Cervical cancer is increasing in Japanese women of reproductive age. Most women who develop cervical cancer are under-screened. This study investigated whether HPV self-sampling (SS) might be an effective means of increasing screening uptake in young Japanese women. It took place in two parts: a feasibility study to examine the acceptability and safety of the SS device in women already attending for screening and a qualitative study investigating the acceptability of the device in women <30yrs of age. Women attending their annual workplace check-up underwent SS followed by a physician-led Pap smear and HPV test. Women found SS significantly less painful, less embarrassing and could relax more (p<0.001). They also found the instructions easy to use. No safety issues were reported. However, in the second study, younger women thought the SS device ‘looked liked a syringe’ or a ‘kitchen utensil’ and they preferred a smaller device. Further studies will take place with the smaller device.

Research field: Public Health and Hygiene

Keywords: Cervical cancer  Test  Self-sampling  Screening
1. Cervical cancer incidence and mortality is increasing in Japan, especially in women of reproductive age. While HPV vaccination status will play an important role in a woman's lifetime risk for cervical cancer, at present, most women who develop cervical cancer are either under-screened or never screened. Non-participation in screening undermines the efficiency of a cervical screening programme, which depends to a large extent on high population coverage. Organized cervical screening coverage in Japanese women is between 30%-40%.

Strategies that overcome barriers to screening are essential to improve uptake, particularly in hard-to-reach women. HPV self-sampling for high risk oncogenic HPV types (hereafter self-sampling) is a simple alternative to clinician-led speculum examination, which allows women to take their own sample using a brush, lavage or other collection device in the comfort and convenience of their own home.

Furthermore, one further advantage of HPV self-sampling is that it gives us the opportunity to obtain vital epidemiological data on HPV prevalence in both vaccinated and unvaccinated cohorts.

One review of the clinical accuracy of HPV self-sampling versus physician-led screening found that self-sampling was “at least if not more” sensitive for cervical intraepithelial neoplasia grade 2 or more (CIN2+) than conventional cytology. It also indicated that self-sampling may improve compliance to screening participation in non-attendees since women report less embarrassment, less discomfort and higher levels of relation during the test compared to physician sampling. However, no study on the acceptability of HPV self-sampling has been undertaken in Japan.

2. The study aimed to investigate whether HPV self-sampling could help engage young Japanese women who had never attended for cervical screening to participate in cervical screening and evaluate the prevalence in high risk HPV infection in vaccinated and non-vaccinated cohorts.

3. Methods

(1) Feasibility study

To ascertain the feasibility, acceptability, and safety of the self-sampling device, we first of all carried out a pilot study in women already attending for screening as part of their annual workplace health check-up. This study took place between November 2013 and March 2014 and involved 203 women aged between 20 and 42yrs (Figure 1).

Women underwent self-sampling, a physician led Pap smear and then filled out a questionnaire developed for a Japanese population and based on previous research on HPV self-sampling acceptability. It assessed socio demographic characteristics, history of tampon use, comprehension of self-sampling instructions, attitudes towards the size of self-sampling device, attitudes towards the self-sampling and physician-led test, ease of use and intention to use self-sampling if it offered as a screening option in the future.

Attitudes towards both tests investigated embarrassment, pain (physical discomfort), unpleasantness (mental discomfort), confidence that the test had been conducted correctly, and degree of relaxation during both tests on a four-point scale ranging from ‘not at all’ to ‘extremely’. Acceptance of self-sampling was assessed by stated willingness to use the test again in the future.

The HPV test was Hybrid Capture 2 (HC2) (Qiagen, Germany) and the HPV self-sampling device was the Evalyn brush (Rover, the Netherlands).

Figure 1. Study flow

(2) Qualitative study

We interviewed 20 young women under the age of 25 years to get their opinion on the Evalyn self-sampling brush and whether they might prefer a smaller, less brightly colored devise that had been devised by an engineering student of Asian origin in Canada (Her Swab, Eve Medical, Canada).
4. 研究結果
(1) Feasibility Study
   □ Usability
   Over 90% of participants found the length and size of the device to be just right and the instructions 'easy' or 'very easy' to understand (Figures 2a, 2b and 2c).

![Figure 2a Impressions of length of the self-sampling device](image)

![Figure 2b Impressions of size of the self-sampling device](image)

![Figure 2c Comprehension of Instruction sheet](image)

□ Acceptability
   Compared to physician-led testing, women found self-sampling significantly less painful, less embarrassing and could relax more (p<0.001). The results of the paired-sample t-test are shown in Table 1. A p-value of <0.05 was considered statistically significant.

Table 1 Differences in perceptions of both tests

<table>
<thead>
<tr>
<th>Feeling during the test</th>
<th>Physician Sampling</th>
<th>Self-Sampling</th>
<th>t</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embarrassed</td>
<td>1.74</td>
<td>1.14</td>
<td>9.19</td>
<td>166</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pain</td>
<td>1.53</td>
<td>1.29</td>
<td>3.76</td>
<td>146</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Unpleasantness</td>
<td>1.14</td>
<td>1.18</td>
<td>-0.93</td>
<td>146</td>
<td>0.36</td>
</tr>
<tr>
<td>Degree of relaxation</td>
<td>2.27</td>
<td>1.90</td>
<td>5.04</td>
<td>146</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Confident done properly</td>
<td>1.37</td>
<td>2.17</td>
<td>-9.93</td>
<td>146</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

df= degrees of freedom

Apart from confidence that the test had been performed correctly, participants had a better or similar experience with self-sampling compared to a physician led test (Figure 3).

![Figure 3. Comparison of experiences with both tests](image)

□ Accuracy and safety.
   No safety issues were reported. Concordance of both tests was good. While there were no cases of CIN2 or more, the Kappa agreement for LSIL was high at 0.82.

(2) Qualitative study
   Based on the results of quantitative studies carried out in the UK,6,7, where young Asian women found the Evalyn brush to be intimidating and 'looking like a utensil to clean the shower tiles', we interviewed 20 young Japanese women to get their opinions on the Evalyn brush compared to a newer option, Her Swab. Similar to the UK study, we found that Japanese women in their 20s regarded the Evalyn brush to be intimidating and compared it to a medical syringe. They also found the bright pink color to be 'too loud' and 'similar to a kitchen utensil'. All 20 women stated they would be more comfortable using the smaller, pastel-colored Her Swab. For this reason we chose to switch the device we would use in the study from the Evalyn Brush to Her Swab. Since Her Swab is not yet available for commercial use in Japan, it took over 18 months for us to be able to obtain the devices and the study investigating acceptability in women <30yrs, as well as high risk HPV prevalence will take place in 2017.

Conclusions
   The result of this first study on HPV self-sampling acceptance in Japanese women are encouraging. They indicate that HPV self-sampling might be an acceptable alternative to conventional physician led cervical screening, if women can be
assured about the accuracy of the test results. Women had no issues with the size of the sampling device and found the instructions for use easy to follow in an unsupervised setting, regardless of SES. However, to assess whether self-sampling may be an effective tool to increase cervical screening rates in Japanese women >30yrs, further large-scale studies are needed.

References:


Presentations (11)


Organized International Symposium (1)

1. 1st International Conference on Preventing Cervical Cancer Through Education, Vaccination and Screening, Hokkaido University, Sapporo, Hokkaido, March 15th-16th 2016

6. Research Organisation

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