screening rate was only 9.6% in 2010.[6] Screening for gastric cancer based on barium contrast imaging also does not have a high sensitivity for detecting early cancer[7] and is associated with considerable exposure to radiation. Furthermore, targeting all people aged 40 years or older for screening is a major problem as people aged below 50 years account for only about 3% of all patients with gastric cancer in Japan.[6,8] Moreover, *H. pylori*-negative patients with minimal or no atrophy of the gastric mucosa are very unlikely to develop gastric cancer,[9–11] and thus, these patients are unlikely to benefit from annual barium contrast screening and are still exposed to the adverse effects of radiation.

The most serious disadvantage with Japan's attempts to prevent gastric cancer was the inability to implement primary prevention, which is understandable as the cause of gastric cancer had not been identified in the 1970s when programs of screening for this cancer were begun. However, we now know that more than 95% of gastric cancers are due to *H. pylori* infection in Japan and Korea.[10,11] As a general rule for cancers caused by infections, such as liver cell cancer and cervical carcinoma, primary prevention based on preventing the infection or early eradication before significant damage is done is preferred over screening (*i.e.*, primary prevention is superior to secondary prevention). Primary preventative measures for gastric cancer have yet to be started in Japan, and Japan has relied on barium contrast screening for 30 years. A decrease in the age-specific mortality rate of gastric cancer has been experienced from 1970 to 2010 in both sexes in Japan. However, this seems most likely to reflect the decrease of incidence rate of gastric cancer known to have occurred in both sexes in Japan during the same period.[8] The aging of the population has increased the population at risk, and thus the number of patients dying from gastric cancer has remained unchanged at around 50,000 per year.[12] The lack of a reduction in the total number of deaths despite the decline in age-standardized mortality rates provided important evidence to the Japanese Government that current programs were not effective in the prevention of gastric cancer deaths.

Effect of *H. pylori* Eradication on Gastric Cancer Incidence

Intervention studies that assessed the preventative effect of *H. pylori* eradication on gastric cancer have been conducted in healthy individuals worldwide.[13–17] In the United States and Europe, however, most studies were terminated before enrolling enough subjects for significant analysis because the incidence of gastric cancer is extremely low in these countries.[18,19] Overall, the annual incidence of gastric cancer has been reported to be only 0.1–0.3%[20,21] in persons infected with *H. pylori*. In contrast, the annual incidence of metachronous recurrence is reported to be in the range of 3–5% of patients who have undergone endoscopic surgery to remove early gastric cancer.[22,23] Our study evaluated recurrence of metachronous gastric cancer in 544 patients who had received endoscopic treatment. They were randomly allocated to *H. pylori* eradication or noneradication groups and were followed up with annual endoscopic examinations for 3 years. As a result, metachronous recurrence was found in nine and 24 subjects from the eradication and noneradication groups, respectively. The eradication group had a significantly lower incidence of metachronous gastric cancer with a hazard ratio of 0.339 according to intention-to-treat analysis.[4]

A large-scale cohort study was reported from Taiwan, in which about 80,000 patients with peptic ulcer were followed up for 10 years after *H. pylori* eradication therapy.[24] The patients were assigned to an early eradication group (patients underwent *H. pylori* eradication therapy at the time of diagnosis) or a late eradication group (patients underwent *H. pylori* eradication therapy at 1 year after diagnosis). As a result, the incidence of gastric cancer was markedly lower in the early eradication group than in the late eradication group ($p < 0.02$). This study is important in showing that while the effect of *H. pylori* eradication therapy in reducing the incidence of gastric cancer is obvious, earlier eradication can be more effective. These studies also suggest that *H. pylori* has a cancer promotion effect over and above its ability to cause atrophic gastritis. In 2011, a possible mechanism was described due to incomplete repair of genes damaged by *H. pylori* infection, which cleaves double-stranded DNA in the nuclei of gastric epithelial cells.[25] In addition, they demonstrated that the genetic defect remained as long as *H. pylori* infection persisted, further supporting the importance of *H. pylori* eradication in high-risk patients.

Gastric Cancer Elimination Project

It has been demonstrated that most gastric cancer is due to *H. pylori* infection (*i.e.*, a necessary but not sufficient cause), and we believe it is time for a major strategic shift in the preventative measures for gastric cancer. Preventative measures for liver cancer have been conducted with the focus on hepatitis viruses since 2002 in Japan, and this has succeeded in decreasing the mortality.[26,27] In marked contrast, annual deaths from gastric cancer have remained at around 50,000 for the last few decades, suggesting that the current preventative measures have been less than satisfactory.[8] Even though viruses and bacteria are not the same, completely different preventive measures should not be taken for liver cancer and gastric cancer when both are caused by infection. In 2012, the section on Current Status of the Basic Plan to Promote Cancer Control Programs of the Japanese Government issued a new plan to determine Cancer Control Programs for next 5 years in Japan, including those caused by microorganisms such as human papillomavirus associated with the development of cervical carcinoma, hepatitis viruses associated with liver cancer, human T-cell leukemia virus Type I associated with adult T cell leukemia and *H. pylori* associated with gastric cancer. For *H. pylori*, the benefits of bacterial eradication should be examined based on findings from Japan and abroad.[28]

Meanwhile, the Japanese Society for Helicobacter Research published a guideline recommending that all *H. pylori*-

infected people receive bacterial eradication therapy.[29] In response to this, the Japanese government has expanded coverage by the national health insurance scheme. In addition to gastroduodenal ulcer, three other indications for *H. pylori* treatment including mucosa-associated lymphoid tissue (MALT) lymphoma, postendoscopic surgery for early gastric cancer and idiopathic thrombocytopenic purpura (ITP) have been newly designated. Japanese insurance coverage for *H. pylori* eradication therapy for an indication other than gastroduodenal ulcer is the first in the world.

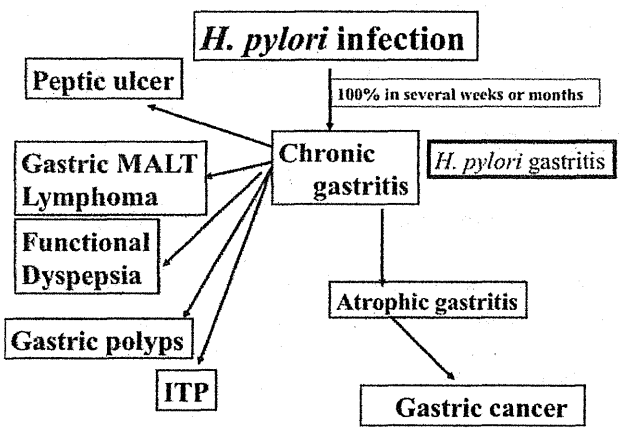

Figure 1. Progress of *H. pylori* infection. *H. pylori*-related chronic gastritis is leading to peptic ulcer, gastric MALT lymphoma, functional dyspepsia, gastric polyps, ITP, atrophic gastritis and gastric cancer.

Currently, the Japanese Minister of Health, Labour and Welfare has been asked to extend insurance coverage to chronic gastritis by the presidents of the Japanese Society of Gastroenterology, the Japan Gastroenterological Endoscopy Society and the Japanese Society for Helicobacter Research, raising expectations that approval of the request will be granted, as the final target to eradicate gastric cancer is to eliminate chronic gastritis due to *H. pylori* infection. The Japanese medical insurance is a universal health insurance system covering all citizens with freedom of choice of medical institution and high-quality services with low costs.[30] This insurance covers 90% of payment of medical expenses in persons aged above 75 years, 80% of payment at 70 to 74 years and 70% of payment less than 69 years. We are currently negotiating with the Japanese Government to expand the application of medical insurance to chronic gastritis. Hopefully, this will be approved in 2013 for patients with *H. pylori*-related chronic gastritis with endoscopy used to confirm the diagnosis of chronic gastritis.

When *H. pylori* eradication therapy for chronic gastritis is covered by national health insurance, different measures should be taken for people aged below 20 years and people aged 50 years or older. Bacterial eradication in persons aged below 20 years may achieve prevention of diseases such as peptic ulcer, gastric MALT lymphoma, functional dyspepsia, gastric polyps, ITP, atrophic gastritis and gastric cancer associated with *H. pylori*-related chronic gastritis (Fig. 1). We reported that incidence of gastric cancer after eradication of *H. pylori* increases along with advancing age (Fig. 2).[31] Thus,

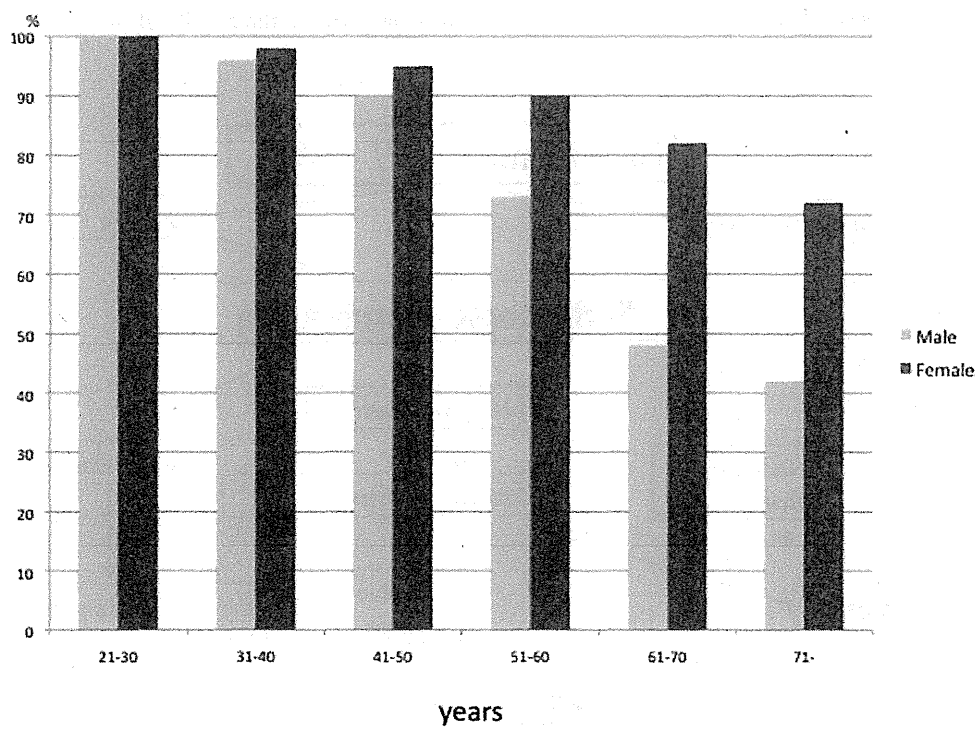

Figure 2. Possible rate of gastric cancer prevention by eradication of *Helicobacter pylori*.[31]

a test-and-treat approach is recommended for younger people that includes universal *H. pylori* testing and immediate bacterial eradication in those with a positive result (Fig. 3).

Because people aged 50 years or older frequently have atrophic gastritis and are likely to be at risk for cancer despite *H. pylori* eradication, we recommend that they will be referred for evaluation of the presence and severity of their *H. pylori*-related gastritis. Those with *H. pylori* infection should receive endoscopic examination (which will be covered by Japanese medical insurance) to evaluate for the presence and severity of atrophic gastritis. If people have a family history of gastric cancer and/or have been diagnosed as having atrophic gastritis by previous endoscopic examination, additional endoscopic examinations will also be offered in cases without *H. pylori* infection.

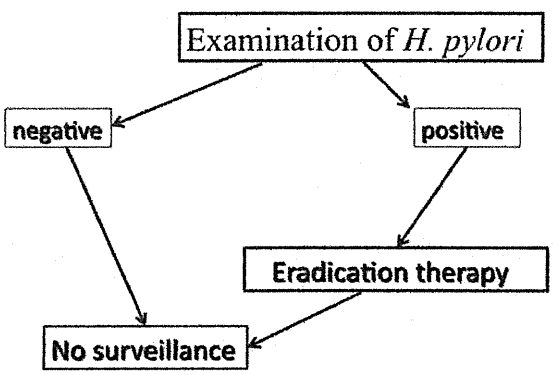

Figure 3. An approach for elimination of gastric cancer deaths in younger generation (before 20 years) in Japan.

We expect that many patients with gastric cancer will be discovered during this endoscopic examination. This project thus includes a form of endoscopic screening supported by medical insurance. Those without gastric cancer should receive bacterial eradication therapy. Persons whose endoscopic examination shows findings close to normal can be transferred to a no-surveillance group. If atrophic gastritis is found in people, a repeat endoscopic examination should be performed 1 to 2 years later and they should be considered for a surveillance program; the frequency and nature of which will depend on the results of ongoing and subsequent research on surveillance based on risk stratification (Fig. 4). As described above, the program combines primary prevention (*H. pylori* eradication) and surveillance with early cancer detection for those remaining at risk for development of gastric cancer despite *H. pylori* eradication.

Financial and Social Effects of Gastric Cancer Elimination

The cost of gastric cancer treatment in Japan is currently around 300 billion yen per year and will exceed 500 billion yen annually if measures are not taken for a decade or so. However, if the incidence of gastric cancer is reduced by *H. pylori* eradication, medical costs should be lowered substantially.[31]

Another important issue, in addition to cost, is the effect on society. By periodical follow-up endoscopy after *H. pylori* eradication therapy, most gastric cancer can be detected at an early stage, resulting in a quite favorable prognosis and a sharp decrease of gastric cancer-related deaths. Potentially, it might be possible to eliminate gastric cancer-related deaths from Japan around the middle of this century.

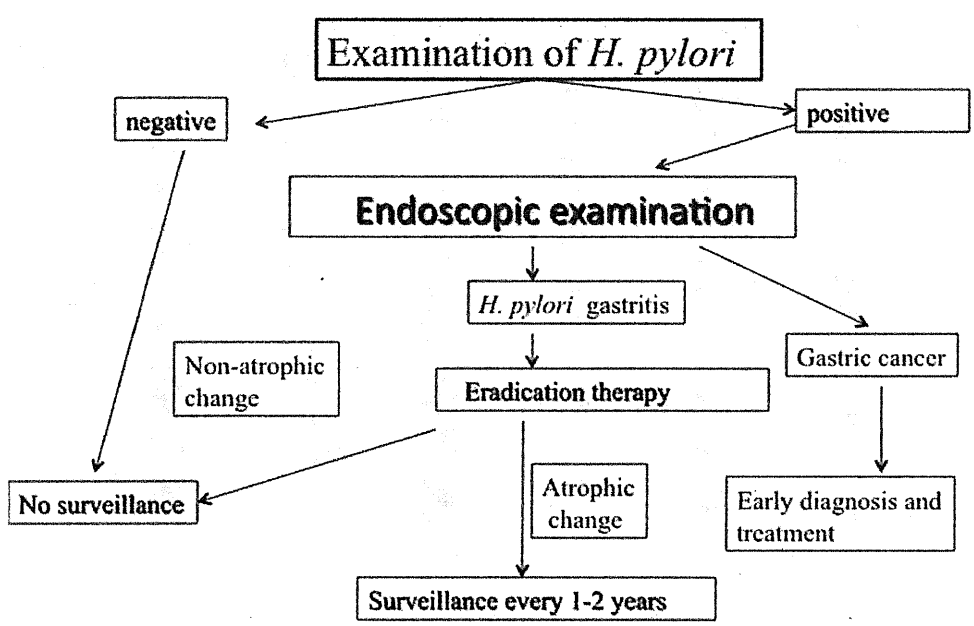

Figure 4. An approach for elimination of gastric cancer deaths after 50 years in Japan.

The principle of "innocent until proven guilty" is accepted in the legal field. Conversely in the field of infectious diseases, the principle of "guilty until proven innocent" applies. Therefore, proactive preventive measures are used for cancers that are suspected to be caused by infection so that the incidence of the target infection is dramatically decreased, thereby resulting in a reduction of cancer-related deaths. The effect of primary prevention based on the causes of cancer is more reliable and durable than secondary measures including screenings, and it also helps to reduce medical costs.

The possible success with elimination of gastric cancer in Japan should lead other countries with a high incidence of gastric cancer such as East Asia and Latin America to consider using a similar strategy, which might then lead to extermination of gastric cancer worldwide.

Conclusion

A gastric cancer elimination project that combines *H. pylori* eradication therapy and surveillance of high-risk patients is both appropriate and feasible for Japan, where excellent methods of diagnosis and endoscopic treatment for early gastric cancer are already available. In this country, the baby-boom generation is now passing 60 years and reaching the cancer-prone age, and therefore, an increase of medical costs related to gastric cancer is impending. Application for medical insurance in patients with *H. pylori*-related chronic gastritis due to the Basic Plan to Promote Cancer Control Programs might be a first step to eliminate gastric cancer deaths in Japan.

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Diagnostic accuracy of urine-based kits for detection of *Helicobacter pylori* antibody in children

Short title: Diagnostic accuracy of urine antibody kits for *H. pylori* in children.

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Abstract:

Background. Rapid urine-HpAb is reported to be a reliable test of *H. pylori* infection in adults, but there is no data on the application of the test in children. ***Objective.*** To evaluate the accuracy of a urine-based ELISA (urine-HpELISA) and immunochromatography (rapid urine-HpAb) kit for anti-*H. pylori* IgG antibody in children, we compared its sensitivity and specificity in reference to the ^{13}C-urea-breath test (UBT) and *H. pylori* stool antigen test (HpSA). ***Materials and methods.*** 101 Japanese children without significant upper-abdominal symptoms were included (mean age, 7.1 years; range 2 to 15 years). Their sensitivity and specificity were evaluated in reference to the ^{13}C-urea breath test (UBT) and *H. pylori* stool antigen test (HpSA). ***Results.*** 37 children were judged *H. pylori*-positive and 64 negative by UBT and HpSA. No discrepancy in the results was observed between UBT and HpSA. Urine-HpELISA showed 91.9% sensitivity and 96.9% specificity with an accuracy of 95.0%. Rapid urine-HpAb showed 78.4% sensitivity and 100% specificity with an accuracy of 92.1%. Seven false-negative results for rapid urine-HpAb were from children aged under 10 years, and their antibody titers of urine-HpELISA were lower than true-positives. ***Conclusions.*** For the diagnosis of *H. pylori* infection in Japanese children, the both tests may be non-invasive, inexpensive, reliable and easy-to-perform methods giving satisfactory accuracy, although the sensitivity of the rapid urine-HpAb kit was inferior to that of the urine-HpELISA kit, especially in children aged under 10 years showing relatively low titer of *H. pylori* antibody.

Key Words: *Helicobacter pylori*, Urine antibody, HpSA, UBT, children

Abbreviations: ELISA, Enzyme-linked immunosorbent assay: urine-HpELISA, Urine-based enzyme-linked immunosorbent assay for anti-*H. pylori* immunoglobulin G

antibody; UBT, ^{13}C-urea breath test; HpSA, *H. pylori* stool antigen test; CI, Cut-off index of urine-HpELISA: rapid urine-HpAb, Rapid urinary IgG antibodies to *H. pylori*

Introduction

Helicobacter pylori is a common pathogen causing chronic gastritis, and gastric and duodenal ulcers in adults [1-3] and children [4]. Many simple, non-invasive, inexpensive but accurate tests are available for the initial diagnosis and epidemiological evaluation of *H. pylori* infection. Serological tests for detection of *H. pylori*-specific IgG antibodies by enzyme-linked immunosorbent assay (ELISA) have been developed and perform well in adults, with sensitivity and specificity values reported to be higher than 90% [5]. However, their usefulness in children remains controversial [6-8]. In our previous study, we reported that urine-HpELISA (URINELISA, Otsuka Pharmaceuticals Co, Ltd, Tokyo, Japan) was a reliable method for diagnosis of *H. pylori* infection in Japanese children [9]. The rapid urine antibody detection test (rapid urine-HpAb) detects the same antigen as urine-HpELISA, and is faster non-invasive and convenient. It has been proved to be reliable with excellent sensitivity and specificity in adults [10-12], but has yet to be evaluated in children. In this study, we evaluate the sensitivity and specificity of the rapid urine-HpAb test in reference to HpSA and UBT.

Subjects and methods

Study population

This study included 101 Japanese children living in Wakayama Prefecture (mean age, 7.1±3.3; range 2-15). We had previously performed an epidemiological study at Wakayama Rosai Hospital on 484 children by HpSA, and found 31 positives [13]. In the present study, we re-invited 37 children, 31 known positives and 6 known negatives to participate. We also invited 64 children whose *H. pylori* status had not been examined. None of the children had significant upper-abdominal symptoms, a history of *H. pylori* eradication or renal disorders. They had not received any antibiotic or other significant medical treatment in the previous four weeks that might have affected the

results. Informed consent was obtained from all parents. All the children provided a urine sample at the day of UBT and a fecal sample within seven days of UBT. The research protocol was reviewed and approved by the Ethics Committee of the institution.

Methods

^{13}C-UBT: Children were fasted at least 4 hours before UBT and breath samples were collected before and 20 min after ingestion of ^{13}C-urea. Dosage of ^{13}C-urea was altered according to age; 50mg for children under 6 years of age, 75mg between 7 to 12 years, and 100mg over 13 years. An infrared spectrometer (UBiT- IR300, Otsuka Electronics Co, Hirakata, Japan) was used in this study and an increase of more than 3.5% was considered positive [14].

Stool antigen test: Stool samples were stored at -20°C until use. An enzyme immunoassay kit (Premier Platinum HpSA, Meridian Diagnostics Inc., Cincinnati, Ohio) utilizing a polyclonal anti-*H. pylori* rabbit antibody adsorbed to microwells was used to detect *H. pylori* antigen in stool according to the manufacturer's instructions. Values greater than or equal to 0.120, between 0.100 and 0.119, and less than 0.100 were considered positive, equivocal, and negative, respectively.

Urine-HpELISA (URINELISA): Single-void urine samples were obtained and stored at 2°C to 8°C until use. Urinary IgG antibodies to *H. pylori* were determined using a urine-HpELISA kit (URINELISA, Otsuka Pharmaceuticals Co, Ltd, Tokyo, Japan) that utilizes a *vacA* and *cagA*-positive *H. pylori* strain isolated from a Japanese gastritis patient as the antigen source [15]. Ninety-six-well microtiter plates coated with *H. pylori* antigen were used according to the manufacturer's instructions. Absorbance at 450 nm was measured and calculations were as follows: Cut-off index (CI) reflects the ratio of absorbance of sample tested / cutoff value. Cut-off values were calculated as the

mean absorbance of 2 positive controls / 8.5 + mean absorbance of 3 negative controls. CI values greater than or equal to 1.0 was judged positive, and those less than 1.0 were judged negative.

Rapid urine-HpAb (RAPIRUN): Rapid urinary IgG antibodies to *H. pylori* were determined using immunochromatography (RAPIRUN, Otsuka Pharmaceuticals Co, Ltd, Tokyo, Japan) using the same antigen as in URINELISA. This test is judged to be positive if red lines appear in both the control and test zone, and to be negative if a red line is observed only in the control zone. Without a visible red line in the control zone, the test is considered to be invalid.

Proteinuria test: Since proteinuria may give a false-positive reaction in the urine-based ELISA [16], BM test® (Roche Diagnostics Co, Germany) was also performed on urine-HpELISA-positive samples.

Determination of *H. pylori* infection: *H. pylori* infection status was determined by positive results in both UBT and stool antigen test.

Results

Measurement of UBT and HpSA

Of 101 children, 37 were positive (mean age, 7.1±3.4; range 2-15) and 64 were negative (mean age, 7.1±3.3; range 2-14), as judged by UBT and HpSA (Table 1). Statistically difference was not detected between positive and negative subjects on age. There were no equivocal results in the HpSA, and no discrepancy was observed between the two tests.

Rapid urine-HpAb and urine-HpELISA

Twenty-nine out of 37 *H. pylori*-positive children by UBT and HpSA were positive with rapid urine-HpAb and one was invalid, while all 64 *H. pylori*-negative children were negative (Table 1). Thus the rapid urine-HpAb showed 78.4% sensitivity (29/37)

and 100% specificity (64/64) with an accuracy of 92.1% compared to UBT and HpSA (Table 2). In comparison, Urine-HpELISA showed 91.9% sensitivity (34/37) and 96.9% specificity (62/64) with an accuracy of 95.0% (Table 2).

To evaluate whether age or antibody titers affected the results of the rapid urine-HpAb, CI of the urine-HpELISA was plotted against age (Fig. 1). There was no significant correlation between the CI values and the age in *H. pylori*-positive subjects (Fig. 1A). CIs of urine-HpELISA of the true positive subjects with negative rapid urine-HpAb ranged from 0.35 to 3.3.

Sixty-two out of 64 true negative subjects showed CI values less than the cut-off value for urine-HpELISA, but all 64 subjects showed negative rapid urine-HpAb (Fig. 1B). It can also be noted that 6 out of 7 false negative urine-HpAb results showed CI values of <3.3 suggesting a strong relationship between antibody titer and sensitivity.

Sensitivity and specificity of the two tests according to age groups were compared (Table 3). In the under 10 age group, sensitivity of the rapid urine-HpAb was lower than that of urine-HpELISA (75.0 vs. 89.3%) and specificity was equivalent. In the over 10 age group, sensitivity and specificity of both tests were adequate. No proteinuria was detected in *H. pylori*- positive subjects.

Discussion

Diagnostic accuracy of the rapid urine-HpAb kit and the urine-HpELISA kit was evaluated in children and the both kits gave satisfactory results, although the sensitivity of the rapid urine-HpAb test was inferior to the urine-HpELISA kit, especially in children aged under 10 years.

It can be a weak point of the current study that subjects with stool antigen test results were included, which could be a bias. If the subjects had been invited according to urine *H. pylori* antibody status, it would have distorted the results. As at the time of

invitation, information of urine *H. pylori* antibody status was lacking, in other words blind, little bias by the selection of the subjects is expected. No discrepancy was there between results of UBT and HpSA. The results are thought to be reliable as gold standard for sensitivity and specificity.

Various epidemiologic studies have revealed a significant relationship between gastric cancer and *H. pylori* infection in the Japanese population [17-18]. It is also reported that *H. pylori* infection is associated with the development of both intestinal-type and diffuse-type gastric cancer [19]. In these studies, gastric cancer was shown to develop only in patients carrying *H. pylori*, which confirms that infection is a main cause of gastric cancer in Japan.

It is also proven that eradication of *H. pylori* infection reduces the occurrence of gastric cancer [20-21]. In a high-risk region of China, a prospective, randomized, placebo-controlled, population-based primary prevention study showed that the incidence of gastric cancer was similar between participants receiving *H. pylori* eradication therapy and those receiving placebo during a period of 7.5 years [22]. However, in the subgroup without precancerous lesions, eradication of *H. pylori* significantly decreased the development of gastric cancer. According to these findings, *H. pylori* eradication in the Japanese population will reduce the development of gastric cancer, and therapy before the development of atrophic gastritis is desirable. This makes the age of eradication for prevention of gastric cancer and the most effective screening test for *H. pylori* infection in children and young adults an important issue.

Urine antibody testing is a simple, low-cost and rapid process with minimal patient discomfort and seems ideal for screening of *H. pylori*. However, the accuracy of antibody tests for *H. pylori* in childhood has previously been considered controversial due to their low sensitivity. We have shown in a previous report that the sensitivity of a

serum-HpELISA kit, HM-CAP, was only 51.4% (18/35) for children below 10 years compared to HpSA [8]. However, an EIA test using serum samples based on Japanese strain-derived antigens, JHM-CAP, had significantly better performance than HM-CAP, which is based on U.S. strain-derived antigens, in a study population of Japanese asymptomatic young children [23]. Similarly, we reported that a urine-HpELISA using *H. pylori* antigens derived from a Japanese strain had 94.4% sensitivity and 96.9% specificity with an accuracy of 96.0% in children [9]. This shows that performance in children is highly dependent on the locality of the *H. pylori* strains used in the ELISA system.

Akamatsu *et al.* performed screening tests for *H. pylori* infection in a study population of 1,224 high school students using the rapid urine-HpAb and found 64 positive subjects [24]. Thirty of these 64 *H. pylori* urine antibody-positive students had an upper gastrointestinal endoscopy in the author's institution and 24 (80%) were diagnosed *H. pylori* positive by histology and culture. Among remaining 6 rapid urine-HpAb positive subjects, two subjects were endoscopically diagnosed as severe atrophic gastritis with serum anti-*H. pylori* positive, indicating 13.3% (4/30 subjects) of false positive in the rapid urine-HpAb test. In this study, as there are no reports on the reliability of a rapid urine-HpAb test in children, we evaluated a rapid urine-HpAb test in children and found that the sensitivity of the rapid urine-HpAb test was lower than urine-HpELISA. While urine-HpELISA was judged according to OD values, rapid urine-HpAb is detected by visualizing a positive reaction band. In 12 *H. pylori* positive urine samples showing a CI value of less than 3.3 by urine-HpELISA, six had negative rapid urine-HpAb results, showing that low antibody titers of the specimens tend to result in a false negative. The difference in diagnostic accuracy between the rapid urine-HpAb and the urine-HpELISA tests was observed only in subjects aged under 10

years. Although negative results for relatively low antibody titer may be the main reason of the inferior sensitivity of the rapid urine-HpAb test, age of the subjects could have something to do with the false negative results.

From these findings, the both kits can be used for children over 10 years of age. For children under 10 years of age, the urine-HpELISA kit may be preferable to the rapid urine-HpAb kit, and because of relatively low sensitivity, additional infection diagnosis with UBT or stool antigen test may be recommended for those with negative urine results, especially for those with clinical significance.

In conclusion, for the diagnosis of *H. pylori* infection in Japanese children, the both tests may be non-invasive, inexpensive, reliable and easy-to-perform methods giving satisfactory accuracy, although the sensitivity of the rapid urine-HpAb kit was inferior to that of the urine-HpELISA kit, especially in children aged under 10 years showing relatively low titer of *H. pylori* antibody.

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Table 1. Evaluation of rapid urine-HpAb (RAPIRUN) test compared to UBT and HpSA

rapid urine-HpAb	Children with indicated *H. pylori* status		
	UBT and HpSA		
	Positive	Negative	Total
Positive	29	0	29
Negative	7	64	71
Invalid	1	0	0
Total	37	64	101

Table 2. Evaluation of urine-HpELISA (URINELISA) compared to UBT and HpSA

Urine-HpELISA	Children with indicated *H. pylori* status		
	UBT and HpSA		
	Positive	Negative	Total
Positive	34	2	36
Negative	3	62	65
Total	37	64	101

Table 3. Sensitivity and specificity of rapid urine-HpAb and urine-HpELISA according to age groups

	Rapid urine-HpAb		Urine-HpELISA	
	Sensitivity	Specificity	Sensitivity	Specificity
Total	78.4	100	91.9	96.9
	29/37	64/64	34/37	62/64
<10 years old (%)	75.0	100	89.3	95.8
positive / total	21/28	48/48	25/28	46/48
>10 years old (%)	88.9	100	100	100
positive / total	8*/9	16/16	9/9	16/16

* One of nine cases had an invalid result.