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Research Article

Evaluating the Lipsense Device for Reducing Oral Dryness in Patients Undergoing General Anesthesia for Elective Daycare Surgeries

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Abstract

Background and Aims: Post operative thirst and oral dryness after general anesthesia is a well-known concern encountered in the post anaesthesia care unit; equally distressing for the patient and the clinician. The Lipsense device (Coolsense ltd, Tel Aviv, Israel) is a novel device which allows controlled delivery of water to relieve thirst and oral dryness. We hypothesized lipsesne will be effective to decrease thirst and oral dryness and thus improve overall patient and care giver satisfaction.

Method: This was a prospective randomized controlled study conducted in 120 adult patients, equally divided into 3 groups receiving Lipsense, wet gauge and no intervention; undergoing daycare surgeries under general anaesthesia and complaining of post operative thirst. Numerical rating scores of thirsts and oral dryness were measured at 0,1,2,3 hrs of post operative period by an independent observer.

Results: The mean difference in intensity scores for thirst and oral dryness from baseline till the end of 3 hours was greater in the Lipsense group (4.12 and 4.26 respectively) than in the wet gauge group (2.92 and 2.82). Lipsense resulted in a greater reduction, i.e. 72% as compared to our hypothesis of 35% reduction. Wet gauge resulted in a 46% reduction in thirst intensity.

Conclusion: Lipsense is an effective device to reduce post-operative thirst and oral dryness with minimal side effects in comparison to wet gauge or no intervention in patients after general anesthesia.

Keywords: Post operative; Thirst; Oral dryness; Lipsense device; Wet gauge

Background

Thirst is a multidimensional symptom, associated with xerostomia or dry mouth, with a high incidence in the Immediate Postoperative Period (IPO), which is about 43.8% to 75% [1]. Amongst all 34 stressors in the postoperative period, thirst is classified as the 5th stressor, hence signifying its importance for patients in the postoperative period [2]. Thirst and oral dryness may arise from several factors in the immediate post-operative period like prolonged fasting, anesthetic drugs used, blood loss in the surgery, anxiety before surgery and pain [3]. Patients have even mentioned death when they are encouraged to describe their thirst experience postoperatively.

Although health care workers recognize the rigorousness of thirst among postoperative patients, they neither record nor systematically assess thirst in the post-operative period usually. The absence of adopted protocols by health care facility for management of thirst opens the way for applying unplanned and disorganized actions about the best strategy and the safe volume used and hence calling the physicians as powerless in this scenario, would not be false [4]. Early ingestion of fluids in the post-operative period has been proven effective, safe to reduce thirst and oropharyngeal discomfort and also increases patient satisfaction in the postoperative period [5].

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Hence, in this study, we aimed to study a new device, known as Lipsense to curb this postoperative menace. The device consists of a water bag, PVC tubing and an oral applicator, that once applied to the patient's mouth allows them to have controlled sips of water, whenever they need to relieve their thirst and oral dryness (Figure 1) It delivers water at a rate, not more than 12ml/hour [6]. This study evaluates the effectiveness of this device, its potential side effects and overall patient and caregiver (nursing personnel) satisfaction in comparison to the routine care (no intervention or water-soaked wet gauge application). We hypothesized that an overall decrease in the intensity of thirst and oral dryness would occur from 60% to 25% after intervention with Lipsense device. The primary outcome was to assess the change in oral dryness score and thirst score in the postoperative period. Secondary outcomes included oral assessment tool, patient satisfaction score, caregiver satisfaction score and incidence of nausea and vomiting along with any other side effects.

Methods

It was a prospective randomized controlled study conducted from November 2018 to October 2019 in the post anesthesia care unit of main operation theatre complex, of a tertiary care hospital in North India. After taking clearance from the institutional ethical committee (NK/4801/MD/012), prospective registration with the Clinical Trials Registry of India (CTRI/2019/03/018091) was done and the study was conducted in accordance with the Helsinki Declaration-2013. 120 adult male and female ASA status I-III patients in the age group of 20-60 years posted for daycare surgeries lasting < 2 hours were included in the study. Patients who refused to give consent, with pre-existing GI disease, impaired mental status, delayed gastric emptying time, mouth breathers, patients who developed complications after surgery or during the period of anesthesia, with blood loss not more than 150 ml during the surgery were excluded from the study.

After the pre-anesthetic checkup and obtaining written informed consent, the study procedure was explained to the patients. This included details of the Lipsense device and wet gauge, procedure of application, oral dryness score, thirst score and satisfaction core in the numerical rating scale. On receiving the patients in postoperative anaesthesia care unit after the surgery, standard monitoring including ECG, pulse oximeter and NIBP were applied. After they met the specified inclusion criteria, the patients were questioned about the presence of thirst, and if they responded positively, then baseline thirst and oral condition were assessed. The assigned anaesthesiologist performed an additional evaluation using the Safety Protocol for the Management of Thirst (SPMT), as a prerequisite before the application of any intervention to avoid fatal complications such as aspiration. SPMT includes 4 parameters such as the consciousness level, airway reflexes (intact coughing and swallowing) and any pre-existing nausea, vomiting felt by the patient in which case they were excluded from the study.

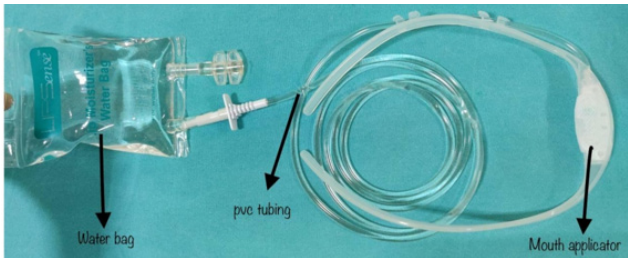

Figure 1: Lipsense device.

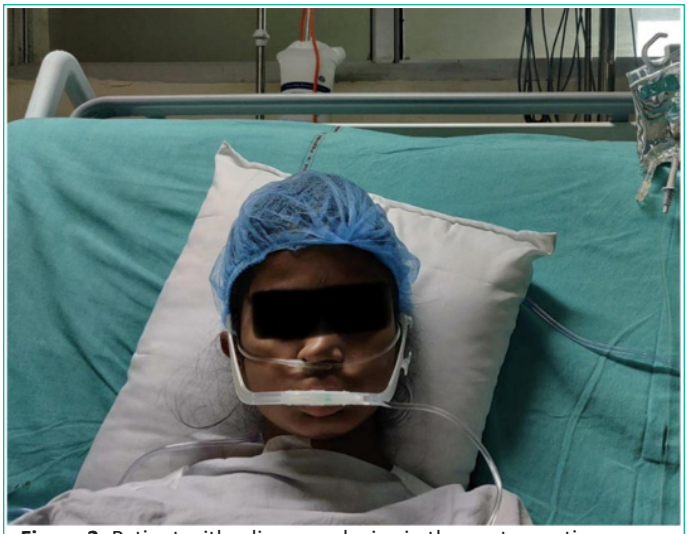

Figure 2: Patient with a lipsense device in the postoperative period.

Then the patients were randomly allotted one of the 3 groups:

- Lipsense group – Lipsense device was applied continuously in the post-operative period.

- DIRECTIONS FOR USING LIPSENSE DEVICE: The sterile dressing was opened and the water bag was filled with with drinking water (approximate capacity of the water bag 150 ml). Then water bag was connected with the transparent tubing and tubing was flushed with water just like for an intravenous fluid line until water drops started appearing on the oral applicator. The tubing was applied over the patient's mouth as the sides of the applicator would fit over the patient's cheeks. (Figure 2)

- Wet gauze group – A sterile gauge soaked with 10 ml of drinking water was applied for 10 minutes in the following way

- Control group – Patients received no intervention.

- The patients were assessed postoperatively using the following scales-

- Thirst Intensity Scale- A numerical rating scale was utilized to study thirst intensity with 1 being no thirst at all to 10 being worst possible thirst experienced by the patient. The scores have been classified as mild (1-3), moderate (4-6), severe (7-10).

- Oral Dryness Scale- It refers to severity, strength or amount of thirst. A numerical rating scale was used to measure dryness intensity with 1 being no dryness at all to 10 being maximum oral dryness felt.

a. Oral Condition Assessment Tool – The tool is designed to measure changes of oral condition as regards: lips, tongue, mucosa and saliva, and the items were scored on a 3-point Likert scale (the lower the score, the better the oral condition).

b. Lip has one score if it is smooth, pink and moist, two scores if it is dry or cracked and three scores if it is ulcerated.

c. Tongue, the score of one if it is pink and papillae present, score of two if it has loss of papillae and score of three if it is blistered or cracked.

d. Mucosa has a score of one if it is pink & moist, the score of two if it is red or white coated, the score of three if it is ulcerated with or without bleeding.

e. Saliva has a score of one if it is watery, a score of two if it is thick and score of three if it is absent.

- Satisfaction Scale (for both patient and caregiver) refers to the overall satisfaction and comfort felt by the patient and caregiver, assessed using a VNS from 1-5 with 1 meaning not satisfied and 5 being, maximally satisfied.

- Any side effects observed were also recorded like nausea vomiting and any others.

Sample Size Calculation

Sample size was calculated using G*Power s.1.0.10 software. Total sample size of 120, with three groups was calculated assuming reduction in the intensity of thirst from mean of 60% to 25%, with power of study 89% and alpha error 5%. The comparisons of quantitative variables between all 3 groups were performed using one-way ANOVA test and the Fisher exact test or χ2 for categorical variables. Repeated measures ANOVA test was performed for time trend (at 10 minutes, 1 hour, 2 hours and 3 hours) variables within groups. Multivariate logistic regression was applied to find out the independent variables significantly associated with the study outcome among those variables whose p-value <0.05 came in univariate analysis. All tests were 2 sided with a 5% level of significance and 95% confidence interval.

Results

From a total of 120 patients, 3 were excluded as they did not complaint of thirst post-surgery. The rest 117 patients were divided into 3 groups namely control, Lipsense and wet gauge group comprising 36, 42 and 39 patients respectively (Figure 3).

Among the 3 groups, there were no significant differences in general characteristics and pre-experimental dependent variables such as age, gender, ASA physical status, duration of surgery, blood loss during surgery, intravenous fluid transfused, duration of fasting. Patients in all 3 groups were operated for daycare procedures in general surgery, urology, orthopedics, radiotherapy, plastic surgery, ENT, gynecology including hysteroscopy (Table 1).

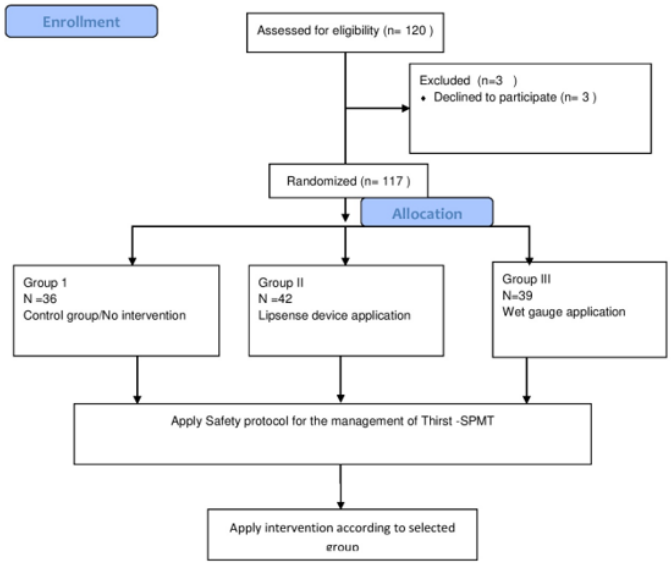

Figure 3: Consort diagram.

Table 1: Demographic data.

Variables		GROUP 1 n=36	GROUP 2 n=42	GROUP 3 n=39	p- value
ASA	I	22	22	25	0.536
	II	14	20	14	
Age in years		42.5±13.1	43.45±12.2	36.9±14.6	0.067
Gender	Male	12(33.3%)	13(31%)	17(43.6%)	0.46
	Female	24(62.7%)	29(69%)	22(56.4%)	
Duration of surgery (in hours)		1.55±0.9	1.47±0.75	1.30±0.66	0.368
Total blood loss (in ml)		180±187.9	147±206.2	96±99.6	1.06
iv fluids (in litres)		1.08± 0.45	1.35±1.01	1.36±0.48	0.162
NPO since (hours)		12.36±1.62	12.67±1.66	12.67±1.66	0.538
Comorbidities	Hypertension	10(76.9%)	9(47.4%)	5(38.5%)	0.011
	Diabetes	0	4(21.1%)	4(30.8%)	
	Hypothyroid	3(23.1%)	1(5.3%)	0	
	Asthma	0	1(5.3%)	0	
	Smoker	0	3(15.8%)	0	
	Cad	0	0	3(23.1%)	
	Obesity	0	1(5.3%)	1(7.1%)	
Department	General surgery	4(11.1%)	16(38.1%)	7(17.9%)	0.885
	Urology	2(5.6%)	2(4.8%)	2(5.1%)	
	Orthopedics	9(25%)	0	0	
	Radiotherapy	1(2.8%)	0	3(7.7%)	
	Plastic surgery	2(5.6%)	1(2.4%)	7(17.9%)	
	ENT	6(16.7%)	11(26.2%)	12(30.8%)	
	Gynaecology	12(33.3%)	12(28.6%)	8(20.5%)	

Values are mean ± SD or percentages

The baseline scores for thirst intensity, oral dryness score, oral condition was comparable in both the groups as shown in Table 2. Mean thirst and oral dryness score at 1,2 and 3 hours post intervention in all the 3 groups are shown in Table 3. Pairwise testing using the Bon Ferroni equation, shows that Lipsense reduced thirst markedly in comparison to the control group (p value 0.001*) and the wet gauge group (p value 0.004*) at 1 hour, at 2and 3 hours. The wet gauge group did not reduce thirst significantly, as compared to the control group (p value 0.279) at 1 hour but the reduction was significant at 2, 3 hours (p value 0.001*). Similarly, pair wise testing showed that Lipsense caused a reduction in oral dryness markedly in comparison to the control group (p value 0.001*) and the wet gauge group (p=0.001*) at 1, 2 and 3 hours. The wet gauge group did not reduce oral dryness significantly compared to the control group (p value 0.248) at 1 hour but reduced significantly at 2, 3 hours (p value 0.001*). The mean difference in intensities between scores from 3 hours to baseline in the control group for thirst score, oral dryness score, and oral condition of lips, tongue, mucosa, saliva was not statistically except in case of

Table 2: Thirst score and oral dryness score.

Scores @ 10 minutes postoperative (Baseline)	Group 1 n=36 (Mean ± SD)	Group 2 n=42 (Mean ± SD)	Group 3 n=39 (Mean ± SD)	p-value
Thirst score	6.33±1.58	5.86±1.73	6.41±1.16	0.210
Oral dryness score	6.33±1.14	5.86±1.53	6.10±1.23	0.290
Lips grading	1.94±0.41	1.98±0.15	2.00±0.00	0.619
Tongue grading	1.31±0.46	1.69±0.46	1.15±0.36	0.035*
Mucosa grading	1.03±0.16	1.02±0.15	1.00±0.0	0.017*
Saliva grading	1.39±0.49	2.12±0.32	2.28±0.45	0.001*

Values are mean ± SD; 2-way ANOVA test, * p-values≤ 0.05 considered significant

Table 3: Thirst score and oral dryness score at 1, 2 and 3 hours post-intervention in all 3 groups.

	Group 1 (n=36) Mean + S.D.	Group 2 (n=42) Mean + S.D.	Group 3 (n=39) Mean + S.D.	P-value
Thirst score @1hour	5.63±1.80	3.88±1.34	5.03±1.54	0.001*
Thirst score@2hour	6.03±1.85	2.51±1.07	4.08±1.66	0.001*
Thirst score@3hour	6.28±2.09	1.73±0.74	3.49±1.52	0.001*
Oral dryness score@1hour	5.61±1.74	3.69±1.19	4.97±1.75	0.001*
Oral dryness score@2hour	5.89±1.78	2.56±1.00	3.97±1.70	0.001*
Oral dryness score@3hour	6.19±1.96	1.61±0.73	3.28±1.52	0.001*
Lips grading @ 1hour	2.00±0.33	1.40±0.49	1.95±0.22	0.001*
Lips grading @ 2hour	1.81±0.40	1.12±0.33	1.64±0.48	0.001*
Lips grading @ 3hour	1.53±0.50	1.02±0.15	1.23±0.42	0.001*
Tongue grading @ 1hour	1.33±0.47	1.17±0.37	1.10±0.30	0.001*
Tongue grading @ 2hour	1.50±0.50	1.05±0.21	1.00±0.0	0.001*
Tongue grading @ 3hour	1.39±0.50	1.00±0	1.00±0	0.001*
Mucous grading @ 1hour	1.00±0	1.00±0	1.00±0	-
Mucous grading @ 2hour	1.00±0	1.00±0	1.00±0	-
Mucous grading @ 3hour	1.00±0	1.00±0	1.00±0	-
Saliva grading @ 1hour	1.64±0.48	1.50±0.50	1.87±0.52	0.005*
Saliva grading @ 2hour	1.89±0.32	1.12±0.33	1.56±0.50	0.001*
Saliva grading @ 3hour	1.69±0.52	1.00±0	1.08±0.27	0.001*

Values are mean ± SD; 2-way ANOVA test, p-value ≤ 0.05 considered significant.

Table 4: Patient satisfaction scale (1-5) and care giver satisfaction scale (1-5).

VARIABLES	GROUP 1 N=36	GROUP 2 N=42	GROUP 3 N=39	P- value
Patient Satisfaction Scale	1.56±0.6	2.98±1.17	3.18±0.68	0.001*
Care Giver Satisfaction Scale	1.53±0.6	3.43±1.15	1.67±0.53	0.001*

Values are mean ± SD

lip condition which was may be due to observer bias. While for Lipsense group, the mean difference in intensities for thirst score, oral dryness score, and oral condition of lips, tongue, mucosa, saliva was statistically significant except in case of mucosa which was not statistically significant. Similarly, for the wet gauge group, the mean difference in intensities for thirst score, oral dryness score, and oral condition of lips, tongue, saliva was statistically significant. In case of mucosa, it could not be computed. The mean scores of patient satisfaction measured by NRS showed that Lipsense group had significantly better patient satisfaction score i.e. 2.98 in comparison to the control group where it was 1.56 (p- value 0.001). The difference was not statistically significant between Lipsense and wet gauge group. Patient satisfaction was also better in the wet gauge group in comparison to the control group. Also.the mean scores of caregiver satisfaction measured by NRS (1-5) were 1.53, 3.43, 1.67 respectively for the control group, Lipsense group and the wet gauge group. Using the Bon Ferroni equation, Lipsense group had significantly better caregiver satisfaction out of the three groups. However, the difference was not statistically significant between the control group and the wet gauge group (Table 4).

Discussion

Post-operative thirst is a common problem with more than half of post-operative patients complaining of moderate to severe thirst [7]. However, clinicians are not very concerned about its occurrence and there is still no consensus on optimal management of postoperative thirst. The most commonly used modalities to manage postoperative thirst include use of wet cotton swabs, chewing gums, acupressure, early fluid ingestion etc [6].

Our results demonstrated that Lipsense relieved thirst and oral dryness for patients in distress because of thirst, after receiving general anesthesia. Because the perception of thirst has multiple components, we therefore used 4 scales, i.e. oral grading, lip grading, mucosa grading and salivation score in addition to the thirst score. As thirst is a behavioral response, NRS can be considered as the gold standard for studying a symptom that is based on an individual's perceptions. Hence, this study is justified to assess the effectiveness of Lipsense device compared with the wet gauge or no care for thirst relief.

The demographic and intraoperative variables were comparable for all the 3 groups, including the baseline thirst and oral dryness intensity scores. Both Lipsense and wet gauge caused a significant reduction in thirst intensity when compared to the control group. Lipsense resulted in a greater reduction, i.e. 72% as compared to our hypothesis of 35% reduction. Wet gauge resulted in a 46% reduction in thirst intensity. The thirst scores measured reduced significantly in the Lipsense group from 5.86 to 1.73, mean difference of 4.12 ± 1.66(p value 0.001); in wet gauge group from 6.40 to 3.49, mean difference of 2.92 ± 1.13 (p value 0.001). Similarly, the oral dryness score in Lipsense group reduced significantly from 5.86 to 1.61, mean difference of 4.26 ± 1.53 and in wet gauge group from 6.10 to 3.28, mean difference of 2.82 ± 0.88 Hence thirst intensity and oral dryness scores decreased from “moderate” (NRS scores from 5 to 6) to “minimal” levels (i.e. scores from 1 to 4) [8]. This finding was also highlighted in the pilot study for Lipsense with 100% results in eliminating discomfort from thirst [6].

The reason for improvement appears to be that the moisture, from the application of Lipsense device and after applying wet gauze, had provided thirst relief by coming in contact with a part of the mouth. Lipsense is a thirst intervention that does not require swallowing of fluids to reach the stomach and therefore appears suitable for many patients especially gastrointestinal surgeries, where they are not permitted to drink oral fluids or are unable to swallow due to other reasons [9]. Hydration helps reduce the incidence of adverse postoperative consequences and hence achieving higher patient satisfaction [10]. However, the effects were temporary with wet gauge, thereby resulting in immediate dryness contrary to Lipsense which gave continuous relief. This was also highlighted by Oh et al, where wet gauge decreased thirst significantly to a mean score of 5.63, but was not as effective as aroma gargling which reduced score to 5.20 [11].

The scores for thirst and oral dryness were reduced significantly within the first hour of intervention in the Lipsense group, in contrast to the wet gauge group, where the reduction was evident only after 2 hours, i.e. after the 2nd application. The oral condition assessment tool showed similar results with regards to lips showing significant improvement with Lipsense at the 1st hour itself. Other scores for tongue and saliva showed improvement for both Lipsense and wet gauge groups at 2nd hour. Another study in ICU showed that using wet gauze with cold saline caused improvement in oral condition as mean values of lips, tongue, mucosa, saliva score of the oral assessment tool showed a significant decrement [12]. Arai S. et al, in their research found a significant difference in the oral condition in the experimental group who had used normal saline and the control group who used tantum (benzydamine liquid used as mouth rinse) solution [4].

In contrast, the caregiver satisfaction scores were significantly higher in the Lipsense group as compared to the control group where no intervention was offered because patients repeatedly complained of thirst. Patients were able to regulate, to some extent, the amount of water that they wanted according to their thirst in a controlled manner. Hence it caused better patient satisfaction. Also, the caregivers were able to devote their concentration to other sicker patients by not getting constantly being called over, for unrelieved thirst.

Out of 42 patients in the Lipsense group, only 1 patient reported nausea in Lipsense group. Despite many interventions for example swabs, ice cubes, and lemonade, to alleviate the patient's thirst, it remains an issue. Currently, there is no standard way of removing the constant feeling of thirst and dryness in the surgical patient. Lipsense proved to be an efficacious alternative in relieving thirst significantly in the first hour of the application itself. Also, minimal side effects were reported, in terms of nausea and vomiting i.e. 0.8%. Henceforth, it is safe, easy to use the device, which keeps the mouth free by the irrigation dripper allowing communication and providing patients with more postoperative independence.

Some limitations of the device were observed. As it was available in a single size, misfit resulted in thin patients, three patients reported leaking from the sides. Lipsense needs some active effort on part of the patient, especially if the thirst is moderate to severe as poor effort resulted in lower scores being reported, at the time of evaluation. Although its cost may not allow its proficient use especially in hospitals, the amount of discomfort experienced by the patient and thereby the relatives may persuade them to go for it eventually. Also giving oxygen to the patient via facemask/ venturi mask postoperatively interferes with the device placement, but nasal prongs could be used easily. Some limitations of this study like a bigger sample size could have been selected. Blinding was not possible as the continously attached Lipsesnse device at the time of evaluation could not allow blinding to the observer.

From the results, we can conclude that there was a significant reduction in thirst intensity in both, the Lipsense group and the wet gauge group. As suggested by our hypothesis, the reduction was greater with the Lipsense group.

Author Statements

Declarations

Ethical approval: The study was conducted after taking clearance from the institutional ethical committee (NK/4801/MD/012), prospective registration with the Clinical Trials Registry of India (CTRI/2019/03/018091)

Authors Contributions

RS: This author helped with concept, design, manuscript writing and editing; AG: This author helped with manuscript writing, cases and statistical analysis; VS, SS: These authors helped with concept, design, manuscript writing; WK, SB and RC: These authors helped manuscript review and editing.

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