

## HELICOBACTER PYLORI ERADICATION THERAPY EXPLANATION FORM (For medical examinees )

This is an important explanation about H. pylori eradication therapy. Please read this explanation form and consult the doctor if you have worries and queries.

### 1. Helicobacter pylori and diseases

H. pylori infection usually has no symptoms, infect mainly until 5 years old and continue to live inside the stomach. According to examination done in Japan, the infection rate in Junior High school students is about 5 ~10%. On the contrary, there is almost no cases of starting to be infected with H. pylori in Junior High school students since their immunity (resistance) builds up and the secretion of gastric acid become same level with adult, and once treated with eradication therapy there is almost nothing to worry about being infected again.

When infected with H. pylori, it will turn into gastritis. It will continue to infect without showing any symptoms and will develop into gastritis. When the gastritis is caused by H. pylori, this could easily lead to gastric ulcer and duodenal ulcer. It has been considered that 90% of gastric ulcer and duodenal ulcer is caused by H. pylori infection. And, it has been learned that H. pylori infection could lead to stomach cancer. In Japan, above 95% of stomach cancer is caused by H. pylori infection. In adult, those who have chronic gastritis, stomach ulcer, duodenal ulcer and stomach cancer can undergo H. pylori eradication therapy using the normal medical treatment covered by Health insurance. Other than stomach diseases, it could also cause lymphoma, anemia and thrombocytopenic purpura. H. pylori infection shows almost no symptoms but could cause various diseases.

### 2. H. pylori treatment (Eradication therapy) procedure

Even if the result of the urine test is positive, chances are 10~30% is not actually infected. Those who got positive or undetermined in the first examination (Urine test) will undergo second examination (Stool antigen test) to make sure if really infected or not. If the result of the second examination is negative, the diagnosis means not infected with H. pylori and there is no need for eradication therapy.

If the result of the second examination is positive, pack formulation (Bonopin pack) should be taken, combined 3 kinds of medicine to suppress the gastric acid secretion (Takecab), Antibacterial drugs (Metronidazole) and Pencilin antibiotics (Amoxicillin) every morning and night, 2 times a day for 7 consecutive days. Based on experience, so far, the success of eradication is more than 90%. But, if taking the medicine has been skipped or forgotten, there is a high probability that the eradication of bacteria will not be successful so make sure to take the medicines within 7 consecutive days.

### 3. Health damages like side effect from treatment

The side effect that needs the most precaution is the drug allergy. Mild rashes occur most of the time but in very rare cases (less than 0.1%), anaphylaxis condition occurs where the air way swells that causes difficulty in breathing, blood pressure drops and so on. When this happens, the patient should be taken to the hospital immediately. The medicine contains antibacterial agent (antibiotic) like penicillin so please inform the Doctor in-charge beforehand if you already had experienced allergic symptoms like rashes.

Antibacterial agent might also cause loose bowel or diarrhea. Most of the side effects are diarrhea and loose bowels because the good bacteria inside the colon will decrease because of taking antibacterial agent to kill H. pylori. If few times of mild loose bowels or diarrhea in a day occur, medical treatment should be continued. But if severe diarrhea or bloody stool occurs, treatment should be discontinued and consult your doctor. Other than these, side effects like taste disorder (the taste of the food seems unpleasant ) or mild nausea (urge to vomit) could also be felt but most of the time the treatment will proceed since both of these will naturally heal when the treatment is completed.

We will discuss about the result of the survey about the safety and side effects of eradication therapy done to infants in Japan. In nationwide survey (year 2013~2014) subsidized by the Ministry of Health, Labor and Welfare (Cancer clinical research project), the details of side effects have been studied through the 18 years old below 342 infants and children who undergone eradication therapy. Overall, 14.7% experienced side effects, loose bowel is 4.1%, mild diarrhea is 5.2%, rashes while taking medicines is 2.1% and so on. And according to the 578 patients reported, there were no severe side effects occurred. In Shiga Jen, in 184 patients who undergone eradication therapy on September 2017, 5.1% experienced side effects but there were no reports of serious condition that needed to be brought to the hospital.

### 4. Not covered by Health Insurance

For adults, the H. pylori eradication therapy covered by Health insurance must undergo endoscopy to confirm if there is chronic gastritis. But for Junior High school students, since there is no progress of gastritis yet, there will be no endoscopic examination in this service. And, according to the attached drug label of the medicine H. pylori treatment, 「the safety for infants are not yet established (limited experience)」. Therefore, eradication therapy is not covered by Health insurance. But, as mentioned earlier, in the survey done about the side effects, the truth is, it has been applied to infants and it has been learned that the side effects have no difference with adult. So, the standard treatment procedure will start from 15 years old above as it is medically considered as adult.

The therapy cost about 8,000~ 10,000 円. It is not covered by health insurance so please ask the details to the designated medical institution.

The parents and the child himself must discuss this matter very carefully and decide if he will undergo therapy or not.

## **5. How to deal when side effects happen**

If the side effects need treatment, and in case the patient needs to be hospitalized due to severe side effect, medical treatment will be done in the hospital provided by the regular health insurance.

## **6. H. pylori Check-up (Confirmatory testing for Eradication of H. pylori)**

After the 7 days of eradication therapy, stool antigen test will be done after 8 weeks, this is to confirm if the eradication therapy has been successful. If the result is positive, you must personally consult the Doctor in-charge about further treatment.

## **7. Precautions against future diseases caused by H. pylori infection**

If the Junior and High school students will undergo eradication therapy, it is almost certain that stomach cancer could be prevented in the future but, compared to those who have never been infected with H. pylori, there is a high risk to have a stomach cancer. And in this project, there is zero number of Junior High school students and below who developed stomach cancer so gastroscopy just like for adult will not be done. For this reason, do not be overconfident, consult a medical institution if you have any symptoms. And if you have any chances to have check-up for stomach like stomach cancer examination in the future, do not miss this chance to undergo examination.

If you do not want to undergo H. pylori eradication therapy, please be aware that there is a high risk of having stomach or duodenal ulcer, polyp or other possible diseases that could lead to stomach cancer in the future so we highly recommend to consult a doctor if you have any symptoms or take future stomach cancer examination.

Since the overall test has no 100% accuracy, if the test result is negative or even the eradication therapy is successful, take a close examination if needed.

## **8. Drug Allergy when taking medication**

Please inform beforehand if you have drug allergy. Listen to the doctor's explanation about the contents of the medication and side effects and do not hesitate to ask the doctor if you have any questions.

※Please read the 「**3. Health damages like side effect from treatment**」 about allergies.