ROLE OF PROTON PUMP INHIBITORS IN UNCONTROLED ASTHMATIC CHILDREN

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ABSTRACT

Introduction: Asthma is a common chronic complex inflammatory airway disorder characterized by variable degrees of recurring symptoms of airflow obstruction and bronchial hyperresponsiveness. The prevalence of symptoms of gastro esophageal reflux among individuals with asthma is substantially higher than in normal population and similarly the prevalence of asthma in individuals with gastro esophageal reflux is also higher than in normal population. ***Objectives*:** To identify role of adding proton pump inhibitor to asthma medications of uncontrolled asthmatic children on the level of asthma control. ***Method*:** one hundered children with uncontrolled asthma (5 year to 12 years of age), included in our study in the period from october 2014 to june 2016 all of them were regularly followed up in the allergy clinic of alhussien university hospital and devided into to equal groups (study and control) with adding proton pump inhibitor to the study group with asthma medications and follow up the level of asthma control within 3monthes .***Results:*** 28 patient of the 50 study group taken proton pump inhibitor with asthma medications show significant improvement in the level of asthma control and school achievement and the rest is un affected while only 22 of the 50 control group show improvement by usual ashma medicayions without adding proton pump inhibitor while the rest show deterioration of the level of their control ***Conclusion:*** we can add proton pump inhibitor with usual ashma medications to children wih difficulty in controlling asthma ***recommendation***: we recommend futher wider studies wih proton pump inhibitor and other anti reflux medications.

Key words: proton pump inhibitor – bronchial asthma - gastro esophageal reflux.

INTRODUCTION

Asthma is a common chronic complex inflammatory airway disorder characterized by variable degrees of recurring symptoms of airflow obstruction and bronchial hyperresponsiveness. (National Institute of Health, National Heart).

Asthma affects an estimated 300 million individuals worldwide. It is a serious global health problem affecting all age groups, with increasing prevalence in many developing countries, rising

treatment costs, and arising burden for patients and the community (GINA 2014).

The goal of asthma care is to achieve and maintain control of the clinical manifestation of the disease for prolonged periods. When asthma is controlled patient can prevent most attacks, avoid troublesome symptoms day and night, and keep physically active. partially controlled patient has more than twice day time attack per week , need for reliever or rescue inhaler more than twice per week and lung function (PEF or FEV1) <80% of predicted or personal best (if known), but no limitation of activities or nocturnal symptoms(awakening).Uncontroll ed patient has three or more features of partially controlled asthma (GINA, 2011).

The association between asthma and gastrooesophageal reflux (GER) has been debated for decades when Sir William Osler first observed the association between worsening asthma and distended stomach in 1892 (N. Kalach et al., 2004).

The prevalence of symptoms of GER among individuals with asthma is substantially higher than in normal population and similarly the prevalence of asthma in individuals with GER is also higher than in controls (B. D. Havemann et al., 2007).

Gastroesophageal reflux (GER) may cause chronic respiratory disease by vagal response and tracheal aspiration of gastric contents (C. Astarita et al., 2000).

Aspiration of gastric contents changes pulmonary resistance and causes reactive airway obstruction (O. Sacco et al., 2007).

Gastrooesophageal reflux may contribute to airway inflammatory events, possibly by sensory nerve stimulation and the subsequent release of inflammatory mediators into the airway (R. N. Patterson et al.,2007).

Many factors can lead to GERD development in asthmatics:

Presence of autonomic dysregulation as previously noted by Lodi and colleagues.

Presence of an increased pressure gradient between the thorax and the abdomen and altered crural diaphragmatic function leading to GER episodes.

Airway obstruction also triggers transient LES relaxations.

Medications used in asthma therapy may also potentiate GER.

Furthermore, asthmatics have lifestyle issues that may predispose

to GER. (Tuchman DN, et al., 2008).

AIM OF THE STUDY

To study the effect of proton pump inhibitors as an anti reflux medication on control of asthma in asthmatic children with no evidence of symptomatic gastro-esophageal reflux.

LOCATION OF THE STUDY

The allergy and pulmonology clinic; Al-Hussein Hospital; Al-Azhar University

PATIENTS AND METHODS

The study was carried out at the Pediatric Allergy and Pulmonology clinic of the Specialized Pediatric Alhussien University Hospital .

One Hundered patients included in the study in the period from October 2014 to june 2016.

Their ages ranged from 5 to 12 years and all of them were regularly followed up in the allergy clinic at alhussien university hospital.

Patients were divided into two groups, fifty patients already on only anti-asthma medications ICS - IB2A - or. Montelu. (group A). and fifty patients take PPI with anti asthma medications for three months. (group B).

All patients fulfilled all inclusion and exclusion criteria of our study.

Inclusion criteria:

1. Documented asthmatic children
2. Age 6-12 years
3. Different level of control

Exclusion criteria:

1. Children less than 6 years of age or more than 12 year
2. Children with chronic chest diseases rather than asthma
3. Children with evidence of GERD.
4. Children receiving chronic medications rather than asthma control therapy.

All the patients included in the study were subjected to the following

Clinical evaluation

Ethical approval: approval by the ethical committee of Faculty of Medicine, Alazhar University.

Detailed clinical evaluation including history, physical examination using the standard sheet of the allergy clinic, and clinical assessment of the severity of asthma and its control.

a) History:

- **Personal data:** name, age, sex, date of birth, order among siblings, address, social class.
- **Complaints:**

- **Present history:**

1. Age of onset of duration, frequency of attacks.
2. Upper respiratory symptoms (sneezing, rhinorrhea, snuffling, sinusitis, ear troubles, itchy nose and croup).
3. Chest symptoms (wheezes, cough, sputum, and dyspnea).
4. Atopic manifestations (rhinitis, conjunctivitis, eczema, urticaria, drug eruption, angioedema, and anaphylaxis).
5. Seasonal variation
6. Precipitating factors
7. Pattern of symptoms: paroxysmal or continuous

- **Severity of the disease:** (frequency of attacks, hospitalization, activity, nocturnal symptoms ,ER visits, need for hospital admission, school performance).
- **Past history**
- **Review of system affection**
- **Family history**
  Bronchial asthma in other family member, history of any allergic condition in family members
- **Environmental history**
  Dust, smoke, contact to animal or birds
- **Perinatal history**

➢ Pregnancy: full term, pre-term, or post term and outcome of pregnancy.
➢ Delivery: normal vaginal delivery, caesarean section, weight, neonatal resusci-tation, incubation, venti-lation, cyanosis, chest infection.

b) Clinical Examination:

➢ Thorough clinical examina-tion with special reference to, examination of the respi-ratory system and search for atopic manifestations

Clinical examination included:

➢ • Anthropometric measures
➢ • Vital signs (HR - RR - PULSE BL.P - TEMP. - SPO2)
➢ • General examination especially respiratory distress, cyanosis.
➢ • Throat and tonsils, head and neck examination
➢ • Limb and skin examination with emphasis on atopic manifestation.
➢ • Abdominal examination (inspection-palpation-percussion-auscultation).
➢ • Cardiac examination (inspection-palpation-percussion-auscultation).
➢ • Chest examination (inspection - palpation - percussion - auscultation).

c) Assessment of asthma control using Asthma Control Test, Ashma Score, Modified Pulmonery Index Score.

d) Laboratory Investigations.

➢ Complete blood count
➢ C- reactive protein
➢ Chest X.ray(P.A view)

RESULTS

Data were analyzed using SPSS© Statistics version 17 (SPSS© Inc., Armonk, NY, USA).

Normality of numerical data distribution was tested using the Shapiro-Wilk test. Non-normally distributed numerical variables were presented as median and interquartile range and intergroup differences were compared using the Mann-Whitney test.

Categorical variables were presented as number and percentage and intergroup differences were compared using Fisher's exact test (for nominal data) or the chi-squared test for trend (for ordinal data).

Analysis for the effectiveness of PPI was done both on per protocol (PP) and intention to treat (ITT) basis. The statistical significance of estimated odds ratios and relative risks was tested using the z-test.

A two-sided p-value <0.05 was considered statistically significant.

Table (1): Basic demographic characteristics of patients incleded in the study.

Variable	Study group (n=50)	Control group(n=50)	U	Z	p-value
Age (years)	9 (8 – 10)	9 (8 – 10)	1161.0	-0.617	0.537¶
Gender					0.548§
M	24 (48.0%)	28 (56.0%)			
F	26 (52.0%)	22 (44.0%)			

Data are median (interquartile range) or number (%).
U, U statistic; Z, Z statistic.
¶Mann-Whitney test.
§Fisher's exact test.

Table 1 show the age of patients enrolled in the study ranged from 5 to 12 year with median 9 in boh groups of the study.There was no ststisticaly significant difference between both groups regardingage and gender. Out of fifty patints of the study group 24 were males and 26 were females. Out of fifty patints of the control group 28 were males and 22were females.

Table (2): Personal and social history of both groups.

Variable	Study group (n=50)	Control group(n=50)	p-value¶
Associated atopic disorders			
Allergic rhinitis	27 (55.1%)	27 (54.0%)	1.000
Eczema	15 (30.0%)	21 (42.0%)	0.298
Allergic conjunctivitis	28 (56.0%)	28 (56.0%)	1.000
Exposure to passive smoking	23 (46.0%)	28 (56.0%)	0.424
Family history of BA	30 (60.0%)	28 (56.0%)	0.840

Data are number (%).
¶Fisher's exact test

Table 2 show no statistically significant difference between both study and control groups regarding personal history of other allergy (Allergic rhinitis, Eczema, Allergic conjunctivitis) or faily history of BA or socialhistory of Exposure to passive smoking.

Table (3): Clinical features of bronchial asthma in both groups.

Variable	Study group (n=50)	Control group(n=50)	U / χ^2	Z / df	p-value
Age at onset of asthma (months)	8 (5 – 12)	7 (5 – 12)	1134.5	-0.800	0.423¶
Severity of asthma			0.093	1	0.760§
Intermittent	9 (18.0%)	7 (14.0%)			
Mild persistent	27 (54.0%)	29 (58.0%)			
Moderate persistent	14 (28.0%)	14 (28.0%)			
Best month					0.743§
JUNE	14(28.0%)	16(32.0%)			
JULY	15 (30.0%)	14 (28.0%)			
AUG	15 (30.0%)	17 (34.0%)			
SEP	6 (12.0%)	3 (6.0%)			
Worst month					0.130§
NOV	1 (2.0%)	6 (12.0%)			
DEC	15(30.0%)	15(30.0%)			
JAN	18 (36.0%)	20 (40.0%)			
FEB	16 (32.0%)	9 (18.0%)			
Triggering agent					
URTI	28 (56.0%)	34 (68.0%)			0.303§
Smoke	30 (60.0%)	38 (76.0%)			0.133§
Dust	25 (50.0%)	22 (44.0%)			0.689§
Toxic manifestations	11 (22.0%)	10 (20.0%)			1.000§
Need for montelukast	29 (58.0%)	34 (68.0%)			0.408§

Data are median (interquartile range) or number (%).
U, U statistic; χ^2, chi-squared statistic; Z, Z statistic; df, degree of freedom.
¶Mann-Whitney test. §Chi-squared test for trend.
¥Fisher's exact test.

Table 3 show no statistically significant difference between both study and control groups regarding Clinical features of bronchial asthma (Severity, Best month Worst month, Triggering agent, Toxic manifestations, Need for montelukast)

Table (4): Comparison of both study and control groups as regards the number of hospital admissions, number of ER visits, asthma score, and MPIS score.

Variable	Study group (n=50)	Control group (n=50)	U	Z	p-value¶
Number of hospital admissions during study period	1 (0 – 2)	1 (1 – 2)	1072.0	-1.298	0.194
Number of hospital admissions during same period the year before	2 (1 – 2)	1 (1 – 2)	1153.5	-.705	0.481
Number of ER visits during study period	2 (1 – 3)	3 (2 – 4)	782.0	-3.289	**0.001**
Number of ER visits during same period the year before	3 (1 -3)	3 (2 – 4)	1084.5	-1.164	0.245
Asthma score at beginning of study	10 (9 – 11)	10 (9 – 11)	1036.5	-1.497	0.134
Asthma score at end of study	8 (6 – 10)	9 (7 – 10)	1038.5	-1.470	0.141
MPIS at beginning of study	9 (7 – 10)	9 (8 – 10)	1175.0	-.525	0.599
MPIS at end of study	5 (4 – 8)	6 (4 – 8)	1048.5	-1.423	0.155

Data are median (interquartile range).
U, U statistic; Z, Z statistic.
¶Mann-Whitney test.

Table 4 showing that there is slight decrease in the Number of hospital admissions of patients of the study group during study period comparing Number of hospital admissions during same period the year before with mean decreased from 2 needs to 1 need. And no difference in the control group. But with no statisticaly significant difference.

Table also showing that there is slight decrease in the Number of ER visits of patients of the study group during study period comparing Number of ER visits during same period the year before

with mean decreased from 3 visits to 2 visits. And no difference in the control group.But with no statistically significant difference.

Table also showing that there is slight decrease in the Asthma score Asthma score at end of study on patients of the study group comparing Asthma score at beginning of study with mean decreased from 10 visits to 8. And the same in the control group with mean decreased from 10 visits to 9. But with no statisticaly significant difference .

Table also showing that there is slight decrease in MPIS at end of study on patients of the study group comparing MPIS at beginning of study with mean decreased from9 visits to 5. And the same in the control group with mean decreased from 9 visits to 6. But with no statisticaly significant difference.

Table 5: Overall effect of treatment on frequency of attacks, school performance, and control of disease.

		Study group (n=50)		**Control group (n=50)**				
Variable		**N**	**%**	**N**	**%**	**χ^2**	**df**	**p-value¶**
Overall effect on frequency of asthmatic attacks	Increased	4	8.0%	11	22.0%	4.669	1	**0.031**
	Unchanged	23	46.0%	24	48.0%			
	Decreased	23	46.0%	15	30.0%			
Overall effect on school performance	Worsened	8	16.0%	11	22.0%	1.502	1	0.220
	Unchanged	20	40.0%	23	46.0%			
	Improved	22	44.0%	16	32.0%			
Overall effect on control of disease	Worsened	0	.0%	29	58.0%	17.338	1	**<0.001**
	Unaffected	22	44.0%	0	.0%			
	Improved	28	56.0%	21	42.0%			

Data are number (%).
χ^2, chi-squared statistic; df, degree of freedom.
¶ Chi-squared test for trend.

Table 5 show the over all effect on:

1. **Frequency of asthmatic attacks:** 23(46%) cases of the fifty case of the study group show marked decreasing comparing the control group which show 15(30%) cases of the fifty case of the control group show marked decreasing.

   With statisticaly significant difference inboth groups.
2. **School performance:** 22(44%) cases of the fifty case of the study group show marked improvement.

   With statistically significant difference inboth groups.
3. **Level of sthma control:** 28(56%) cases of the fifty case of the study group show marked improvement in the level of asthma control comparing the control group which show 21(42%) cases of the fifty case of the control group show slight improvement in the level of asthma control.
   With statistically significant difference in both groups.

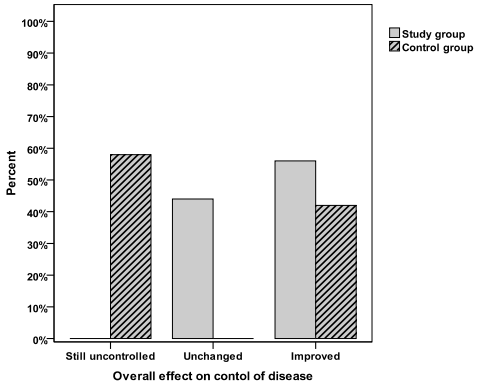

Figure (1): Overall effect of interventions on control of disease.

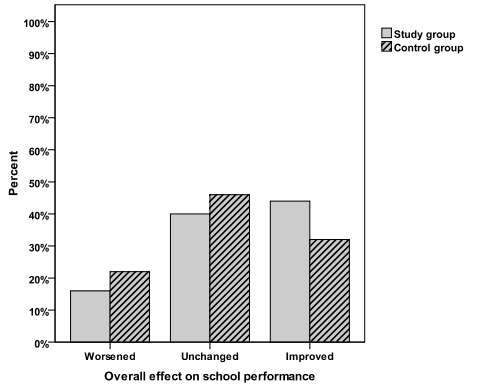

Figure (2): Overall effect of interventions on school performance.

DISCUSSION

The association between asthma and gastrooesophageal reflux (GER) has been debated for decades when SirWilliam Osler first observed the association between worsening asthma and distended stomach in 1892. (N. Kalach et al., 2004).

The prevalence of symptoms of GER among individuals with asthma is substantially higher than in normal population and similarly the prevalence of asthma in

individuals with GER is also higher than in controls (B. D. Havemann et al., 2007)

Gastrooesophageal reflux may contribute to airway inflammatory events, possibly by sensory nerve stimulation and the subsequent release of tachykinins into the airway (R. N. Patterson et al., 2007).

Because of the high incidence of gastro-esophageal reflux (GERD) in patients with asthma the complex relationship between them, and finally the difficulty of diagnosing GERD among asthmatic patients we designed this study. **(J. Kwiecien et al., 2011)**

GERD may simply represent just an associated unrelated finding with asthma, it may worsen the severity of asthma, orcould be a consequence of asthma itself **(V. Khoshoo et al., 2006)**

Prescriptions of proton-pump inhibitors (PPI) for the treatment of poorly controlled asthma have increased substantially in the past decade even though the US Food and Drug Administration (FDA) has not approved any PPI for the treatment of asthma symptoms. In recent years, the FDA reports an 11-fold increase in new prescriptions for very young children from 2002 to 2009.

There were fewer new patient prescriptions, thus the rise in the number of prescriptions was likely due to children receiving these drugs chronically (Talley NJ et al., 2004)

Indeed, there is no verified indication for use in over 75% of patients on long-term PPI treatment (Coughlan JL et al., 2005).This phenomenon is labeled 'therapeutic creep' which is the use of a treatment with proven efficacy in one population, in another population for whom efficacy has not been proven (Kiljander TO etal., 2003)

Of the six studies evaluating PPI use for treatment of asthma in children, five have been either of small sample size, not blinded, or used a combination of antireflux treatments making it difficult to determine the efficacy of PPI therapy. (Katz PO et al., 2004).

In our study there is no statisticaly significant difference in Demographic characteristics, Personal and social history, Clinical features of bronchial asthma beween both study groups.

In the current study, we found some improvement in the level of asthma control in the group of

patients given PPI for 3 months with the other asthma medications

We found that there is also noticed improvement in the school performance of childs included in the study.

There is also noticed decrease in the number of ER visits, need for hospital admission with also some improvement in both asthma score and modified pulmonary index score used as tests for classifying acute ashma exacervation attacks.

This agreed with a number of studies done in asthmatics.

Khoshoo and Haydel, 2007 showed a significant improvement in asthma symptoms and decreased requirement for asthma medication in 25 nonatopic asthmatic children treated with acid suppressor treatment .

Khoshoo et al. 2009, found that continued treatment with a proton pump inhibitor/prokinetic combination in children with moderate-persistent asthma and hidden GERD had shown significant clinicalimprovement in asthma symptoms and no exacerbation for more than 3 months

In the current study, childhood-asthma control test show some improvement in the group of patients given PPI with the other asthma medications this agree with the study done by Y¨uksel et al. 2006, that show that hidden GERD therapy with PPI significantl y decrease respiratory symptoms in preschool children with asthma and with improvement in asthma contro test.

Another study done by Yoshida et al. 2008, showed that the anti-GERD treatment significantly improved bronchial hyper reactivity as indicated by methacholine challenge test in thirty nonatopic children with persistent asthma.

In our study we found that there is some improvement in the frequency of attacks of asthma exacerbation and symptoms of asthma regarding SOB, cough, and nocturnal symptoms this agree with the study done by Harding et al. 1996, showing that omeprazole improved asthma symptoms in 67% of asthmatics with GERD after 3 months of therapy.

In another study Calabrese et al. 2005 found that treatment with pantoprazole for 6 months caused significant improvement of asthma symptoms and FEV1 in the adult asthmatics.

However, Størdal et al. 2005 found that PPI treatment did not improve asthma symptoms or lung functions in children with asthma. This dissimilarity from the result

of our study may arise from the difference in their studied group which included only children with mild or moderate persistent asthma, and relatively well-controlled asthma on daily inhaled steroids; so that further improvement in asthma outcome may be difficult to be obtained.

Disagree with our study **Toni O. Kiljander,** 2012 revealed that esomeprazole treatment does not universally improve asthma outcome in patients with moderate to severe asthma. However, the current study demonstrated that esomeprazole can improve PEF in patients with asthma who present with both GERD and NOC symptomss. In this study the improvements were of borderline clinical significance.

The authors believe that the most important analyses of the study were those by stratum, which revealed that esomeprazole treatment can affect PEF, and indicated which groups of patients are more likely to respond to esomeprazole treatment.

Of the three subgroups analyzed, statistically significant improvements in morning PEF and evening PEF were only observed in subjects presenting with NOC and GERD. This observation may support the previously reported link between nocturnal gastro-esophageal reflux and asthma (Gislason T et al, 2002). It is of interest that nocturnal asthma symptoms are a classical sign of difficult to control asthma (Barnes PJ et al, 1998) and therefore this results indirectly suggest that GERD may be a factor that makes these subjects' asthma more difficult to control. Furthermore, a *post hoc* analysis revealed improvements in morning PEF and evening PEF in subjects taking LABAs, which are often used to manage asthma that is poorly controlled by other treatments. Also, within the LABA subgroup, the largest improvements in evening PEF were also observed in subjects who presented with both GERD and NOC.

In conclusion, gastric acid suppression provided by treatment with esomeprazole daily over 16 wk improves morning and evening PEF in subjects with moderate to severe asthma who present with GERD symptoms and NOC. Also, subjects taking LABAs may benefit from esomeprazole treatment.

Patients who do not suffer from GERD symptoms and

NOC do not appear to benefit from esomeprazole treatment. Future studies are required to define more precisely the optimal

target asthma population and to clarify the clinical significance.

The difference between this study and our study can be explained by several points as this study done on awider age range , include patients already suffering from manifested GERD, use esomeprazole by name and finally the author himself recommend frther studies

In another hand The improvement of patient with NOC asthma and in morning PEF support our finding.

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دور مثبطات مضخات البروتون في حالات الربو الشعبي في الأطفال الغير مستجيبين للعلاج

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المقدمه: يعتبر الربو الشعبي اضطراب التهابي مزمن ومعقد للممرات الهوائية ويتميز بدرجات متفاوتة من تكرار أعراض انسداد الجهاز التنفسي وزيادة حساسية الشعب الهوائية. وتنتشر أعراض ارتجاع المرئ في مرضي الربو الشعبي بصورة أكبر منها في الاشخاص الطبيعيين وبالمثل فإن مرض الربو الشعبي يعتبر اكثر شيوعا ي مرضي ارتجاع المرئ عنه في الاشخاص الطبيعيين

الهدف من البحث: هو تحديد دور مثبطات مضخات البروتون في مستوي التحكم في شده الربو الشعبي عند اضافتها لأدوية الربو.

تشتمل الدراسة علي مائه طفل يعانون من الربو الشعبي (صعب التحكم) وتم تقسيمهم الي مجموعتين (مجموعه مرضي ومجموعه مراقبه) في الفترة من أكتوبر 2014 وحتى يونية 2016 وجميعهم يتابعون في عيادة حساسية الاطفال بمستشفي الحسين الجامعي وقد تم اضافه مثبطات مضخة البروتون لعلاج مرضي الربو الشعبي صعب التحكم وتم متابعه الحالات علي مدي ثلاثة اشهر.

النتائج : أظهرت الدراسة تحسن مستوي التحكم في الربو وفي الأداء الدراسي في 28 من أصل 50 طفل (مجموعه المرضي) عند اعطائهم مثبطات مضخة البروتون بالإضافة لعلاج الربو الشعبي بينما تحسن 22 طفل فقط من أصل 50 طفل (مجموعه التحكم) بأدوية الربو الشعبي دون إضافة مثبطات مضخة البروتون.

ويستخلص من الدراسة انه يمكن الاستفادة من إضافة مثبطات مضخة البروتون الي علاجات الربو الشعبي المعتادة.

وتوصي الدراسة بإجراء دراسات أكبر مستقبلا علي مثبطات مضخة البروتون وأدوية ارتجاع المرئ الأخرى لمرضي الربو الشعبي.