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Original Research Article

Efficacy of once a week versus daily supplementation of 200 mg of ferrous sulphate for control of anaemia in school going menstruating adolescent girls

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ABSTRACT

Background: Anaemia is one of the most common global public health problem among adolescents affecting developing and developed countries with major consequences for health as well as socio-economic development. India accounts for high prevalence of anaemia in adolescent girls. The objective of the study was to find the efficacy of once a week vs. daily oral iron supplementation of 200 mg of ferrous sulphate, in terms of increase in haemoglobin levels, in mild and moderate anaemic menstruating adolescent girls.

Methods: Total 588 menstruating adolescent girls studying in selected eight schools of Handignur PHC were included in the study. Structured questionnaire was administered. Haemoglobin estimation was done at baseline, one, two and three months of iron supplementation. Data was analyzed by SPSS 16.0 version. Intention to treat analysis was carried out.

Results: Prevalence of anaemia in menstruating adolescent girls was 94.6% (95% CI 92.83 to 96.37). There has been statistically significant increase in mean haemoglobin in daily at the end of two and three months of supplementation ($p<0.001$). At the end of three months of iron supplementation haemoglobin values became normal at 75th percentile in daily group and at 90th percentile in weekly group.

Conclusions: The present study concludes that daily iron supplementation results in much higher levels of haemoglobin at the end of three months when compared with once a week supplementation. All the adolescent girls need iron supplementation-daily for anaemic and once a week for non-anaemic girls.

Keywords: Anaemia, Adolescent girls, Menstruation, Daily supplementation, Ferrous sulphate, Open label trial

INTRODUCTION

Anaemia, affects both developing and developed countries with major impact on human health as well as social and economic development.[1] Adolescent girls are particularly more prone to get affected by anaemia because after first year of life they are growing faster than the growth at any time of life. Early marriage and adolescent pregnancy aggravate anaemia and result in poor iron stores in the offspring.[2] Globally anaemia affects 1.62 billion people with about 293 million children of preschool age, 56 million pregnant women, and 468 million non-pregnant women.[3] Highest prevalence of anaemia is in World Health Organization regions of South-East Asia, Africa, and Eastern Mediterranean regions.[4] In high-risk groups, the burden of anaemia in Africa and Asia account for more than 85%, India being the worst hit. Studies conducted in Bangladesh, Indonesia, Nepal, Myanmar, and Sri Lanka reported that the prevalence of anaemia in adolescent girls ranges from 26.4% to 70.1%.[5-9] In India, the prevalence of anaemia is high because of low dietary intake of iron i.e. less than 20 mg/day and folic acid intake i.e. less than 70 µg/day, poor bioavailability of iron (3-4% only) in phytates and fibre-rich Indian diet; and chronic blood loss due to infections such as malaria and hookworm infestations.[10,11] The apparent reduction in iron intake in the NNMB surveys 2000-2001 and beyond was due to the fact that only 50 percent of the iron in Indian diets is absorbable.[12] Adolescence is a crucial period of life as it offers the second and last chance to catch up growth in the life cycle. This period begins when the secondary sexual characteristics appear and ends when somatic growth is completed and the individual is psychologically mature, capable of becoming a contributing member of society. Nutrient requirements are increased during adolescent age to support a period of dramatic growth and development. If adolescent girls eat right food at right time, nutritional deficiencies especially iron deficiency anaemia will be controlled.[13] Indians have the lowest rate of meat consumption in the world. Indian diet is generally deficient in food rich in iron. Approximately only 30% of the people in India consume meat. They do so infrequently because of cultural and economic reasons.[14] In India, an estimated 14.2 million adolescent girls are married at an early age every year of which most of the adolescent girls are anaemic and are at an increased risk of preterm delivery and low birth weight babies. These babies are likely to be ill and do not reach the age of one year. There is increased risk of maternal death for anaemic adolescent girls when they grow into adult women with compromised growth, both physical and mental. About one third of all maternal deaths take place in young women in the age group of 15 to 24 years.[15,16] Although several studies have been carried out on the efficacy of once a week vs daily iron supplementation in developed and developing countries, the results of some studies have not been conclusive. Some studies have reported that weekly iron-folic acid supplementation (WIFS) is a preventive long term approach to improve iron status and also for reducing the prevalence of anaemia.[17] The administration of daily oral iron results in iron doses far exceeding the capacity of an individual to assimilate (absorbs, utilize, and metabolize) iron safely. In various studies, the positive impact of WIFS reported the "mucosal block" hypothesis, wherein administration of iron every seven days allows time for shredding of cells loaded with iron from a previous dose, thereby increasing iron absorption.[18,19]

In view of the several controversial results of various studies, this study on the efficacy of once a week vs daily supplementation of 200 mg of ferrous sulphate for control of anaemia in school going menstruating adolescent girls has been undertaken.

METHODS

An efficacy of once a week vs daily supplementation of 200 mg of ferrous sulphate for control of anaemia in school going menstruating adolescent girls was carried out using a stratified individually randomized open label control trial study design. The study was carried out from 11th August 2009 to 24th August 2015. Total 588 menstruating adolescent girls studying in selected eight schools of Handignur PHC from Belgaum district, Karnataka, India were selected based on power analysis formula.

As the prevalence of anemia varied from 60-70%, hence, the lowest 60% has been considered for computing sample size with 20% effective size (reduction in prevalence by iron supplementation) at 95% confidence interval and 80% power (non inferiority trial).

$$N = \frac{2\times(Z1-\alpha/2+Z1-\beta/2)\ 2\times P\times Q}{\text{Effect size}^2}$$

Where P = Prevalence of anemia 60%

d = Reduction in prevalence by 20% (12 percent points)

Q=100-P, $Z1-\alpha/2 = 1.96$, $Z1-\beta/2 = 1.28$

$n = 2\times(1.96+1.28)^2\times60\times40/(12)^2 = 350$

The sample size has been increased to 500 to account for follow up and non-response losses. Out of the total 624 menstruating adolescent girls, 588 anaemic girls were selected for the collection of baseline data after excluding 31 girls whose haemoglobin was normal. All the girls were treated with 400 mg of Albendazole. A total of 517 anaemic adolescent girls with Haemoglobin levels between 8-11.9 gm/dl were randomised into two groups. Stratified random sampling was used to select the samples. Menstruating adolescent girls who had fulfilled the inclusion criteria like studying in selected schools of higher primary and high schools of Handignur PHC and consented to participate in the study, those who attained menarche, in the age group of 12-16 years and studying in fifth to ninth standard and those who's haemoglobin less than 12 gm/dl were subjected to intervention based on computer generated randomization list into two groups. In group A, daily supplementation of 200 mg of ferrous sulphate (60 mg of elemental iron), in group B, weekly supplementation of 200 mg of ferrous sulphate (60mg of elemental iron). Adolescent girls having severe anaemia i.e. haemoglobin less than 8 gm/dl (referred to KLE's Hospital for treatment), had history of any bleeding disorders and known cases of systemic diseases, were excluded from the intervention. Ethical clearance was obtained from the Institutional Ethical Committee of KLE University. At baseline, structured questionnaire was administered to collect the socio-demographic information, knowledge and practice regarding anaemia and its prevention. Measurement of height and weight was done. All the girls were dewormed and haemoglobin estimation was carried out by cyanmethaemoglobin method. The drug was manufactured by Arya Pharmaceuticals, Indore.

The dose and duration of iron therapy in the present study was as per the standard recommendations. The center for disease control and prevention advocates 60 to 120 mg of elemental iron a day for a period of 2 to 3 months to treat anemia in adolescent girls.[1,3,5]

Haemoglobin estimation was done at baseline, one, two and three months of iron supplementation to know the improvement in two groups. Data was analysed by SPSS 16.0 version wherein frequency distribution and variation in the data were observed by calculating percentage, mean, median, standard deviation and percentiles. Association between haemoglobin levels and selected independent variable like socio-demographic features, menstrual pattern, bleeding days, was done using Chi square,' t' test and 'z' test. Chi square,' t' test, 'z' test and multivariate linear and logistic regressions were used to establish the differences between treatment and Haemoglobin levels in daily and weekly group. P value <0.05 was considered significant. Intention to treat analysis was carried out. (The registration number for this trial is CTRI/2017/11/010453).

RESULTS

Prevalence of anaemia in menstruating adolescent girls was 94.6% (95% CI 92.83 to 96.37), of whom 77.89% had moderate anaemia, followed by 12.07% severe and 10.03% mild anaemia. More than one fourth of adolescent girls were aged 13 years and 94.6%were Hindus by religion. Majority 33.7% of fathers of adolescent girls had secondary education, almost three fourth were from joint family and 64.14% were taking mixed diet. Consistent increase in mean height of menstruating adolescent girls of age 12 to 16 years was 1.30 meters to 1.52 meters and mean weight 28.7 kg to 45.9 kg. Mean BMI for the 12 and 13 years has been less than 18 (underweight) whereas the mean BMI of the girls at 14, 15 and 16 years have been within normal range (18.5-24.9). More than three fourth had heavy and regular/irregular 3-4 days bleeding during menstruation. Irrespective of their BMI, 79.3% were bleeding during menstruation for 3-4 days. Majority (82.14%) had normocytic normochromic type of anaemia. At baseline, 50th percentile of haemoglobin levels in daily and weekly supplementation groups were similar 9.8 gm/dl (respective mean- 9.65 with SD - 0.84, and Mean - 9.72 with SD - 0.84), whereas at one month, the similar figures were 10.2 gm/dl (Mean 10.13, SD 0.83) in daily and 10.1 gm/dl (Mean -10.00, SD - 0.83) in weekly regimen, at the end of two months 11.0 gm/dl (Mean 10.97, SD 0.76) in daily as compared to weekly group 10.6 gm/dl (Mean 10.47, SD 0.82), after three months of iron supplementation the haemoglobin values in the daily and weekly groups were 11.9 gm/dl (mean 11.84, SD 0.71) and 11.0 gm/dl (mean 10.94, SD 0.79) respectively. There has been statistically significant increase in mean haemoglobin in daily and weekly regimen at the end of two and three months of supplementation ($p<0.001$). Daily regimen girls reached to normal haemoglobin earlier i.e. 12.5 mg/dl at 75th percentile, however weekly regimen girls reached at 90th percentile. Almost 40% of the moderately anaemic adolescent girls in the daily group became normal at the end of three months when compared with 2% in weekly group. With respect to adolescent girls with mild anaemia, 96% became normal at the end of three months in daily group when compared with 70% in weekly group. Generalised multivariate regression model reveals that the regimen wise differences in haemoglobin levels at baseline (standardised for bleeding days, menstrual pattern, BMI and age) were not statistically significant, though the daily regimen haemoglobin levels were lower by 0.10 gm/dl as compared to weekly regimen at 9.96 gm/dl.

Table 1: Socio demographic characteristics of study subjects (n=588).

Variable	N	%
Age in years		
12	77	13.1
13	186	31.1
14	169	28.7
15	125	21.3
>16	31	5.3
Mother's education		
Illiterate	186	31.6
Primary	222	37.7
Secondary	120	20.0
Higher secondary	60	10.2
Father's education		
Illiterate	38	6.4
Primary	190	32.3
Secondary	198	33.6
Higher secondary	160	27.2
Graduate	2	0.34

Continued.

Variable	N	%
Type of family		
Nuclear family	158	26.8
Joint family	430	73.1
Type of diet		
Vegetarian	213	36.2
Mixed	375	63.7
Body mass index		
<18.5	264	44.8
18.5-24.9	289	49.1

Table 2: Comparison of mean height and body mass index of adolescent girls with WHO standards (n=588).

Age in years	Number	Mean height		Mean BMI	
		Mean	WHO standard	Mean	WHO standard
12	77	130	151.2	16.72	18.0
13	186	135	156.4	17.86	18.8
14	169	142	159.8	20.01	19.6
15	125	148	161.7	20.53	20.2
16	31	152	162.5	19.92	20.7

Table 3: Distribution of adolescent girls by number of bleeding days and severity of anaemia (n=588).

Hb levels (gm/dl)	No. of bleeding days of adolescent girls						Total	
	<3		3-4		>5			
	N	%	N	%	N	%	N	%
Severe (<8)	9	12.7	56	78.9	6	8.5	71	12
Moderate (8-10.9)	66	14.4	369	80.6	23	5	458	77.8
Mild (11-11.9)	17	28.8	41	69.5	1	1.7	59	10
Total	92	15.6	466	79.3	30	5.1	588	100

χ^2=11.10;df=4; p<0.03.

Table 4: Percentiles of haemoglobin levels at different months in daily and weekly regimen.

Percentiles	Hb values at different months in daily and weekly groups							
	Baseline		One month		Two months		Three months	
	Daily	Weekly	Daily	Weekly	Daily	Weekly	Daily	Weekly
5	8.2	8.3	8.9	8.7	9.6	9.0	10.6	9.6
10	8.6	8.7	9.1	8.9	10.0	9.4	10.9	10.0
25	9.0	9.0	9.4	9.4	10.5	9.9	11.3	10.4
50	9.8	9.8	10.2	10.1	11.0	10.6	11.9	11.0
75	10.2	10.3	10.7	10.6	11.6	11.0	12.5	11.5
90	11.0	11.0	11.6	11.3	12.1	11.8	12.9	12.0
95	11.1	11.1	12.0	11.5	12.8	12.0	13.4	12.5

Table 5: Generalised multivariate regression model to estimate haemoglobin levels at different assessment months standardized for bleeding days, menstrual pattern, BMI and age.

Parameter	Baseline	SE	One month	SE	Two months	SE	Three months	SE
	B		B		B		B	
Intercept	9.96	0.84	10.11	0.82	10.90	0.77	10.67	0.71
Regimen								
Daily	-0.10	0.09	0.10	0.09	0.49***	0.08	0.89***	0.08
Weekly	-	-	-	-	-	-	-	-
Bleeding days								
<3	0.43	0.22	0.39	0.22	0.38	0.21	0.43*	0.19
3-4	0.11	0.20	0.08	0.19	0.06	0.18	0.13	0.17
>5	-	-	-	-	-	-	-	-

Continued.

Parameter	Baseline B	SE	One month B	SE	Two months B	SE	Three months B	SE
Menstrual pattern								
Heavy and regular	0.23	0.47	0.24	0.46	0.26	0.43	0.36	0.40
Heavy and irregular	-0.01	0.48	0.04	0.47	0.07	0.44	0.19	0.41
Normal	0.03	0.52	0.02	0.51	0.02	0.48	0.33	0.44
Scanty	-	-	-	-	-	-	-	-
BMI								
<18	-0.76***	0.20	-0.67***	0.19	-0.73***	0.18	-0.67***	0.17
18-24.99	-0.25	0.19	-0.20	0.19	-0.27	0.18	-0.30	0.16
>25	-	-	-	-	-	-	-	-
Age in years	-0.03	0.05	-0.02	0.04	-0.04	0.04	0.00	0.04

Note: ***; p<0.001 and *; p<0.05.

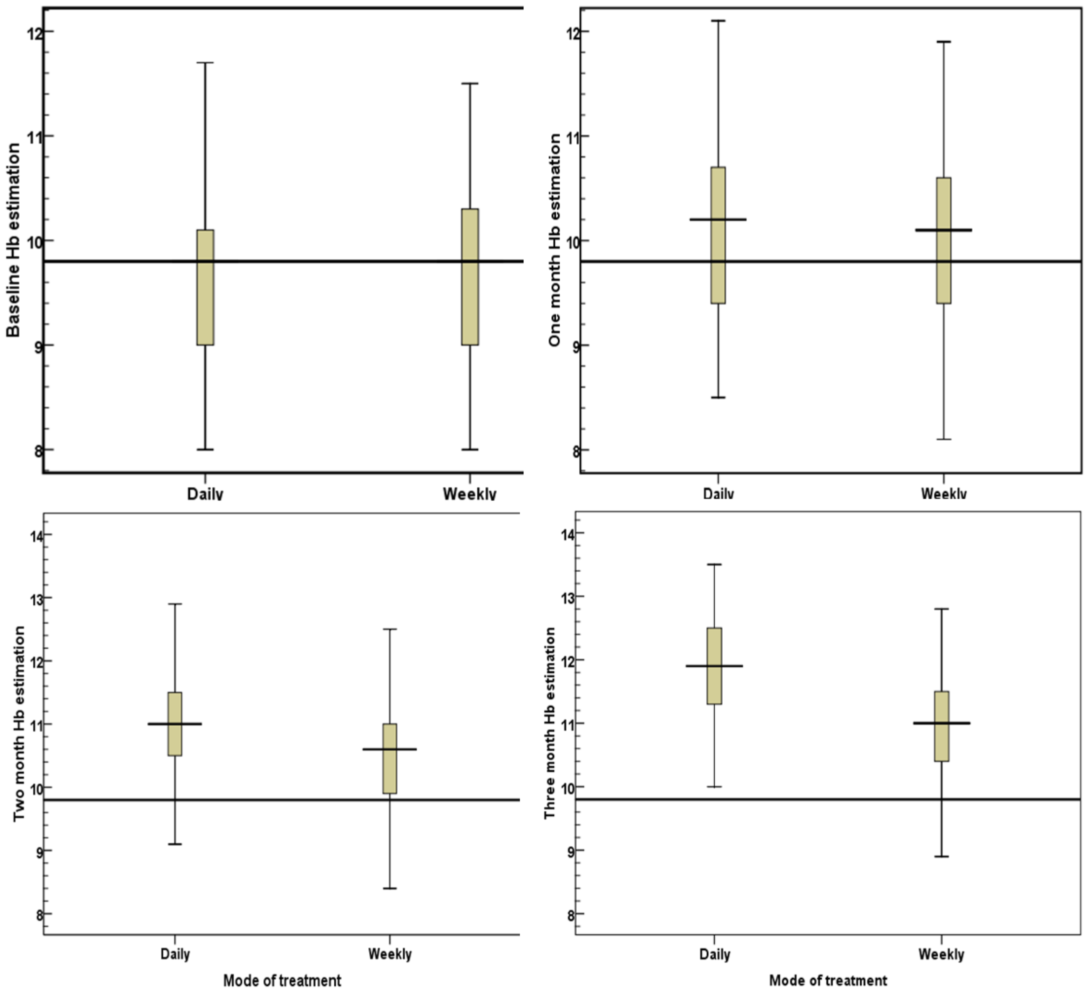

Figure 1: Box plot of haemoglobin levels at different months in daily and weekly regimen.

When these figures were compared with WHO child growth standards, our subjects were much more stunted in height at all the age groups. In comparison with WHO child growth standard our subjects mean BMI was slightly less for 12 and 13 years but almost same for14, 15 and 16 years.

More number of girls with severe and moderate degree of anaemia were bleeding for 3-4 days and more than 5days compared to those with mild anaemia where the proportion of girls bleeding for less than three days was highest.

After three months of iron supplementation the Hb values in the daily and weekly groups were 11.9 gm/dl and 11.0 gm/dl respectively. Adolescent girls from daily regimen reached to normal Hb earlier i.e. 12.5 gm/dl at 75th percentile. However adolescent girls from weekly regimen reached the same level at 95th percentile, though the normal Hb value of 12 gm/dl was reached at 90th percentile.

Regimen wise differences in haemoglobin levels at baseline were not statistically significant, though the daily regimen haemoglobin levels were lower by 0.10 gm/dl as compared to weekly regimen at 9.96 gm/dl.

At the end of three months of iron supplementation, daily iron supplementation had higher increase in haemoglobin levels i.e. 11.9 gm/dl than weekly 11.0 gm/dl respectively.

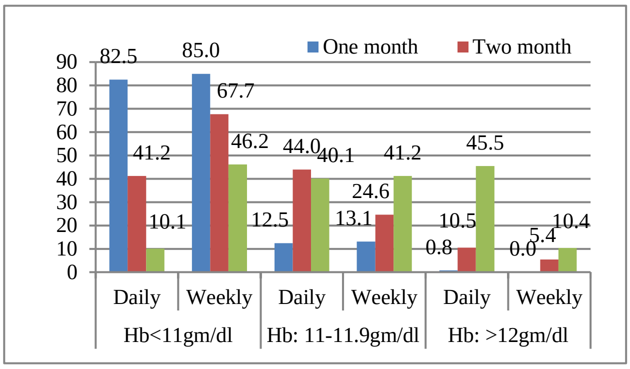

Figure 2: Improvement in haemoglobin levels at different assessment time by regimen in mild and moderately anaemic girls.

Above figure reveals that the girls who were moderately anaemic at baseline in the daily regimen (Hb <11 gm/dl), 82.5% after one month, 41.2% after two months and 10.1% after three months of iron supplementation remained moderately anaemic whereas in weekly supplementation group 85.0% after one month, 67.7% after two months and 46.2% after three months of iron supplementation remained moderately anaemic.

DISCUSSION

Although there was an increase in the number of girls as the age advanced, definite pattern was not observed. Out of the total 588 adolescent girls, slightly less than one third girls were of 13 years, the least being at the age of 16 years. This could be perhaps due to the fact that in rural areas the parents do not encourage their daughters to go for higher education after seventh standard. The majority 556 (94.6%) of adolescent girls were Hindus. Slightly less than 70% mothers and 93.5% fathers of adolescent girls were literate. When compared with Government of Karnataka figures, the female literacy is similar whereas literacy rates for males has been much higher in our study (Karnataka figure 82.47%).[21] As against this the literacy rates for females and males at the national level have been lower i.e. 59.4% and 82% respectively.[22] Slightly less than three fourths of the adolescent girls belonged to joint family.

Although the mean height of our adolescent girls has increased with increase in age, it has been less when compared with WHO standards. When the mean increase in height was compared with WHO child growth standards, our girls were much more stunted in height at all the ages, the difference being in the range of 10-25 cms indicating that all our adolescent girls are malnourished. As against this, the study conducted in Karad, Maharashtra revealed that the mean height of the adolescent girls was higher at 13 and 14 yrs and was almost equal to NCHS values.[23] Although there was gradual increase in mean weight from 12 to 16 years, the increase has been comparatively less between the ages of 15 to 16 years (Table 4). Several studies conducted at West Bengal and Tamil Nadu have also observed the similar results.[10,24]

More than 80% of the girls in our study had normocytic normochromic anaemia, followed by 59 (10.03%) microcytic hypochromic, 39 (6.63%) normocytic hypochromic and 7 (1.19%) dimorphic anaemia. In our girls it is mainly the nutritional deficiency that has led to anaemia. Whereas in a study conducted in rural area of Maharashtra, the pattern of peripheral smear was different where more than 50% of the girls had normocytic normochromic and 13.11% had dimorphic anaemia.[11]

In the present study, proportion of girls bleeding for 3-4 days was highest in severely anaemic (haemoglobin <8 gm/dl) and moderately anaemic (haemoglobin 8-10.9 gm/dl) girls. Proportion of girls having <3 days bleeding was highest in girls with mild anaemia. The difference observed was statistically significant ($p<0.03$). Although the bleeding has been only for 3-4 days, it has been heavy in most of the girls (>95%) and hence has resulted in moderate and severe anaemia.

At 50th percentile, baseline haemoglobin levels in daily and weekly supplementation of 200mg of ferrous sulphate groups were similar in our study i.e. 9.8 gm/dl. After one month of supplementation haemoglobin levels were slightly higher in the daily group. However, at the end of second month there was significant increase in haemoglobin levels in daily group when compared with weekly group. Similar results were observed at the end of three months. At the end of three months of iron supplementation haemoglobin values became normal at 75th percentile in daily group and at 90th percentile in weekly group. Several studies have also shown almost similar results.[25]

In our study, there was significant increase in mean haemoglobin levels in both daily and weekly group at the end of two and three months of iron supplementation ($p<0.001$), however increase is more in daily than in weekly group (Table 4, Figure 2). Similar results were seen in other studies which were conducted in developed and developing countries.[26] On the contrary some studies have revealed that weekly supplementation was as good as daily supplementation.[27,28]

CONCLUSION

The present study concludes that daily iron supplementation results in much higher levels of haemoglobin at the end of three months when compared with once a week supplementation. All the adolescent girls need iron supplementation-daily for anaemic and once a week for non-anaemic girls. If all the adolescent girls are provided with the much required iron supplementation till the age of 19 years through AWW's, school teachers and ANM's, it will be possible to achieve MDG 4 and 5 for India.

Limitation

The study was carried out in school going adolescent girls; hence, the results of the study may not be applicable to all rural girls, or all school going adolescent girls of the Belgaum District, or other parts of Karnataka. Therefore, a larger study may be required.

Since, the study was open labeled; there was the possibility of girls in the weekly group demanding for daily supplementation. This was overcome by explaining the protocol in detail to all the study participants and clarifying all the doubts.

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