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TREATING ANEMIA WITH IRON /FOLATE CAN ERADICATE HELICOBACTER PYLORI INFECTION IN WOMEN OF CHILD BEARING AGE.

Biological Science

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ABSTRACT

Helicobacter pylori (H. pylori) infection is the most common chronic bacterial infection in world wide. We assessed the effect of H. Pylori eradication with and without use of anti H. Pylori therapy among H. Pylori infected women.

Randomized placebo controlled double blind clinical trial was done on 81 women of aged 18 to 35 yrs. The women were randomly divided into two groups: Group A, received oral iron /folate supplements of 3 months and Group B received anti h. pylori therapy of 1 week then received iron/ folate supplements for 3 months. At baseline hemoglobin was comparatively lower of Group B than Group A (97.06 (g/L) vs 100.81 (g/L)) respectively. Results were expressed as Mean (SD). Paired t-test was to compare quantitative values. Both groups showed a significant increase in Hemoglobin, Ferritin and MCV values at the end of 3 months when compared with baseline measurements. Anti h. pylori therapy combined with iron/folate supplementation is more effective in Group B than Group A.

KEYWORDS

Helicobacter pylori; Child bearing age, Iron/Folate supplementation, Anemia.

INTRODUCTION:

Iron deficiency anemia (IDA) is a global public health problem affecting both developing and developed countries, with major consequences for human health as well as social and economic development, especially in Asia [1-3]. H. Pylori infection affects nearly half of the world's population. In developing countries, the prevalence of infection is as high as 90%. Whereas in developed countries, excluding Japan, that is below 40% [4].

Less attention has been paid to maternal anemia of pregnancy due to iron (Fe) deficiency despite the fact that this was a major global health problem, currently affecting nearly half of all pregnant women worldwide. Manifestations of this anemia were the postpartum depression, poor maternal/infant behavioral interactions, impaired lactation, small-for-gestational age babies, premature delivery, intrauterine growth retardation and increased fetal and neonatal mortality. Women with hemoglobin (Hb) status of less than 110 g/L, unfortunately, did not show any improvement either in their pregnancy outcomes or infant's morbidity and mortality by supplementing any micronutrients including iron-folate [5]. H. pylori are a gram-negative bacterium well-known to cause gastric ailments, such as ulcers and gastric cancers in humans. In addition, H. pylori was well-known to create achlorhydria leading to Fe-deficiency in humans [6], very limited information was available showing its effects on maternal anemia and/ or pregnancy outcomes. The objective of this study was to evaluate the outcomes of eradication of H. Pylori infected women with and without anti H. pylori therapy where both group received iron /folate supplementation.

Subject:

The women were participated in our study from the metropolitan city of Kolkata, India. **Inclusion criteria:** Patients included in the present study were those with (i) women age 18 to 35 years (ii) Hb 115g/L (iii) BMI<20 kg/m^2 (iv) willing to participate in the study, (v) staying within a reasonable distance from the study site and (vi) positive for H. pylori antibody. **Exclusion criteria:** Patients with the following conditions were excluded from the study (i) acute and chronic diseases such as aplastic anemia, thalassemia, (ii) blood transfusion or blood donation within the last 4 months and (iii) pregnancy.**Written informed consent** was obtained from the participants. Baseline history and clinical examination result on the women enrolled were recorded on a pre tested data collection form. The tests had done at admission to the study included determination of Hb, ferritin, serum iron, total iron binding capacity and [13C] urea breath test to detect H. pylori infection. This study was approved by the Ethical Review Committees of the Society for Applied Studies, Kolkata, India and the University of Alabama at Birmingham, USA.

Enrollment

Capsules of Iron and Folic Acid prepared by a reputed pharmaceutical company were used for this study. Each iron capsule contained dried Ferrous Sulphats 150 mg (50 mg elemental iron) and folic acid 0.5 mg; each woman received two capsules a day. The Women (Group B) were treated with a 7 day course of anti-H. pylori therapy consisting of clarithromycin 250 mg bid, lansoprazole 30 mg bid, and tinidazole 500 mg bid. Eradication of H. pylori infections were confirmed by Urea Breath Test (UBT) after a 4 week wash out period for antibiotics.

Sample size:

Both Group A and Group B patients were determined to be infected with H. pylori. We estimated that about 39 patients (taking into account 10% drop out) would be required for each group to detect differences between the groups with an alpha level=0.05, and power = 80%. We wanted to recruit initially about 41 H. pylori infected subjects in each group. Considering further a success rate of eradication of about 90%, based on our previous experience, therefore, a total of 105 H. pylori infected, undernourished and iron-deficient patients were recruited.

STATISTICAL ANALYSIS:

The data were entered in a suitable data base program and analysed using statistical program STATA Version 11.2. Paired t-test was used to compare the difference in the parameters in the two groups and p value of <0.05 was considered as significant.

RESULT:

During this study period, 19.5% Group B and 32.5% Group A were lost to follow up.

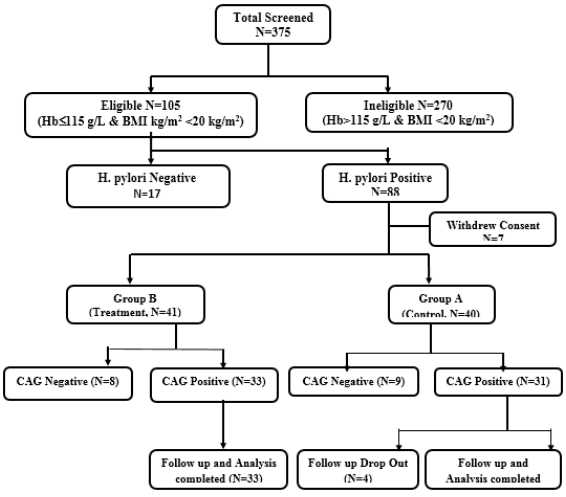

Figure-1: Profile of the study population.

The women came from low socio-economic society (Table 1).

Table 1: Socio-economic status of the families

Variables	Number (%)
House with cement floor, wall, roof	7 (11%)
Lives and cooks in one room	54 (70%)
Family income (median)/month	$73 (55, 91)
Education:	
Illiterate	18 (23%)
Can Sign Only	13 (17%)
1-5 years of school	35 (46%)

Table 2: Difference in hematologic indicators between the baseline and 3 month values

Variable	Change in 3 month Mean(SD)	95% CI	P-value
Ferritin (ng/mL):			
Group A (n=27)	8.83 (16.63)	2.25 to 15.41	0.02
Group B (n=33)	8.31 (14.89)	3.03 to 13.59	0.003
Total Iron Binding			
Group A (n=27)	5.89 (65.58)	-20.05 to 31.83	0.64
Group B (n=33)	11.70 (66.46)	-11.87 to 35.26	0.32
MCV			
Group A (n=27)	1.87(4.48)	0.102 to 3.65	0.04
Group B (33)	2.36 (5.30)	0.48 to 4.24	0.02
PCV			
Group A (n=27)	2.57 (2.96)	1.40 to 3.74	<0.001
Group B (n=33)	0.75 (3.88)	0.63 to 2.12	0.27
MCHX			
Group A (n=27)	-0.43 (1.33)	-0.96 to 0.09	0.103
Group B (n=33)	-0.53 (1.74)	-1.14 to 0.09	0.092

From the above table showed a clear and impressive trend in the improvement of hematologic indicator level in the Group A and the Group B, of baseline and 3 months values. Both groups showed a statistical significant increase in serum Ferritin and MCV ($p<0.05$).

Table 3: Difference in Hemoglobin (g/L) from base line at 1,2 and 3 month, median (quartile)

Month	Group A (n=27)	Group B (n=33)
1	3 (-4,12)	6 (-1,10)
2	5 (1,15)	5.5 (-5,13.5)
3	7 (1,18)	9 (1,14)

Increase in Hb (g/L) as a percent of base line also showed a secular trend of better increase in group even though the sample size is small.

DISCUSSION:

This study proposed to investigate the association between H. pylori infection and iron deficiency anemia and the outcomes on IDA as regard hemoglobin, serum iron and serum ferritin, after eradication of H. pylori with and without anti h. pylori therapy.

Iron deficiency women were mostly related with h. pylori infection. In the present study, we saw that 83.8 % women were H. pylori positive and others (16.8%) were negative. So H. pylori and IDA has a relation but it is not controversial.

We have noted a clear and impressive trend and in the improvement of blood Hb level even in this small sample. Vast majority of 80% women were also Cag A positive.

Maternal morbidity is increased when iron level is low through effects on immune function with increased susceptibility to infections, poor work performance, and impairment of postpartum cognition and emotions [7].

IDA also has an effect on fetal and infant development [8]. The women may have palpitation, breathlessness and increased cardiac output which can end with cardiac failure.

After the completion of anti H. pylori therapy, there was a significant difference in parameters reflecting hemoglobin, Ferritin, MCV between baseline and completion of therapy both the Group B and in Group A. But at the same time there were not significant differences in Serum iron, Total Iron Binding and Transferrin.

We saw that the mean difference of Hb levels (from baseline to 1st month) of Group B patients' were statistically significant ($p<0.05$) and for Group A were not statistically significant ($p=0.6174$). Again the mean differences of Hb levels (from baseline to 2nd and 3rd months) were statistically significant of both Group B and Group A patients'.

A meta analysis by Qu et al based on RCTs concluded that eradication of H. pylori improved Hb and Ferritin levels but not significantly increased [9].

Now let us consider the lessons learnt. Firstly, for treatment of H. pylori infection with three antibiotics we need to consider DOT (directly observed treatment) method (as is done for Tuberculosis). This will assure compliance. Secondly, using a lower dose of iron (say 50 mg/day) may improve compliance without losing efficacy (we used 100 mg/day).

Helicobacter pylori infection is transmitted from person to person by ingestion; both faecal-oral and oral-oral transmission have been postulated [10-12].

CONCLUSION:

This study concludes that, eradication of h. pylori infection is associated with recovery from the accompanying IDA. The rate of recovery was faster and greater when oral iron (lower dose) supplementation is given with anti h. pylori therapy.

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