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DEVELOPMENT OF A NEW DEVICE FOR IDENTIFICATION OF NUTRITIONAL NEEDS OF DYSPHAGIC INPATIENTS

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Abstract: *Objectives:* Dysphagia in elderly patients can cause serious health problems. The aim of this study was to investigate the effects of a new method for the identification of the elderly dysphagic patient. We hypothesized that a simple identification device could reduce errors in providing food and therefore reduce negative outcomes. *Design:* Two group of participants were enrolled (experimental and control). Each patient received a diagnosis of the severity of his/her own dysphagia disorder on a scale ranging from 1 (no swallowing problem) to 5 (unable to swallow). Inpatients of the experimental group only worn a bracelet with a specific color code for each level of the dysphagia disorder. Operators were trained to check the bracelet color and provide the corresponding diet to the patients. Participants were tested three times over a two months period. *Setting:* The participants were hospitalized in three nursing homes of the same institute. The colored bracelet method was adopted in two of these nursing homes. *Participants:* Fifty-five participants were enrolled for the study (44 in the experimental group, 78% female, mean age = 88.9±6.6 years). Forty-two operators (86% female, 64% of age between 36 and 55)) filled in an evaluation questionnaire. *Measurements:* Several measures of nutrition, hydration, and clinical condition were collected. *Results:* The method significantly improved hydration ($p = .002$) and BMI ($p = .010$) and reduced the risk of bedsore ($p < .001$) of the patients. *Conclusion:* The colored bracelet method is an effective instrument for managing the diet of elderly dysphagic inpatients.

Key words: Dysphagia, malnutrition, nutritional intervention, aged, nursing homes.

Background and objective

Dysphagia is an alteration in the swallowing process due to degeneration and ageing of involved organs.

The number of dysphagic inpatients in rehabilitation centres and residential structures is going to increase with the extension of life expectancy. Dysphagia occurs in 15% to 23% of older persons living in the general non-patient population and it is prevalent in hospitalized patients (1).

Dysphagia may lead to serious health and life-threatening complications such as malnutrition and aspiration pneumonia (2). Malnutrition from dysphagia is considered a risk factor for pressure ulcers in elderly people (3). Errors in providing the correct type of nutrition to the patients could have serious consequences such as suffocation, aspiration pneumonia, denutrition, dehydration and, eventually, death. A recent study (4) showed that patients who suffered from dysphagia or malnutrition had poor outcome with regard to mortality, and that patients suffering from both dysphagia and malnutrition had the poorest outcome.

Guidelines of the International Dysphagia Diet Standardisation Initiative (IDDSI) and of the Italian Society of Artificial Nutrition and Metabolism (SINPE) for the management of dysphagic patients recommended that all patients with dysphagia should be assessed by a specialist (speech therapist) and should be referred to a dietitian to develop individual nutrition care plans.

Functional severity of dysphagia makes recommendations for nutritional therapy. The primary aim of nutritional therapy is to meet nutritional requirements of individuals and prevent adverse events such as aspiration pneumonia.

A simple and fast method to identify the severity of dysphagia in elderly patients could reduce the probability of feeding errors and, consequently, increase the health quality of patients.

Aim of the study

In this study, we aimed at investigating the effects on patients and operators of a device for the identification of severity of inpatients' dysphagia using colored bracelets.

We hypothesized that the introduction of this method could improve the health of the inpatients, and could reduce the number of adverse events, such as feeding errors and consequently aspiration pneumonia. Specifically, we are interested in measuring the effects of the colored bracelets method on:

a) nutrition of the inpatients
b) hydration of the inpatients
c) risk of bedsore of the patients

Furthermore, we were interested in evaluating the operators' perception of the usefulness and ease of use of the device.

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Methods

Design of the study

At the beginning of the study each patient received an evaluation of the severity his/her own dysphagia disorder by a speech therapist using Bedside Swallowing Assessment and the Smithard's Three-oz Water Swallow Test (5). Patients with the most severe clinical conditions took also an instrumental phoniatric examination with Fiberoptic Endoscopic Examination of Swallowing (FEES). The evaluation of the severity of the dysphagia disorder ranged from 1 (no swallowing problem) to 5 (unable to swallow), it was identified by a different color-code (1 = green, 2 = blue, 3 = yellow, 4 = orange, 5 = red) and was associated to a specific diet. Three nursing homes were involved in the study: the participants of the experimental group were enrolled from two of them, while the control group was sampled from the third nursing home. The three clinics had similar procedures, patients had similar health and personal characteristics, and staff were equally trained and experienced. A colored bracelet indicating the severity of dysphagia was always worn by the patient of the experimental group. A speech therapist trained the operators every six month in the physiopathology of the dysphagia disorder and in the management of the diet of dysphagic inpatients. During this course, the operators of the experimental group were also trained to check the bracelet color and provide the corresponding diet to the patients. Participants of both groups were tested at the beginning of the study, i.e., before the introduction of the bracelet method (T0), after one month from the beginning of the study (T1), and after two months (T2).

Sample

Fifty-five participants were enrolled in the study (78% female, mean age = 88.9±6.6 years). Three participants died before the end of the study, therefore there were only 52 observations in T2. The experimental group included 44 inpatients, while the control group comprised 11 inpatients. Furthermore, 42 operators (86% female, 64% of age between 36 and 55, 71% with secondary school degree or higher) working in the nursing homes of the experimental group were asked to fill in a questionnaire to evaluate their perception of the of the usefulness and ease of use of the device for the identification of the dysphagia severity.

Measures

Several measures were collected to evaluate the nutritional status of the patients: Body Mass Index (BMI), Mini Nutritional Assessment (MNA) (6), and calorie intake through food.

BMI was calculated with the classical formula W/H^2 (W = weight [kilograms]; H = height [metres]).

The MNA test comprises simple measurements and brief questions that can be completed in about 10'-15'. The full MNA includes 18 items grouped in 4 rubrics: a) anthropometric assessment; b) general assessment; c) short dietary assessment; and d) subjective assessment. It provides a single, rapid assessment of nutritional status in elderly patients. The MNA score distinguishes between elderly patients with adequate nutritional status (MNA ≥ 24 up to 30), patients at risk of malnutrition (MNA between 17 and 23.5) and patients with protein-calorie malnutrition (MNA < 17).

Calorie intake was estimated from the patient's diet. The diet was prescribed according to the nutritional needs of elderly population indicated by the Italian Human Nutrition Society (SINU) (7). Each diet of the inpatients was determined accordingly considering age, sex and clinical status. Therefore, the calorie intake is an esteem of the nutritional needs.

Hydration was evaluated using three measures collected by a physician: blood pressure, tongue moisture, and skin turgor (the degree of elasticity of skin). Furthermore, a subjective hydration score (ranging from 0 = very low hydration to 5 = good hydration) was provided by the physician after a physical examination of the patient. Given the high correlation of these indices, a general hydration index (GHI) was calculated performing a principal component analysis (PCA) on these measures.

The risk of bedsore of the patient was measured with the Braden Scale for Predicting Pressure Sore Risk (BS) (8). It comprises six subscales representing the most common risk factors for pressure ulcers. It ranges from 6 to 23, with higher scores indicating lower risk of developing sores. A cutoff score of 18 is generally used to designate increased risk of pressure ulcer development. It has been shown that this measure has adequate levels of validity and reliability (9, 10).

Several other variables were collected from the medical records to obtain a more detailed assessment of the health of the patients and to be used as control variables in the statistical analyses. Alzheimer dementia, Parkinson's disease, and stroke data were collected. Furthermore, comorbidity was measured with the Cumulative Illness Rating Scale (CIRS) (11). CIRS provides two scores (a) severity of the illness; and (b) comorbidity.

Two items were administered to the operators to investigate their perception of the usefulness and ease of use of the bracelet method. Both item responses were collected on a Likert scale ranging from 1 = "not at all" to 5 = "a lot". We considered mean ratings of no less than 4 on either characteristic as a satisfactory result (12).

Results

Linear mixed models (LMMs) (13) were used to assess the effect of the use of bracelet on the measures of nutrition (BMI and MNA), hydration, and risk of bedsore while controlling for background and clinical characteristics.

Four LMMs were specified, one for each dependent variable (i.e., BMI, MNA score, GHI score, BS score). Predictors of the model were a) treatment (experimental or control), b) time of the observation (T0, T1, T2), c) daily calorie intake,

Table 1

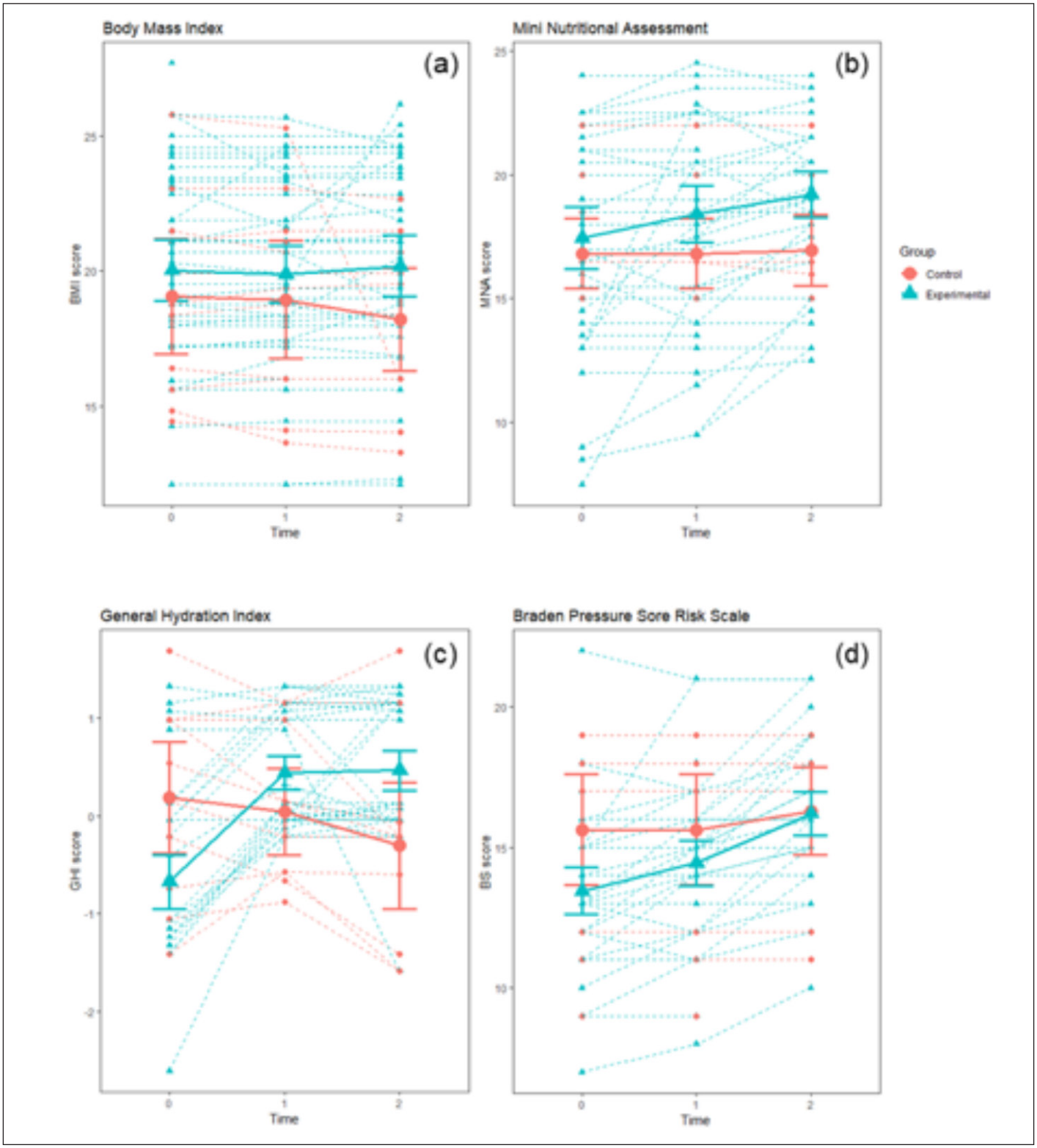
Results of the four linear mixed models performed (only fixed effects are shown)

Dependent variable:	BMI					MNA					GHI					BS				
	Estimate	Std. Err	df	t	sig	Estimate	Std. Err	df	t	sig	Estimate	Std. Err	df	t	sig	Estimate	Std. Err	df	t	sig
(Intercept)	-318.10	187.80	36.06	-1.69	0.10	128.51	132.47	42.51	0.97	0.34	2.90	26.63	38.82	0.11	0.914	136.10	123.60	39.52	1.10	0.278
Group	2.94	1.79	52.01	1.64	0.11	-1.39	1.66	59.89	-0.84	0.41	-1.02	0.41	67.35	-2.51	0.015*	-5.32	1.40	59.36	-3.79	0.000***
Time	-0.56	0.25	47.58	-2.21	0.03*	-0.03	0.39	48.06	-0.09	0.93	-0.24	0.12	48.66	-1.97	0.054	0.03	0.30	44.17	0.09	0.927
KCAL intake	0.00	0.00	88.32	-0.50	0.62	0.00	0.00	106.71	1.16	0.25	0.00	0.00	128.10	8.20	0.000***	0.00	0.00	98.55	-0.31	0.757
Dysphagia level 1 vs 2	-1.57	0.78	123.70	-2.03	0.05*	-0.01	0.93	124.34	-0.01	0.99	0.12	0.23	78.82	0.54	0.592	-1.10	0.77	135.00	-1.43	0.155
Dysphagia level 1 vs 3	-1.36	1.40	112.30	-0.97	0.33	2.91	1.79	137.55	1.63	0.11	0.03	0.47	97.79	0.06	0.955	-0.50	1.46	136.80	-0.34	0.733
Dysphagia level 1 vs 4	2.09	1.17	135.10	1.79	0.08	-1.99	1.16	79.80	-1.71	0.09	-0.15	0.26	55.88	-0.58	0.567	-1.75	1.01	89.45	-1.73	0.088
Dysphagia level 1 vs 5	2.08	1.66	127.30	1.25	0.21	-2.78	1.94	102.20	-1.43	0.16	-0.01	0.52	80.59	-0.03	0.977	-2.23	1.62	115.90	-1.38	0.170
Alzheimer	3.19	3.59	35.77	0.89	0.38	-1.19	2.52	42.46	-0.47	0.64	-0.06	0.51	39.38	-0.12	0.902	0.37	2.36	39.29	0.16	0.875
Parkinson	0.10	3.01	35.66	0.04	0.97	-1.49	2.10	41.58	-0.71	0.48	0.51	0.42	37.63	1.21	0.233	0.42	1.97	38.84	0.21	0.832
Stroke	1.84	4.11	35.80	0.45	0.66	-0.05	2.88	42.37	-0.02	0.99	-0.16	0.58	39.26	-0.28	0.784	2.40	2.69	39.28	0.89	0.379
Diabetes	1.17	1.44	36.00	0.81	0.42	2.66	1.01	43.18	2.62	0.01*	-0.06	0.21	40.31	-0.30	0.766	-1.13	0.95	39.80	-1.20	0.238
CIRS severity	0.81	3.19	36.15	0.25	0.80	2.43	2.26	43.15	1.07	0.29	0.26	0.46	39.65	0.57	0.569	2.05	2.11	39.98	0.97	0.337
CIRS comorbidity	-0.54	0.57	36.46	-0.93	0.36	-0.65	0.41	44.64	-1.58	0.12	-0.07	0.08	41.53	-0.79	0.437	-0.14	0.38	41.02	-0.37	0.711
Artificial Nutrition	-1.76	2.54	57.68	-0.69	0.49	-2.11	2.25	89.81	-0.94	0.35	0.35	0.56	78.87	0.62	0.540	-2.16	1.96	86.84	-1.10	0.273
Gender	3.06	1.39	36.76	2.19	0.03*	-1.07	0.99	45.02	-1.08	0.29	0.03	0.20	42.12	0.17	0.870	0.58	0.92	41.46	0.63	0.530
Age	0.17	0.10	36.01	1.76	0.09	-0.06	0.07	42.48	-0.85	0.40	0.00	0.01	38.85	-0.25	0.804	-0.06	0.06	39.48	-0.98	0.336
Group*Time interaction	0.76	0.30	54.12	2.53	0.01*	0.81	0.46	54.76	1.78	0.08	0.46	0.14	55.33	3.23	0.002**	1.34	0.35	50.68	3.82	0.000***

Significance Codes: < 0.001 '***'; < 0.01 '**'; < 0.05 '*'; < 0.1 '.'

Figure 1

Group-time interaction effects for each dependent variable. Each dashed line represents a participant. Thick solid lines represent group means. Error bars represent 95% confidence intervals of the mean scores.



d) severity of dysphagia, e) Alzheimer dementia diagnosis, f) Parkinson's disease diagnosis, g) past stroke diagnosis, h) diabetes diagnosis, i) comorbidity (CIRS S and CIRS C scores), j) artificial nutrition with nasogastric intubation, k) sex, and l) age.. While the focus variables were treatment, and time, the rest of the predictors were included in order to reduce the bias in the estimate of the effect of the treatment due to the impossibility to randomly assign patients to treatment levels.

Results are reported in Figure 1 and in Tables 1. As for BMI, participants in the experimental group had a higher BMI than controls ($p = .035$) and an overall decrease of BMI over time ($p = .031$) was observed; also the group-by-time interaction was statistically significant ($p = .014$), due to a decrease of BMI in the control group and a lack of substantial change in the experimental group (Table 1 and Figure 1a).

The LMM for MNA revealed a significant fixed-effect of diabetes on MNA ($p = .018$, inpatients with diabetes diagnosis had higher scores), but the group-by-time interaction was only marginally significant ($p = .081$). However, the mean score of the experimental group tended to increase from T0 to T2, while the mean score of the control group remained substantially stable (Table 1 and Figure 1b).

A significant fixed-effect of the amount of daily calorie intake ($p < .001$) on the GHI score was found, where higher amounts of daily calorie intake was associated to higher hydration scores. The group-by-time interaction was statistically significant ($p = .002$), showing an increase of the hydration level in the experimental group and a decrease in the control group form T0 to T2 (Table 1 and Figure 1c).

Finally, a significant fixed-effect of the group ($p = .004$) was found on the BS score: inpatients of the experimental group had lower scores on the BS and therefore higher risk of pressure sores; also the group-by-time interaction was statistically significant ($p < .001$) due to a reduction of the sore risk in the experimental group from T0 to T2, while no change was observed in the control group (Table 1 and Figure 1d).

One-sample t-tests were used to test whether the operators' ratings of usefulness and ease of the use of the device differed from the expected result (score 4). Both t-test revealed that the target rating was achieved since there were not a statically significant differences (Usefulness: $M = 3.80 \pm 1.27$; $t(39) = -0.98$, $p = .331$, $d = 0.16$; Ease of use: $M = 3.75 \pm 1.31$; $t(39) = -1.19$, , $p = .241$, $d = 0.19$).

Conclusion

The aim of this study was to test the efficacy of a new method for the identification of elderly dysphagic patients in improving their health outcomes. The method uses a color code on a bracelet worn by the inpatients that indicates to the operator the severity of the dysphagia. Results supported the efficacy of the method as they showed an overall improvement of the health condition of the inpatients of the experimental group with respect to those of the control group. The average BMI of the patients in the experimental group was stable across time, while it decreased in the control group. Hydration level significantly increased in patients identified with bracelets, while it decreased in the other patients. Finally, participants of the experimental group had lower pressure sore risk over time. The method was also considered adequately useful and easy to use by operators. Taken together, these findings suggest that the colored bracelet method is an effective method to manage the diet of elderly inpatients and it has a positive impact on their nutritional status and health condition.

Some limitations of this study have to be acknowledged. It was not possible to randomly assign the participants in the experimental and control group. Then the sample resulted unbalanced, although its size is not small. In this study differences of the two groups were statistically controlled, but a different sampling with more participants could solve this issue in the future. Furthermore, the study last for only two months. Next studies should enrol a higher number of and they should be conducted for longer period. These changes in the design of the study should allow to evaluate the impact of the colored bracelet method on aspiration pneumonia and related death incidence in elderly dysphagic inpatients.

Conflict of interest: Dr. Bortolazzi (francesca.bortolazzi@email.it) reports personal fees from NOEMA CONGRESSI during the conduct of the study; to have other relationships with nursing homes in Genoa; and to be consultant of KORIAN group and GRUPPO INSIEME. Dr. Calabrò (alessiocalabro83@gmail.com) reports personal fees from NOEMA CONGRESSI during the conduct of the study; and to have other relationships with nursing homes in Genoa; and to be manager of GRUPPO INSIEME. Dr. Pesce (pesce.matteo1@gmail.com) reports to be consulent for SERENITA S.R.L. and CITTADELLA S.R.L. (GRUPPO INSIEME); Dr. Tortorolo (umberto.tortorolo@pcdo.it) reports to have other relationships with nursing homes in Genoa and to be health director in KORIAN group. Dr. Piccinno (piccinno@vie-srl.com) reports grants from Noema S.r.L. Unipersonale during the conduct of the study. Dr. Masini (masini@vie-srl.com) has nothing to disclose. Dr. Chiorri (carlo.chiorri@unige.it) has nothing to disclose.»

Ethical standard: All procedures performed in the study were in accordance with the ethical standards of the institutional and/or national research committee, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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