkert scale is shown in Figure 2. For all the criteria studied, the ONS-H was significantly superior to the other ONS, while ONS-G was significantly inferior to the by-criterion best ranked supplement. The Madrid scale confirmed these findings, by showing a higher sensory perception of ONS-H on the other studied supplements ($p < 0.05$) and a significant lower sensory perception of ONS-G in relation to ONS-H, ONS-F and ONS-E supplements ($p < 0.05$).

Data on DM group obtained by the Linkert scale is shown in Figure 3. The participants considered ONS-K significantly better than the others ONS for aroma, color and consistency criteria and then ONS-J for taste ($p < 0.05$). ONS-K and ONS-I were similar for taste ($p > 0.05$). For all the criteria studied, ONS-J was significantly worse than the other ONS. The Madrid scale only confirmed the worse sensory perception of ONS-J in relation to the other ONS.

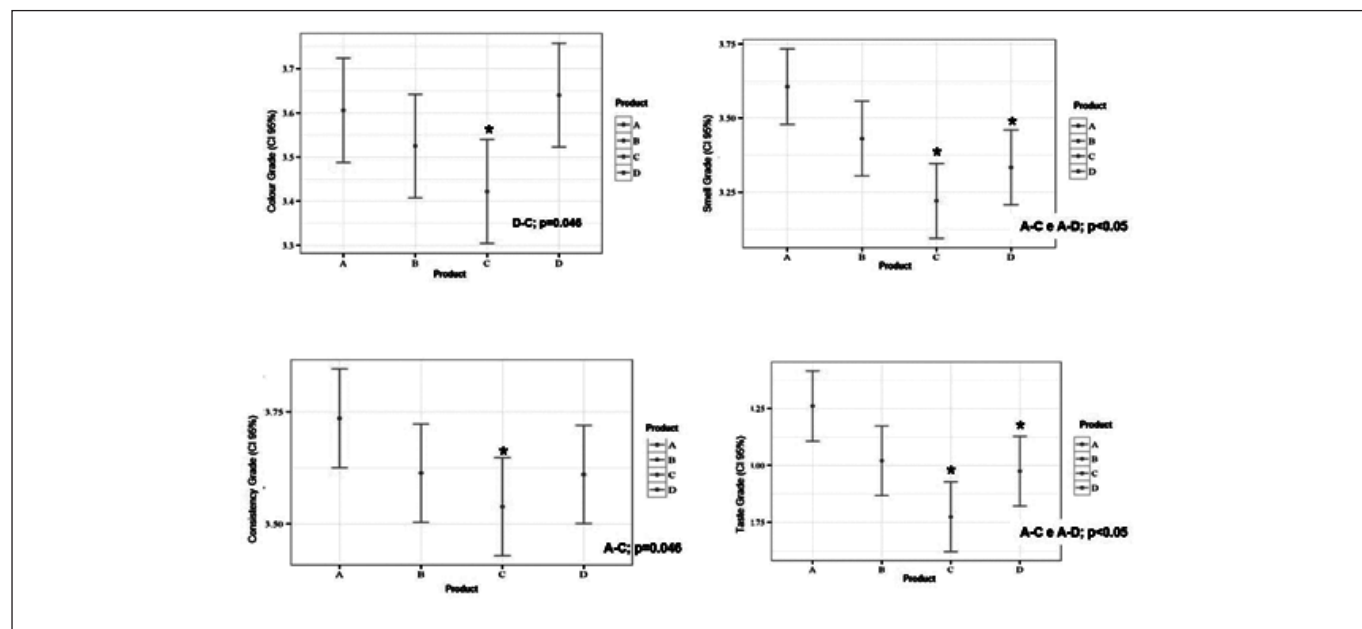


Figure 1

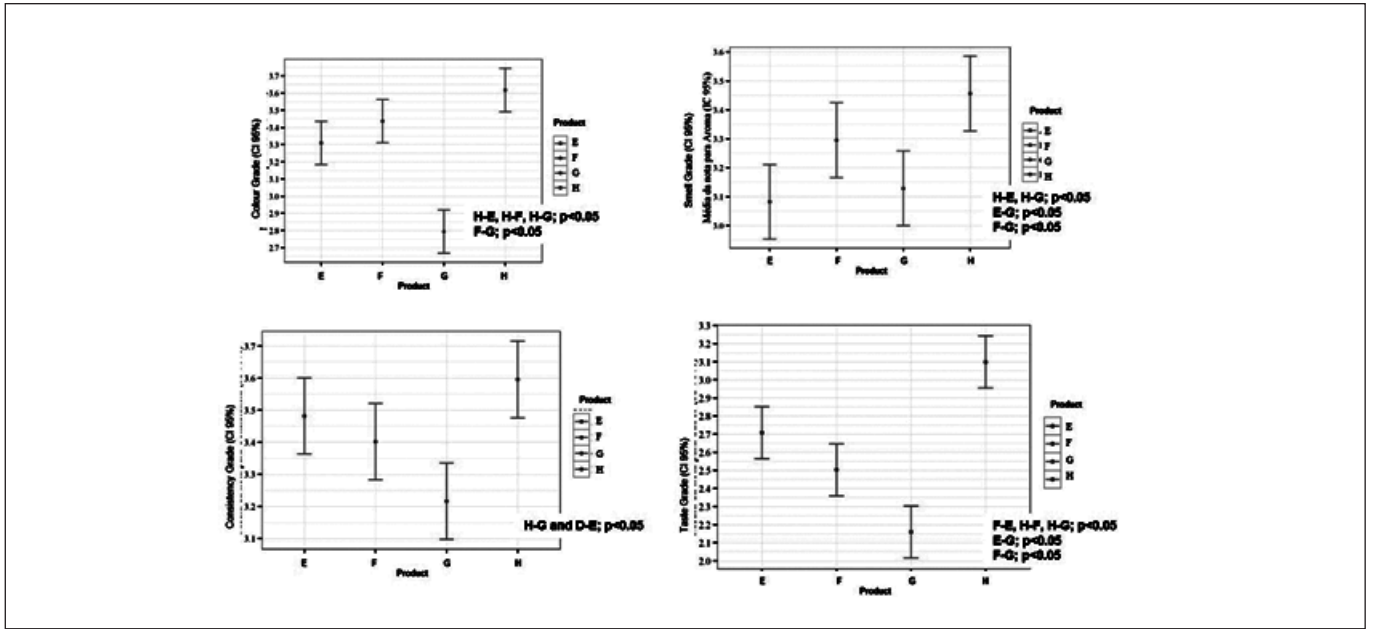


Figure 2

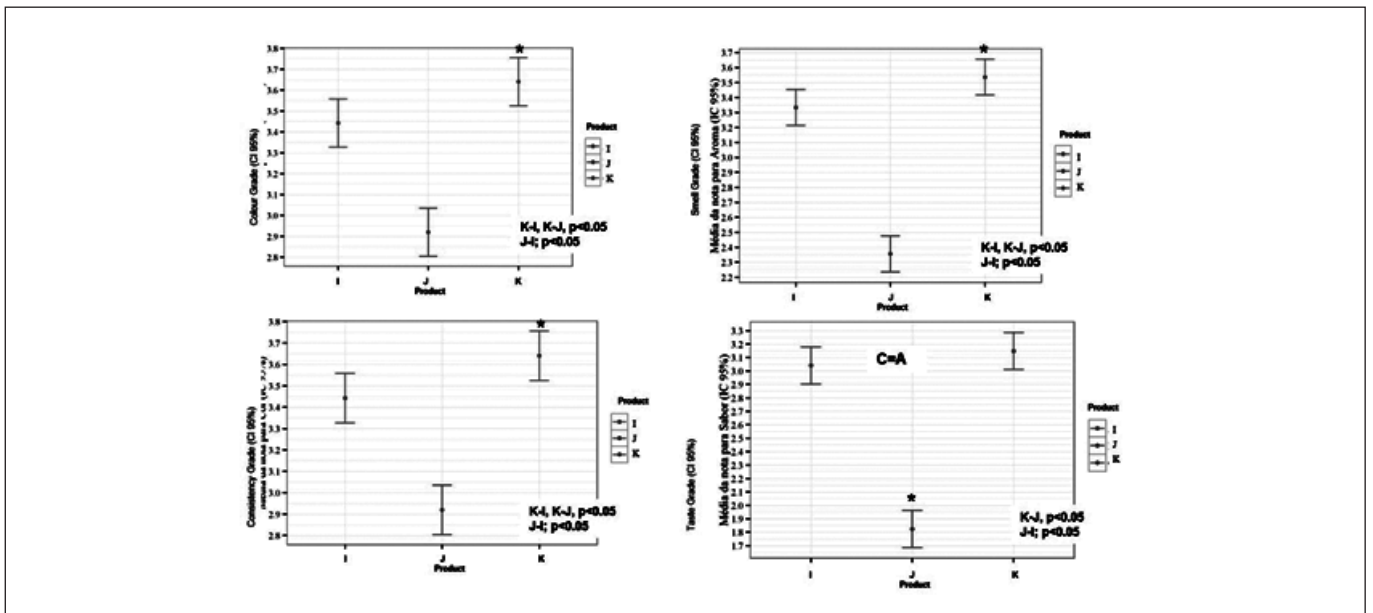


Figure 3

DISCUSSION

Success of oral nutritional therapy in hospitalized patients may be compromised by lack of ONS acceptance. Monotony effect, low palatability and taste changes could be the main determinants factors for adherence to oral nutritional therapies. In this context, the general appearance and palatability of ONS can be important to allow and improve its acceptance by patients, favoring their therapeutic compliance. Our study tested the perception of 11 ONS, from different brands commercially available to attend 3 kinds of nutritional support, aiming to identify

their strengths and weaknesses in terms of organoleptic criteria (aroma, color, consistency and taste) and overall impression (Madrid scale).

The expression “we eat with eyes” reflects the importance of food appearance to stimulate our interest for eating and may determine whether its consume is accepted or rejected^{11,12}.

In our study, data on ONS color and consistency reflected this quality attribute. ONS ranked as having an attractive color and consistence usually had shown best results on general perception, supporting that ONS appearance can be relevant for its acceptance.

Smell and taste were similarly ranked among the studied ONS and contributed to its general impression, except for hypercaloric / hyperproteic ONS. We previously have shown that the smell of ONS correlate with its taste and comprise the most relevant factor that influences its final impression⁹. Our present data suggest that protein enrichment may interfere in the ONS smell and taste, so caregivers should monitor carefully the acceptability of hyperproteic ONSs by the patients to design their nutritional intervention.

One systematic review highlighted a positive association between higher energy-density ONS and compliance, resulting in improvement in total energy intake by patients¹³. In our study a higher score for general impression was found for ONS with higher calorie and lower protein values (ONS-A, 1.52 Kcal and 14.00%, respectively) than the other studied ONS. However, the best ranked hypercaloric / hyperproteic ONS (ONS-H) presented a lower score for general impression than the best ranked normocaloric ONS for diabetes (ONS-K).

Notably, ONS-H also have higher protein content than ONS-K (27% vs. 19%, respectively), reinforcing that protein enrichment may impair the sensorial ONS impression. The form protein is provided through ONS may influence its taste. Patients with pelvic malignancy (even before and after pelvic radiotherapy) and healthy controls classified with higher values, for taste, elemental nutritional supplements than polymeric supplements and ranked them as significantly better than peptide supplements¹⁴.

Flavor preference is a very personal matter and may be an additional factor influencing the adherence to oral nutritional therapies. Variations among ONS flavors and categories (milk-based or fruit-based) must be considered in order to improve the patients' adherence to long-term oral nutrition therapy. In fact, the patient's adherence to nutritional oral therapy seems to decrease along time. Elderly patients in acute care wards showed a better compliance with ONS compared to those at longstay wards¹⁵. In this scenario, changes in ONS flavor may be a good strategy to avoid monotony and improve patient adherence to the nutritional intervention. However, our data highlighted that ONS with the same flavor can provide different sensorial perceptions and this should be considered during ONS prescription.

We choose to study milk-based ONS with vanilla flavor like Darmon et al.⁷ study, because vanilla, coffee and strawberry/raspberry flavor milky sip-feeds are usually well rated and represent "reliable" products, while chocolate flavor appears to be slightly less appreciated. The authors also reported that unflavored milk-based products should be avoided and sweet fruit-juice type ONS do not seem to be really appreciated, while salty fruit-juice type ONS (tomato-flavored) can be useful in some patients.

It is worth to note that the brands included in our study offer different flavors for each assessed ONS. This may explain why no specific commercial brand achieved best organoleptic and overall impression results among all the 3 groups of nutritional supplements evaluated. However, our study did not assess whether different flavors from a same supplement could influence its overall impression to confirm this hypothesis.

Another limitation of our study was the assessed population, comprised by health care providers. Although, previous studies have shown that ONS preferences were similar between patients with cancer and healthy subjects, dietitians are well informed about nutritional products and their perceptions may differ from the general population^{14,16}. However, even among the same patient population the organoleptic criteria can vary and be affected by the disease treatment^{17,18}. Another limitation is that our studied population also was predominantly female and taste preferences can differ by gender.

Finally, the range of nutritional products tested in this study did not encompass all ONS commercially available, but reflected the type of ONS commonly ordered/recommended in clinical practice in Brazil. A wider variety of products might yield different results, especially ONS designed to attend specific patient population. For instance, hemodialysis patients may prefer to sacrifice taste in favor to renal-specialized ONS, because of its low fluid contribution and phosphate-binder requirements¹⁹.

Despite these limitations, our data highlighted that ONS with the same characteristics and flavor and with similar composition can provide different perceptual experiences. These findings suggest that health care providers should take into account patients sensorial perception of ONS to improve their adherence to nutritional oral therapy.

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