UDC: 616-0.53-616.3

EFFECTIVENESS OF STANDARD TRIPLE ERADICATION TREATMENT IN ARMENIAN CHILDREN WITH HELICOBACTER PYLORI ASSOCIATED GASTRODUODENAL DISEASE AND FUNCTIONAL DYSPEPSIA

Shahinyan T.[1,2]
[1] *Arabkir Medical Center - Institute of Child and Adolescent Health, Pediatric Gastroenterology, Yerevan, Armenia*
[2] *Yerevan State Medical University after Mkhitar Heratsi, Chair of Pediatrics N2, Yerevan, Armenia*

Received: 08.09.2020, reviewed: 10.10.2010, accepted: 14.10.2020

Keywords: *Helicobacter pylori, eradication therapy, children, antibiotic resistance, treatment efficacy.*

Helicobacter pylori (Hp) is a gram-negative bacterium, which leads to development of inflammatory conditions of the upper gastrointestinal (GI) tract which may further progress to peptic ulcer disease (PUD). The infection is acquired in the early childhood, the roots of transmission are fecal-oral, oral-digestive and oral-oral. In 1994, Helicobacter pylori (Hp) was declared as a main cause of gastric cancer in adults. In comparison with adults, children and adolescents, however, infrequently develop these complications of infection [12]. The prevalence of Hp is highly variable in relation to geography, ethnicity, age and socioeconomic factors, reaching 70% in developing countries [12]. Armenia is a country with high prevalence of peptic ulcer disease and gastric cancer in adults. Seropositivity of Hp in healthy individuals in Armenia is 41.5% [6]. Prevalence of Hp in Armenian children is not investigated. Nevertheless, high incidence of Hp in children appears to be a contributing factor to high incidence of gastric cancer in adult population in several areas [14].

Successful eradication is an important factor in prevention of Hp complications. The recommended goal for Hp treatment is an eradication rate of at least 90% to avoid further investigations and antibiotic use [15]. The leading factors limiting treatment effectiveness are low adherence to the treatment due to the antibiotic resistance. Surveillance of antibiotic resistance rate in different geographic areas is recommended [15]. One study showed that Armenia ranks among countries with Hp low macrolide resistance rate and moderate fuoroquinolone resistance rate in adult population with dyspepsia [6]. Hp antibiotic resistance in Armenian children is not studied yet.

The aim of the study is to investigate efficacy of the standard triple Hp eradication treatment in Armenian children with gastroduodenal disease (GDD) and functional dyspepsia (FD).

*** ADDRESS FOR CORRESPONDENCE**

T. Shahinyan
YSMU, Department of pediatrics No. 2
Address: *2 Koryun Street, 0025, Yerevan, Armenia*
E-mail: *shahinyan_tatevik@yahoo.com*
Tel.: *(+374) 93 35 33 35*

Materials and Methods

230 patients referred to Arabkir MC from November 2015 to December 2017 because of recurrent abdominal pain and/or dyspeptic symptoms.

Inclusion criteria were: children and adolescents aged 2-18 years with recurrent abdominal pain and/or dyspeptic symptoms.

Exclusion criteria were: use of non-steroidal anti-inflammatory and PPI up to 2 weeks and use of antibiotics up to 4 weeks prior to investigation, Familial Mediterranean Fever, coeliac disease.

Specially developed questionnaire was used for structured collection of anamnestic and clinical data. The patients signed a consent form for study enrolment approved by the Ethics Committee of Yerevan State Medical University (2016).

All patients underwent esophagogastroduodenoscopy (EGD) under general anesthesia with 4 biopsies by video endoscopes Olympus GIF-XP170N and Olympus GIF-H170. Two biopsies were taken from the antrum (one for rapid urease test and histology, one for Hp culture), one from the duodenal bulb and one from the distal esophagus. A rapid urease test (Helpyl test, Association of Medicine and Analytics, Russian Federation, http://www.amamed.ru/index.php?i=7) has been used [8]. The histology was assessed according to the updated Sydney system [20]. Gastric and duodenal biopsy specimens were stained by modified Giemsa staining for Hp infection for all patients. Biopsies for culture were transferred to the lab in special transport media (Portagerm) within

15 minutes and drawn to Columbia agar with 5% sheep blood (Biomerieux, France) and selective Hp media (ChromID, Biomerieux, France).

One of the antral biopsies specimens was cultured in Hp selective media and Columbia agar with 5% sheep blood. Antibiotic susceptibility test was performed by the disk diffusion method. Patients were considered Hp positive when 2 invasive tests showed presence of Hp.

They received standard triple Hp eradication therapyfor 10 days: amoxicillin (AMO)(50mg/kg/day bid) and clarithromycin (CLA) (15mg/kg/day bid) or amoxicillin and metronidazole (MET) (20mg/kg/day bid) combined with proton pomp inhibitor (PPI) rabeprazole. The patients-were prescribed treatment before the drug sensitivity results were known. Hp eradication rate was checked by a Hp stool antigen test (CER test Biothec, Hp one step card test, colored chromatography immunoassay, qualitative detection) at least 8 weeks after the treatment.

The Statistical Package for Social Science (SPSS version 20) program was used for data analysis. Bivariate analysis was carried out by using the chi-square for comparing categorical variables. A p value ≤0.05 and two tailed Fisher exact coefficient value ≤0.05 were considered significant.

Results and Discussion

150 patients aged 2-18 years (70 males and 80 females, mean age 9.2±3.9y) were selected. 106 of them (43 with FD and 58 with GDD) were Hp positive (70.6%) and received standard triple eradication therapy.

47 (44.3 %) out of 106 patients returned for evaluation by aHp stool antigen test. 21 (44.7%) of the re-evaluated patients were males and 26 (55.3%) were females. The main symptoms of the patients were abdominal pain (91.5%), nausea (59.6%), regurgitation (21.3%), night time pain (19.1%) and heartburn (10.6%) (Figure 1).

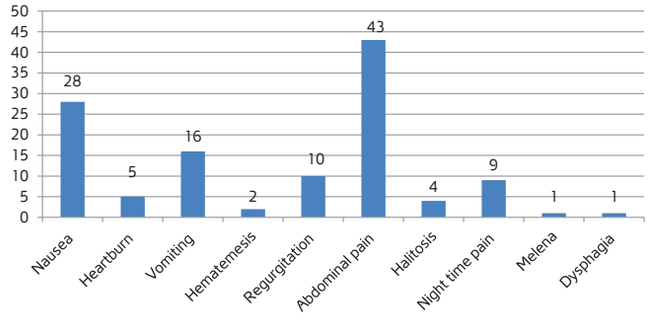

Fig. 1. *Clinical symptoms of Hp associated GDD and FD patients*

There was a peptic ulcer disease (PUD) and Hp associated gastro-duodenal disease (GDD) in the family history of 23 patients (48.9%). At the same time, the family members of half of the patients (24 patients - 51%) had different dyspeptic symptoms in anamnesis (Figure 2). No patients had family history of a gastric cancer.

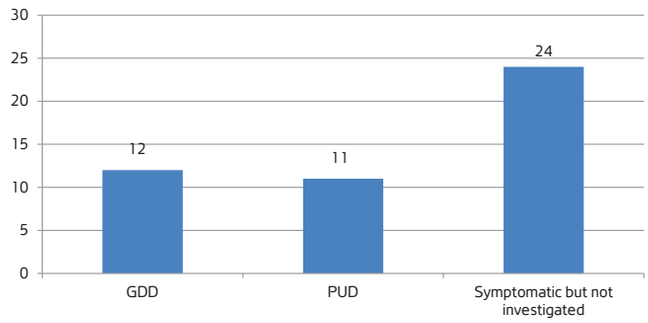

Fig. 2. *Family history of patients with Hp associated GDD and FD*

Endoscopic data analysis showed presence of superficial gastritis in 25 (53.2%), erosions - in 15 (32%) patients, nodular gastritis - in (8.5%) patients, and gastric ulcers - in 2 (4.2%) patients. Erosive duodenitis was detected in 24 (51%) patients, superficial duodenitis – in 21 (51%) patients, and duodenal ulcers – in 1 (2.1%) patient (Figure 3).

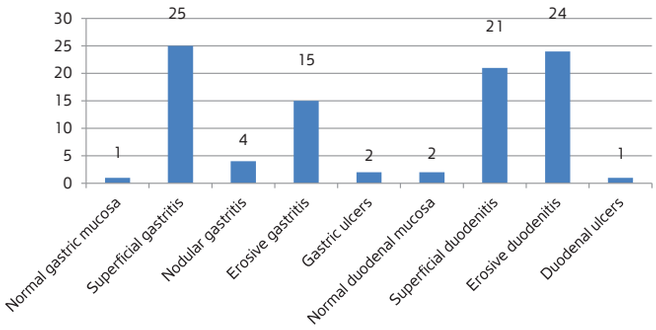

Fig. 3. *Endoscopy data of the Hp associated GDD and FD patients*

The rapid urease test was positive in 46 cases (97.9%), Hp was isolated from 10 (21.3%) of the 47 cases (21.3%) and the histological examinations showed that 46 cases (97.9%) had Hp.

The main histological findings in the cohort of Hp positive patients were chronic non-active gastritis in 42 (89.4%) and chronic non-active duodenitis 28 (59.6%). Nevertheless, atrophic gastritis was detected in 3 (6.4%) patients, and gastric metaplasia of duodenal mucosa - in 3 (6.4%) patients (Figure 4).

The susceptibility test was possible to conduct for 8 out of 10 isolated Hp strains. Seven strains were resistant to metronidazole (87.5%), 2 - to clarithromycin (25%), 6

- to doxycycline (75%). Three (37.5%) strains were monoresistant (2 to MET, 1 to DOX), 3 (37.5%) strains were double resistant (MET+DOX), 2 (25%) strains were triple resistant (CLA+MET+DOX). All strains were susceptible to amoxicillin and levofloxacine (0%) (Figure 5). 41 (87.2%) patients received PPI-AMO-CLA based treatment and 6 (12.8%) patients received PPI-AMO-MET based treatment (3 of them received CLA based treatment in the past, 1 patient had cholelthiasis and CLA was avoided because of its prokinetic effect, 2 patients had undesirable effect of CLA and were switched to MET).

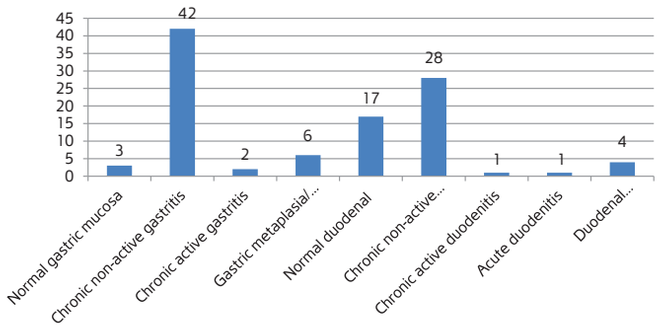

Fig. 4. *Histological data of the Hp associated GDD and FD patients*

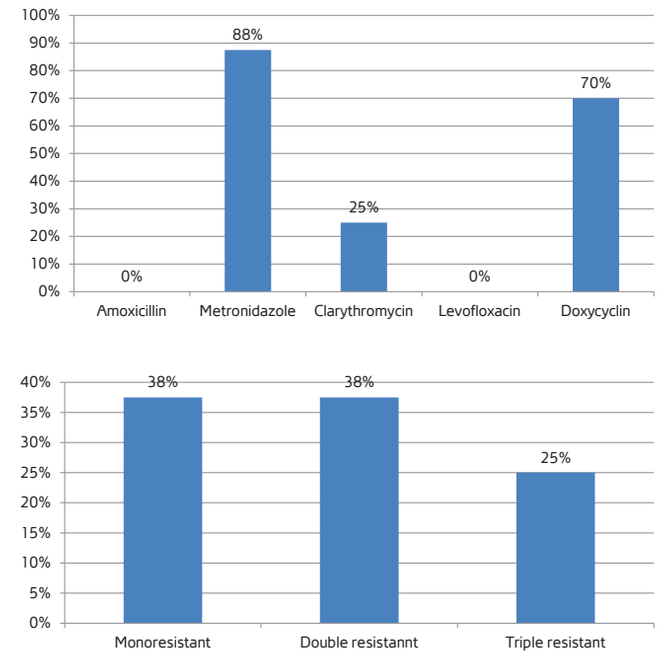

Fig. 5. *Hp antibiotic resistance in patients with GDD and FD*

Compliance with the treatment was high in all patients. Two patients (4.3%) developed diarrhea but completed the treatment in spite of it, 2 (4.3%) patients had abdominal pain. No other side effects, allergic reactions to antibiotics were registered in the rest of the patients 43 (91.4%).

Hp eradication was achieved in 36 (76.6%) patients (30 received CLA based and 6 MET based treatment, m=15 and f=21) out of 47. The eradication was unsuccessful in 11 (23.4%) patients (all on CLA based treatment, m=6 and f=5). Our analysis showed that symptoms disappeared or health condition improved in 22 (69.5%) patients after the successful eradication therapy.

The presented study is the first in Armenia assessing the efficacy of Hp eradication treatment in children with GDD and functional dyspepsia FD.

According to the latest European Society of Gastroenterology Hepatology and Nutrition (ESPGHAN) guideline on the management of Hp, the main goal of the upper endoscopy investigation is to reveal the cause of dyspepsia and/or abdominal pain, but no targeted Hp testing [11]. The main indications for endoscopy in pediatrics are duration of the symptoms from 6-12 months and presence of vomiting and/or pain altering routine life of a child [13]. Median duration of the symptoms in our cohort of patients was 2.19±0.32 years.

Digestive manifestations of Hp, such as abdominal pain or dyspepsia are non-specific and are not limited only to Hp positive children [15]. The main symptoms in our cohort were abdominal pain, nausea and regurgitation.

Different studies indicate gastric nodularity as one of pathognomonic endoscopic signs for Hp associated gastritis [5,7,11]. The main endoscopic findings in our patients were superficial gastritis (53.2%), duodenitis (44.7%) and erosions (32% and 51% respectfully). Gastric nodularity was noticed only in 8.5% of the cases.

PUD is a rare diagnosis in pediatric population of the developed world [4,13], but it may reach the incidence of 33.2% in developing countries [15,19, 22]. We identified PUD in 6.4% of the cases, which might be underestimated, because the majority of the patients with ulcers were excluded from the study due to proton pump inhibitor PPI use shortly before the endoscopy.

The main histological manifestations of Hp infection described in the literature are chronic (88.5%) and active (63%) gastritis [17, 21]. Similarly, the most frequent histological changes in our cohort of patients were chronic non-active gastritis and duodenitis (89.4% and 59.6%).

According to the pediatric Hp infection management guideline, eradication should be an association of a PPI and two antibiotics (amoxicillin, metronidazole or clarythromycin) for 7-14 days [13]. Our patients received 10 day treatment and high compliance of the patients was observed.

Hp antibiotic resistance differs in developed and de-

veloping countries and depends on the spectrum of antibiotic consumption [5]. Clarythromycin resistance is one of the defining factors for the further treatment regimen, it is highly variable in different countries (0-50%), metronidazole worldwide resistance prevalence is 20-95%, the lowest is the resistance to Amoxicillin, making 0-30% [19].

One study in adult population of Armenia showed resistance to Calrythromycin (3.6%) and Fluroquinolon (12.8%). Hp antibiotic resistance in Armenian children was not studied before and may differ due to different spectrum of antibiotic consumption [14, 18].

In our study,the Hp antibiotic resistance was possible to identify in 8 patients (17%) out of 46 due to technical reasons. A high resistance to metronidazole in 7 patients (87.5%) and clarithromycin in 2 patients (25%) was revealed. Interestingly, that doxycycline resistance was detected in 6 patients (75%). This data might be explained by a parental transmission of the infection [22].

Despite of high compliance, the Hp eradication rate was low in our cohort of patients (76.6%). It is in accordance with the pediatric studies in other countries [18 - 20]. This might be explained by high resistance data to Clarythromycin and Metronidazole, as well as 10 day treatment regimen.

Conclusion

The eradication rate of a standard triple Hp eradication therapy in Armenian children is as low as 76.6%.

High resistance to commonly used antibiotics Clarythomycin (25%) and Metronidazole (87.5%) is noticed.

Adaptation of the last ESPGHAN guidance on management of Hp infection in children [11] for Armenian pediatric population is necessary to increase the efficacy of HP eradication rate. Implementation of gastric biopsy cultures in pediatric gastroenterology practice as well as proper observance of the antibiotic treatment regimens in common practice is recommended.

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ԱՄՓՈՓՈՒՄ

HELICOBACTER PYLORI ՍՏԱՆԴԱՐՏ ԵՌԱԿԻ ԷՐԱԴԻԿԱՑԻՈՆ ԲՈՒԺՄԱՆ ԱՐԴՅՈՒՆԱՎԵՏՈՒԹՅՈՒՆԸ ԳԱՍՏՐՈԴՈՒՈԴԵՆԱԼ ՀԻՎԱՆԴՈՒԹՅԱՄԲ ԵՎ ՖՈՒՆԿՑԻՈՆԱԼ ԴԻՍՊԵՊՍԻԱՅՈՎ ՀԻՎԱՆԴ ՀԱՅԱԶԳԻ ԵՐԵԽԱՆԵՐԻ ՇՐՋԱՆՈՒՄ

Շահինյան Տ.[1,2]
[1] «Արաբկիր» բժշկական համալիր, Երեխաների և դեռահասների առողջության կենտրոն, Երևան
[2] ԵՊԲՀ, մանկաբուժության թիվ 2 ամբիոն

Բանալի բառեր՝ *Helicobacter pylori, էրադիկացիոն բուժում, երեխաներ, կայունություն հակաբիոտիկների նկատմամբ, բուժման արդյունավետություն:*

Հետազոտության նպատակներն ու խնդիրները: Հայաստանը մեծահասակների շրջանում խոցային հիվանդության և ստամոքսի քաղցկեղի լայն տարածվածությամբ երկիր է: Վարակը սովորաբար ձեռք է բերվում վաղ տարիքում, ուստի արդյունավետ էրադիկացիան կարող է հանգեցնել Helicobacter pylori-ով (Hp) պայմանավորված բարդությունների կանխարգելմանը: Սույն հետազոտության նպատակն էր գնահատել ՀՊ-ի ստանդարտ եռակի էրադիկացիոն բուժման արդյունավետությունը գաստրոդուոդենալ ախտաբանությամբ (ԳԴԱ) և ֆունկցիոնալ դիսպեպսիայով (ՖԴ) հայազգի երեխաների շրջանում: Բուժման արդյունավետությունը գնահատվել է 106 հիվանդից 47-ի (44.3 %) դեպքում: Հիվանդների հիմնական ախտանշաններն էին որովայնային ցավը (91,5%), սրտխառնոցը (59,6%), գխտոցը (21,3%), գիշերային ցավը (19,1%) և այրոցը (10,6%): Էնդոսկոպիկ տվյալների վերլուծությունը ցույց է տվել, որ մակերեսային գաստրիտ է եղել 25-ի (53,2%), էրոզիվ գաստրիտ՝ 15-ի (32%), նոդուլյար գաստրիտ՝ 4-ի (8,5%) և ստամոքսի խոցեր՝ 2-ի (4,2%) դեպքում: Էրոզիվ դուոդենիտ դիտվել է 24-ի (51%), մակերեսային դուոդենիտ՝ 21-ի (51%), տասներկումատնյա աղիքի խոցային հիվանդություն՝ 1-ի (2,1%) դեպքում: ՀՊ-ով դրական հիվանդների շրջանում հիմնական հյուսվածաբանական արտահայտությունները եղել են քրոնիկական ոչ ակտիվ գաստրիտը 42-ի (89,4%) և քրոնիկական ոչ ակտիվ դուոդենիտը 28-ի (59,6%) դեպքում: Ատրոֆիկ գաստրիտը նկատվել է 3 (6,4%), իսկ տասներկումատնյա աղիքի լորձաթաղանթի ստամոքսային մետապլազիա 3 (6,4%) հիվանդի դեպքում: 47 հիվանդներից 10-ի դեպք առանձնացվել է ՀՊ շտամ, հակաբիոտիկների նկատմամբ զգայունության թեստը հնարավոր է եղել նրանցից 8-ի դեպքում: Նրանցից յոթը դիմացկուն էին մեթրոնիդազոլի (87,5%), 2-ը՝ կլարիտրոմիցինի (25%), 6-ը՝ դոքսիցիկլինին (75%) նկատմամբ: Երեք շտամ (37.5%) մոնոռեսիտենտ էին, 3-ը (37.5%) կայուն էին, 2 հակաբիոտիկների, 2 (25%) կայուն են 3 հակաբիոտիկների նկատմամբ: Բոլոր շտամերը զգայուն էին ամոքսիցիլինի և լևոֆլոքսացինի նկատմամբ (100%): Էրադիկացիոն բուժումը արդյունավետ էր 47-ից 36 (76,6%) հիվանդների դեպքում: Կլինիկական բարելավում նկատվել է 22 (69,5%) հիվանդների դեպքում արդյունավետ էրադիկացիոն բուժումից հետո:

Եզրակացություն. ստանդարտ եռակի էրադիկացիոն բուժման արդյունավետությունը հայազգի երեխաների շրջանում ցածր է (76,6%), որը հավանբար պայմանավորված է լայնորեն կիրառվող հակաբիոտիկների՝ կլարիթրոմիցինի (25%) և մեթրոնիդազոլի (87,5%) նկատմամբ մեծ կայունությամբ:

РЕЗЮМЕ

ЭФФЕКТИВНОСТЬ СТАНДАРТНОЙ ТРОЙНОЙ ЭРАДИКАЦИОННОЙ ТЕРАПИИ *HELICOBACTER PYLORI* У ДЕТЕЙ АРМЯНСКОЙ НАЦИОНАЛЬНОСТИ С ГАСТРОДУОДЕНАЛЬНОЙ ПАТОЛОГИЕЙ И ФУНКЦИОНАЛЬНОЙ ДИСПЕПСИЕЙ

Шагинян Т.[1,2]
[1] Медицинский Центр «Арабкир» – Институт здоровья детей и подростков, Ереван, Армения
[2] ЕГМУ им. М. Гераци, Кафедра педиатрии №2

Ключевые слова: *Helicobacter pylori, эрадикационная терапия, дети, антибиотикорезистентность, эффективность лечения.*

Армения – страна с высокой распространенностью язвенной болезни и рака желудка у взрослых. Инфекция обычно приобретается в раннем детском возрасте, поэтому эффективная эрадикация может привести к профилактике осложнений, связанных с *Helicobacter pylori (Hp)*. Целью настоящего исследования явилась оценка эффективности стандартной тройной терапии эрадикации Hp у армянских детей с гастродуоденальной патологией и функциональной диспепсией. Эффективность эрадикационной терапии была оценена у 47 (44,3 %) из 106 пациентов. Основными симптомами у пациентов были боль в животе (91,5%), тошнота (59,6%), отрыжка (21,3%), ночные боли (19,1%) и изжога (10,6%). Анализ эндоскопических данных показал наличие эритематозного гастрита у 25 (53,2%); эрозий у 15 (32%); нодулярного гастрита у 4 (8,5%); язвы желудка у 2 (4,2%); эрозивного дуоденита у 24 (51%), эритематозного дуоденита у 21 (51%), язвы двенадцатиперстной кишки у 1 (2,1%) пациента. Основными гистологическими находками в когорте Hp-положительных больных были хронический неактивный гастрит у 42 (89,4%); хронический неактивный дуоденит у 28 (59,6%); атрофический гастрит у 3 (6,4%) и желудочная метаплазия слизистой оболочки двенадцатиперстной кишки у 3 (6,4%) больных. У 47 пациентов было выделено 10 штаммов Hp; тест на чувствительность к антибиотикам был возможен у 8. Семь из них были устойчивы к метронидазолу (87,5%), 2 – к кларитромицину (25%), 6 – к доксициклину (75%); три штамма были (37,5%) монорезистентными, 3 (37,5%) были устойчивы к 2-м антибиотикам, 2 (25%) штамма были устойчивы к 3-м антибиотикам. Все штаммы были чувствительны к амоксициллину и левофлоксацину (100%). Эрадикационное лечение было эффективным у 36 (76,6%) пациентов из 47. Клиническое улучшение наблюдалось у 22 (69,5%) пациентов после успешной эрадикационной терапии.

Выводы. Уровень стандартной тройной эрадикационной терапии Hp у армянских детей низкий (76,6%). Отмечен высокий уровень резистентности к широко используемым антибиотикам: кларитромицину (25%) и метронидазолу (87,5%).