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Effect of Pre-op Vitamin D level on functional recovery in immediate post TKR period.

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Abstract:
Background: *It's well known that Vitamin d influences the development and maintenance of bone mass and reduce the risk of osteoporosis. It also improve lower limb neuromuscular function. TKR is advised to a patient when the knee has reached end-stage and conservative measures don't seem to work. The primary goal of TKR is to relieve pain and help you resume normal activities. TKR also helps to improve knee function, mobility and to correct deformity. It improves the overall quality of life for the patient. There are several studies which proves poor patient related output measure (PROM`S) following THR or TKR.*
Methods:*This is a prospective cohort study that include 64 patients. Patient were divided in to two groups (n=32 each) according to their Vitamin D level assessed on the day of admission; Group A vitamin D deficient group with serum vitamin D level <30 ng/ml; Group B vitamin D sufficient group with serum vitamin D level ≥ 30ng/ml. Group B was further divided in two subgroups (n=16 each), subgroup B1 with serum vitamin D level ≥30 ng/ml to ≤ 50ng/ml: subgroup B2 with serum vitamin D level > 50ng/ml. Functional performance tests like TUG (Timed up & Go) Test, ROM (Range of Motion) were performed on Day of admission and Day 3 & Day 14 of postoperative period and NKSS (New knee society score) was recorded one day before and three months after TKR to assess their functional performance in post-operative period. Pain assessment tools like VAS (Visual Assessment Score) And PCA (Patient Controlled Anaesthesia) consumption were also used to compare pain threshold post-operatively between various groups.*
Result:*The mean time taken for post-operative TUG test was significantly higher for vitamin D-deficient group A than vitamin D sufficient group B1 and B2 at day 3 and day 14 clinically but was not statistically significant (F= 0.4, NS, P=0.7 at Day 3and F= 1.1, NS, P=0.3 at Day 14). The mean values of ROM in post-operative period was significantly lower for vitamin D-deficient group A than in the vitamin D sufficient group B1 and B2 at day 3 and day 14 clinically but these were not statistically significant (F= 0.7, NS, P=0.5 at Day 3 and F= 2.4, NS, P=0.1 at Day 14). The mean values of VAS in post-operative period were comparable (F= 1.1, NS, P=0.3 at Day 3 and F= 0.3, NS, P=0.7 at Day 14) in all three groups, vitamin D-deficient group A and vitamin D sufficient group B1 and B2 clinically at day 3 and day 14 but with no statistically significant difference. The mean consumption of PCA was higher in vitamin D-deficient group A than in the vitamin D sufficient group B1 and B2 clinically at day 2 but these were not statistically significant (F=1.4, NS, P=0.26). The mean values of NKSS in post-operative period were comparable (F=0.1,NS,P=0.9).in all three groups, vitamin D-deficient group A and vitamin D sufficient group B1 and B2 clinically at 3 months with no statistically significant difference.*
Conclusion:*There was no difference in functional outcome between vitamin D deficient group and vitamin D sufficient group, however the trend with both range of motion and TUG test was that it was better with vitamin D sufficient group but statistically difference was not significant also the mean PCA consumption, there was no significant difference between vitamin D deficient group and vitamin D sufficient group, however the trend was that there was higher consumption of PCA in vitamin D deficient group but statistically difference was not significant. So we recommend, may be in a study where larger number of patient are studied, the difference may come out to be significant*
Key words:*Total knee replacement, Vitamin D, NKSS, Functional outcome after TKR*

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I. Introduction

Knee replacement surgery was first performed in 1968. Joint replacement surgery is a safe and effective procedure to relieve pain, correct leg deformity, and helps one resume normal activities.

Total Knee Replacement (TKR) is a type of surgery in which arthritic or the worn-out rough surfaces of the knee joint are removed and replaced with artificial material. The primary goal of TKR is to relieve pain

and help you resume normal activities. TKR also helps to improve knee function, mobility and to correct deformity. It improves the overall quality of life for the patient.

It is well known that vitamin D influences the development and maintenance of bone mass and reduces the risk of osteoporosis. Furthermore, it is also thought to improve lower limb neuromuscular function. The beneficial effects of vitamin D on the absorption and use of calcium and phosphorus, its contribution to the development of solid bones, and its ability to reduce the risk of osteoporosis are recognized by different health authorities, including Health Canada, the U.S. Food and Drug Administration (FDA), the Institute of Medicine (IOM) and the European Food Safety Authority (EFSA). According to these agencies, data support the conclusion that there is an independent cause-and-effect relationship between calcium and vitamin D intake and the growth, development and maintenance of bones and teeth, and a reduced risk of osteoporotic fracture.

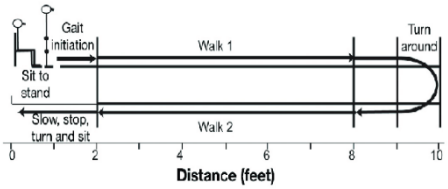
Vitamin D regulates blood calcium levels by improving the intestinal absorption of calcium and minimizing its elimination in the urine. It also plays a role in the deposit of calcium in bone and the removal of calcium from bone to meet the body's needs. A vitamin D deficiency results in a low absorption of calcium and elevated concentrations of parathyroid hormone (PTH), a hormone that acts to increase blood calcium levels by releasing calcium from the bones.

Over the long term, vitamin D deficiency leads to a loss of bone mass, which weakens the bones and causes osteoporosis. Adequate vitamin D intake decreases bone loss by reducing the secretion of PTH and prevents excessive bone remodeling (bone turnover). Several data show that high bone remodeling rates increase bone fragility.

The extra-skeletal effects of vitamin D are well documented, affecting almost every cell type through the vitamin D receptor, and deficiency has been linked to a myriad of conditions, including cancer, auto-immune disease, cardio-respiratory disease and depression. There are several studies which proves Vitamin D deficiency has been linked to poorer patient-reported outcome measures (PROMs) following total hip replacement (THR) and total knee replacement (TKR). A similar result was found in patients undergoing TKR by study done by Shin et al (2017), and reported a statistically significant lower functional Knee Society score, as well as a longer 6-m walk time, following TKR surgery in patients with vitamin D deficiency than in those with a normal level. In a German study of over 1000 arthroplasty patients, vitamin D deficiency was associated with a significantly longer stay following surgery, by 4.3 days (mean 15.6 vs. 11.3 days), even when adjusting for confounders in multivariable analysis . The same authors reported a significantly greater prevalence of vitamin D deficiency in patients presenting at their unit for revision surgery due to peri-prosthetic joint infection, compared with those presenting with aseptic loosening or for primary surgery.

Knee range of motion (ROM) and physical functional performance are major outcomes after TKA. Preoperative measures of joint function and functional performance are robust predictors of postoperative outcomes8. However, clinicians often do not have access to preoperative outcome measures in the postoperative clinical setting.

The TUG test measures the time it takes a patient to rise from an armed chair walk 3 meters, turn, and return to sitting in the same chair. Patients were instructed to walk as quickly as they felt safe and comfortable. A stopwatch was used to measure the time to complete the TUG within the nearest one hundredth of a second. The TUG is widely used to measure mobility in older adults with excellent test-retest reliability.

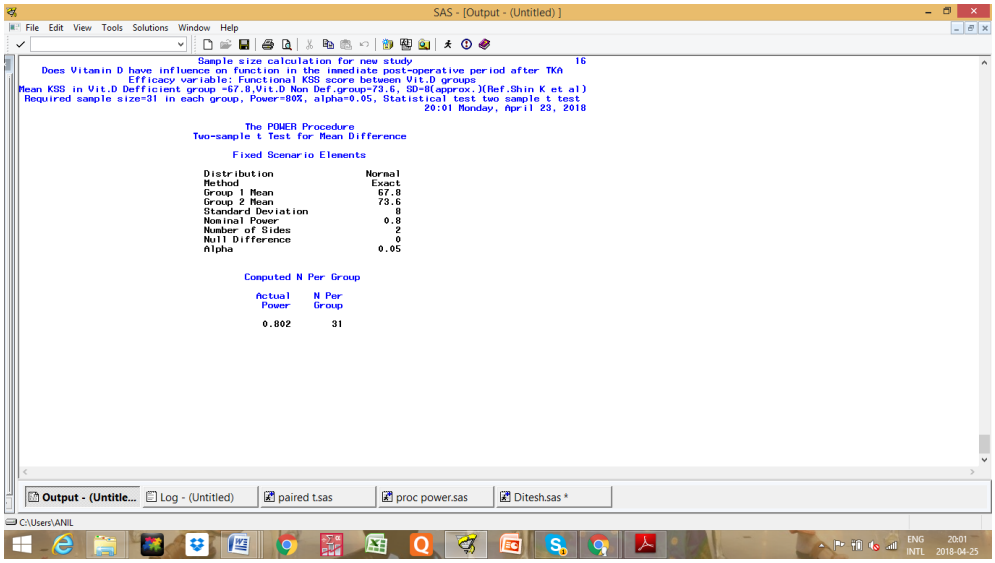


The new Knee Society Knee Scoring System is physician and patient derived. It includes versions to be administered preoperatively and postoperatively. Patients then record their satisfaction, functional activities, and expectations. The new Knee Society Knee Scoring System has been developed and validated, in part, to better characterize the expectations, satisfaction, and physical activities of current patients undergoing TKA. The new score provides sufficient flexibility and depth to capture the diverse lifestyles and activities of patients.

II. Methods

Study Design:This is a prospective cohort study that include 64 patients.
Study Location: This was tertiary care teaching hospital based study done in Department of Orthopaedics at Lilavati Hospital and Research Center, Bandra, Mumbai, India.
Study Duration: 12 Months from March 2018 to March 2019.
Sample Size: 64 Patients

Sample size calculation:
Sample size was determined using SAS 9.2 statistical package. Estimates taken for sample size calculation
Efficacy variable: Functional KSS score between Vit.D groups
Null Hypothesis H0: Mean KSS in Vit.D Deficient group =67.8, Vit.D Non Def. Group=73.6, SD=8(approx.) (Ref. Shin K et al)[2]
Required sample size=31 in each group, Power=80%, alpha=0.05, Statistical test two sample t test



Subject and Selection Method: Patient were divided in to two groups (n=32 each) according to their Vitamin D level assessed on the day of admission; Group A vitamin D deficient group with serum vitamin D level <30 ng/ml; Group B vitamin D sufficient group with serum vitamin D level ≥ 30ng/ml. Group B was further divided in two subgroups (n=16 each), subgroup B1 with serum vitamin D level ≥30 ng/ml to ≤ 50ng/ml: subgroup B2 with serum vitamin D level > 50ng/ml
Functional performance tests like TUG (Timed up & Go) Test, ROM (Range of Motion) were performed on Day of admission and Day 3 & Day 14 of postoperative period and NKSS (New knee society score) was recorded one day before and three months after TKR to assess their functional performance in post-operative period. Pain assessment tools like VAS (Visual Assessment Score) And PCA (Patient Controlled Anesthesia) consumption were also used to compare pain threshold post-operatively between various groups.

 Inclusion Criteria:
1. All the patients undergoing primary unilateral total knee replacement and who were able to perform functional assessment test on the day of admission.
2. Patient of both sex Male & Female were included.
3. Patients able to understand and provide informed consent for study and fill the questionnaires.

 Exclusion criteria:
1. All the patients above age of 80 years.
2. Patients undergoing bilateral total knee replacement surgery.
3. Patients undergoing revision total knee replacement surgery.
4. Patients with Valgus knee deformity Pre-operatively.
5. Patient with Trauma History to the knee.
6. Patient with any neurological Disease.
7. All patients who developed any post-operative complication and are unable to continue in the study was excluded from study.

III. Procedure and Methodology:

Pre-operative Protocol:
Pre-operatively all the patients had undergone a thorough work-up 15 days prior to surgery by a team of physician, cardiologist, and anaesthetist for fitness. Any patient with co-morbidities were optimized before taking the patient for surgery.

Written and informed consent was taken. Serum vitamin D level, New KSS Score, ROM test and TUG Scoring was done and recorded. All the patients was divided in two major groups based on serum vitamin D, i.e. Group A and Group B.

Intra-operative Protocol:

Patients were taken up for surgery by same surgeon under Regional Anesthesia or General Anesthesia. All patients had a similar surgical approach. Total knee replacement was performed for all in similar surgical fashion following standard of protocols.

Post-operative protocol:

The patient's knee was immobilized in compressive bandage immediate post operatively. Patient was made to stand and walk few steps in the evening

First post op day: In bed exercise with walking out of room with walker and commode chair training started. Post-op check dressing done & Drain was removed.

Second Postoperative day: Intravenous antibiotics and painkiller were stopped and patient was put on oral pain killers. Postoperative x-ray of knee taken in all subjects. Physiotherapy was continued.

Third Postoperative day: High commode training and staircase climbing was done and most patient gets discharged. TUG scoring and ROM was assessed.

Day 14th Postoperative day, Sutures were removed and patient was advised to continue regular physiotherapy. TUG scoring and Rom was assessed and recorded.

Final Follow up

Patient in study groups were assessed finally at 3 month from the date of surgery and New KSS (Knee Society Score) was obtained to analyse function outcome.

Statistical Analysis:

Data was analysed using SPSS V15.0 (Statistical Package for Social Sciences, Version 15.0). Data was given as Mean ± SD (n) for continuous data and Number (Percentage) for categorical data .Comparison of means was carried out by Student's unpaired t test for numerical data. Fisher Exact Probability test or Chi square tests was applied to compare percentages for categorical data. Student's paired t test was applied to compare paired data at Pre and Post values. If the data are non-normal, corresponding non parametric tests Mann Whitney U test or Wilcoxon Signed Rank test was applied. All statistical tests was two tailed. Alpha (α) Level of Significance was taken as $P<0.05$.

IV. Results

All groups were demographically compatible. The functional performance was evaluated between Group A and Group B based on appropriate statistical analysis test.

Table 1C: Demographic Data and distribution in study population;

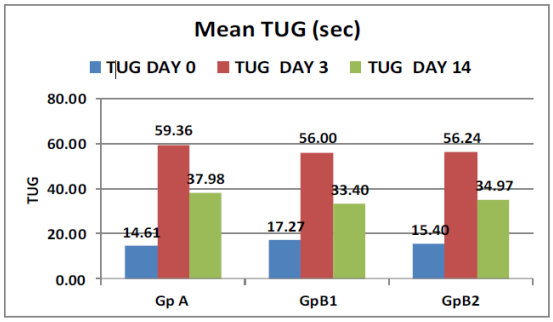
DEMOGRAPHIC	Gp A (n=32)	Gp B1 (n=16)	Gp B2 (n=16)	P-VALUE
HEIGHT	158.38 ± 10.13	155.09 ± 6.79	154.69 ± 6.27	F=1.3,NS, P=0.3
WEIGHT	80.69 ± 16.05	77.69 ± 10.84	70.84 ± 9.73	F=2.8,NS, P=0.07
BMI	32.18 ± 4.13	32.36 ± 4.52	29.74 ± 4.14	F=2.1,NS, P=0.10
AGE	64.94 ± 7.81	65.56 ± 4.76	66.44 ± 7.26	F=0.2,NS, P=0.8

Statistical Test

ANOVA One Way and Post hoc Scheffe

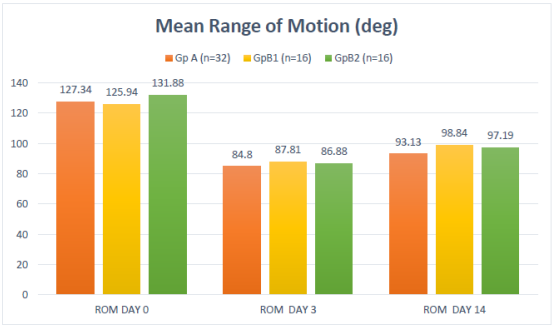
Conclusion: No Significant Difference for Height, Weight, BMI& Age among 3 groups

The mean time taken for post-operative TUG test was significantly higher for vitamin D-deficient group A than vitamin D sufficient group B1 and B2 at day 3 and day 14 clinically but was not statistically significant (F= 0.4, NS, P=0.7 at Day 3and F= 1.1, NS, P=0.3 at Day 14).



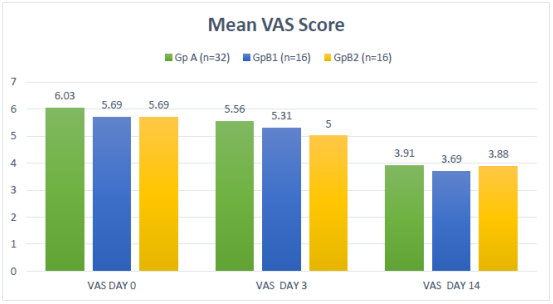
TUG (sec)	Gp A (n=32)	GpB1 (n=16)	GpB2 (n=16)	P-VALUE
TUG DAY 0	14.61 ± 3.60	17.27 ± 6.06	15.40 ± 3.85	F= 2.0, NS, P=0.15
TUG DAY 3	59.36 ± 14.09	56.00 ± 10.29	56.24 ± 17.10	F= 0.4, NS, P=0.7
TUG DAY 14	37.98 ± 13.35	33.40 ± 8.12	34.97 ± 6.32	F= 1.1, NS, P=0.3

The mean values of ROM in post-operative period was significantly lower for vitamin D-deficient group A than in the vitamin D sufficient group B1 and B2 at day 3 and day 14 clinically but these were not statistically significant (F= 0.7, NS, P=0.5 at Day 3 and F= 2.4, NS, P=0.1 at Day 14).



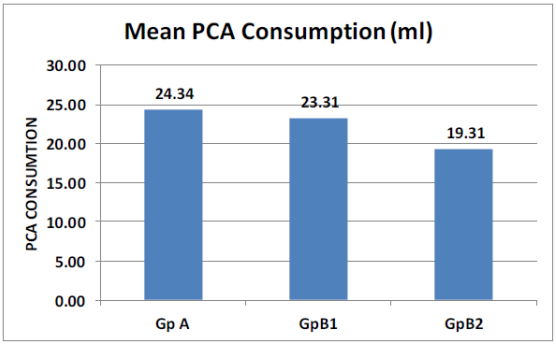
ROM (deg)	Gp A (n=32)	GpB1 (n=16)	GpB2 (n=16)	P-VALUE
ROM DAY 0	127.34 ± 16.21	125.94 ± 17.82	131.88 ±14.36	F= 0.6, NS, P=0.5
ROM DAY 3	84.88 ± 10.11	87.81 ± 6.32	86.88 ± 5.12	F= 0.7, NS, P=0.5
ROM DAY 14	93.13 ± 9.31	98.44 ± 10.76	97.19 ± 4.46	F= 2.4, NS, P=0.1

The mean values of VAS in post-operative period were comparable (F= 1.1, NS, P=0.3 at Day 3 and F= 0.3, NS, P=0.7 at Day 14) in all three groups, vitamin D-deficient group A and vitamin D sufficient group B1 and B2 clinically at day 3 and day 14 but with no statistically significant difference.



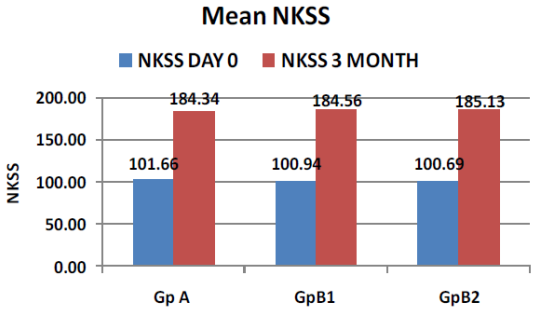
VAS	Gp A (n=32)	GpB1 (n=16)	GpB2 (n=16)	P-VALUE
VAS DAY 0	6.03 ± 1.00	5.69 ± 1.20	5.69 ± 1.14	F= 0.8, NS, P=0.5
VAS DAY 3	5.56 ± 1.27	5.31 ± 1.30	5.00 ± 1.21	F= 1.1, NS, P=0.3
VAS DAY 14	3.91 ± 1.06	3.69 ± 0.87	3.88 ± 0.50	F= 0.3, NS, P=0.7

The mean consumption of PCA was higher in vitamin D-deficient group A than in the vitamin D sufficient group B1 and B2 clinically at day 2 but these were not statistically significant (F=1.4, NS, P=0.26).



PCA (ml)	Gp A (n=32)	GpB1 (n=16)	GpB2 (n=16)	P-VALUE
PCA COMNSUMTION	24.34 ± 9.70	23.31 ± 11.88	19.31 ± 8.59	F=1.4, NS, P=0.26

The mean values of NKSS in post-operative period were comparable (F=0.1,NS,P=0.9).in all three groups, vitamin D-deficient group A and vitamin D sufficient group B1 and B2 clinically at 3 months with no statistically significant difference.



NKSS	Gp A (n=32)	GpB1 (n=16)	GpB2 (n=16)	P-VALUE
NKSS DAY 0	101.66 ± 22.89	100.94 ± 26.84	100.69 ± 26.86	F=0.1,NS,P=0.9
NKSS 3 MONTH	184.34 ± 18.80	184.56 ± 22.69	185.13 ± 28.79	F=0.1,NS,P=0.9

V. Discussion

Vitamin D also play a significant role in musculoskeletal function and activities. *KY Shin et al* [1], in his study has proven the detrimental effect of Vitamin D deficiency on functional performance after TKR. Vitamin D deficiency can lead to poor functional performance, increase risk of falls, decrease muscle strength is well proven. Vitamin D deficiency is very common in certain risk groups, such as children with low birth weight (premature and small for gestational age), pregnant women, older people, and non-Western immigrants. Vitamin D status can be poor in adolescents as is seen in studies in Europe, the Middle East, and Asia. Pregnant women, especially non-Western pregnant women and their children, are at high risk of vitamin D deficiency.[2]

Hennie CJP Jansen et al[3] study demonstrate that vitamin D deficiency greatly influence the muscle function and increase risk of fall in elderly population. Healthy elderly people, is accompanied by a reduction in muscle mass and muscle strength. The gradual loss of muscle strength (below a certain threshold) results in functional impairment

Wicherts et al[4], studied that Serum vitamin D level is associated with physical performance of an individual. Compared with individuals with serum Vitamin D levels above 30 ng/ml, physical performance was poorer in participants with serum vitamin D less than 10 ng/ml

Ajay G et al[5], studied the Vitamin D Deficiency in India and its prevalence. Countrywide studies have reported vitamin D deficiency in as high as 70%–100% of ostensibly healthy individuals. High prevalence of vitamin D deficiency was reported from northern to southern and western to eastern India, in ostensibly healthy children, adolescents, young adults and those ≥50 years old. All over India, vitamin D deficiency was highly prevalent in pregnant women and lactating mothers.

Jansen and Haddad[3] studied the plasma 25(OH) D3 levels measured in a group of 139 elderly patients with advanced OA. In 33 patients (24%), a vitamin D deficiency (< 40 nmol/L) was found and in all cases, it was associated with a secondary hyperparathyroidism. The mean preoperative Knee Society Score (KSS) was significantly lower in the vitamin D deficient group than in the vitamin D sufficient group[6].

In this study it is concluded that TUG test time taken by Group A is more than Group B1 and B2 on day 3 and day 14 as indicated by mean TUG test score. These findings were consistent with the findings of *Keun-Young Shin et al*[2] which shows that at 3 month post-operative period TUG test time has higher values for mean time taken in the vitamin D-deficient group than in the vitamin D non-deficient group. It is also concluded that ROM achieved by Group A is less than Group B1 and B2 on day 3 and day 14 as indicated by mean ROM;

These findings were also consistent with the findings of *Keun-Young Shin et al* as range of motion in integral part of the NKSS we can say it's consistent with the findings.

Here we can conclude that VAS was comparable in all three groups post-operatively as there was no statistical difference.

Although the study done by *Pinar Kuru et al)*[7] shows that there was significant difference in VAS score between Vitamin D deficient and sufficient group but my study didn't show any significant difference may be due to smaller sample size.

The PCA consumption was lower in Group B1 and B2 as compared to group A.

This finding is consistent with finding of *Anna Lee et al*[8] as they have found that hypo-vitaminosis D is consistent with increased intensity of pain in post-operative period.

VI. Conclusion

In our study, there was no difference in functional outcome between vitamin D deficient group and vitamin D sufficient group, however the trend with both range of motion and TUG test was that it was better with vitamin D sufficient group

The mean PCA consumption, the trend was that there was higher consumption of PCA in vitamin D deficient group but statistically difference was not significant. So we recommend, may be in a study where larger number of patient are studied, the difference may come out to be significant

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