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On educational and publicity activities of JGOG

Kazunori Ochiai, M.D., Ph.D. President, JGOG

JGOG has been emphasizing educational and publicity activities since it was established. The activities are targeted at a variety of persons including ordinary members, manufacturers that kindly support the activities, and ordinary citizens. In order to accomplish multi-facility joint clinical trials, which JGOG regards as an important project, it is critical before everything for members to share common understanding, and sense of mission and values. The activities serve as a bridge between this organization and members.

A Web site is run in the first place as a part of the publicity activities. The Web site (URL: <http://www.jgog.gr.jp/>) pages open to the public carries JGOG operation, ongoing clinical trials, accomplished studies and their results, and journals in which completed studies appear. On the pages that accept only members appear the list of members, the list of the committee members, protocols for clinical studies, and application and related forms for clinical trial enrollment. The publishing business includes the Chemotherapy News, which was launched in 1992 and is published quarterly, having reached a total of 70 issues. This Newsletter carries a special feature series of topics on cancer therapy, members' opinions, and explanations of protocols in progress. Supporting members' efforts have made it possible for the Newsletter to be widely distributed to and read by not only members but also Japanese gynecologists as well as manufacturers.

We have recently devoted ourselves to educational projects. We hold a two- overnight seminar in August every year to train gynecological oncologists who are expected to lead clinical trials. A lot of physicians wish to apply for this seminar, in which the ratio of number of lecturers to that of physicians who attend a seminar is as dense as 1:1. Moreover, overseas dispatches count 17 as of this year, having provided dispatched physicians with opportunities for visiting conference-related institutions, attending special lectures, and observing or joining surgical operations on occasion of overseas conference attendance. On the other hand, JGOG accepted officials and fellows dispatched from the Thai Gynecologic Cancer Society in

the last April to educate them at 4 member institutions. We help also education of CRCs that support clinical trials through paying entry fee and transportation expense to about 20 participants each twice a year.

JGOG educational and publicity activities have been thus extended to a variety of projects, being supported by leading members' self-sacrificing efforts in every aspect. It is really our mission to train younger oncologists who will be capable of driving forward Japanese clinical studies in future.



Letter from Korean Gynecologic Oncology Group (KGOG)

Soon-Beom Kang, MD, PhD President of Asian Society of Gynecologic Oncology
President of Korean Gynecologic Oncology Group
Professor of Seoul National University

Dear JGOG colleagues,

I am very pleased to have this opportunity to share my thoughts with all members of the Japanese Gynecologic Oncology Group (JGOG). On behalf of Korean Gynecologic Oncology Group (KGOG), I appreciate your active contribution and support that you have constantly given us for international cooperation with KGOG.

Since KGOG was established in 2002, we have been conducting many multicenter trials and doing lively activities to lay a solid foundation for joint researches with other organizations from all over the world. Based on these passionate activities, KGOG has grown up with over 200 members from 66 institutions across the nation. Until now, we have developed 54 clinical protocols, actively engaged in on-going 18 trials, and published our trial results on 11 SCI papers. KGOG finally joined GOG and GCIG in 2007 and has been conducting many multicenter trials as well as doing fruitful activities together.

Now, KGOG and JGOG are performing two big clinical trials together such as S-1 and GCIG/JGOG 3017. I am convinced that these ongoing trials help set the global standard treatment of gynecologic cancer. We can only achieve success through intergroup and international collaboration. Fortunately, JGOG and KGOG have been in close contact, and I am sure that our collaboration system is as good as to be a great example for the other organizations of gynecologic oncology in the world.

ASGO is another memorial result of Japan-Korea cooperation. As you know, ASGO started the first biennial conference in Tokyo last November wonderfully, where doctors not only from Asia but also from around the world participated and showed their interests in ASGO. Far earlier than that, we had been holding Japan-Korea Joint Conference of Gynecologic Oncology Group (JKGOG) annually since 2002. And ASGO was inaugurated to expand the spirit of cooperation of JKGOG to all Asian countries in Seoul in 2008. Here I dare to say that ASGO could have not started without the previous JKGOG meeting between Japan and Korea. As like we were together at the very beginning of the ASGO, we are getting along with each other all the way for the purpose of the ASGO, which is ultimately to improve the standard of practice and outcomes of patients with gynecologic cancers.

Lastly, I deeply appreciate your heartfelt efforts again to keep our relationship close. I believe the high quality collaboration network that we have now is the key to get through with our tasks.

Best wishes to all members of the JGOG.

About JGOG's activities



Education, Publication and Public Relations activities

Yasuhiro Udagawa, M.D., Ph.D. Vice President, JGOG

The Board of Education supports the dispatch of JGOG's young members to internationally highly rated cancer treatment facilities, especially those in the USA, as well as to meetings of academic societies including the Society of Gynecologic Oncology, American Society of Clinical Oncology, International Gynecologic Cancer Society, etc. Thus far, 78 members have participated in this program and are in positions of leadership in clinical trials, education and research in the field of the gynecologic oncology.

Beginning in 2007, 3-day training seminars have been offered with the aim of "training young gynecologic oncologists to become well versed in chemotherapy for gynecologic cancer and clinical trials, and of teaching them to become capable of implementing global activities." Sixty-one doctors have participated over these 3 years. Furthermore, CRC seminars are offered for nurses and data managers

who support clinical trials. We also hold town hall meetings to increase awareness and enlighten the general public on gynecologic cancer.

The Public Relations Committee manages our organization's website, provides information on JGOG to the general public, oversees the delivery of information to members and prepares the annual report of activities. This JGOG newsletter is also issued by this Committee.

In the area of publication, the journal titled "Chemotherapy News" is edited and issued quarterly by the Chemotherapy News Editorial Committee. The journal offers the latest news and information about new chemotherapies in a timely manner through "feature articles" and "voices from members." It also reports on progress of clinical studies currently implemented by the JGOG.

Education, Publication and Public Relations



Education Committee

Noriaki Sakuragi, M.D., Ph.D. Chairperson, Education Committee

Preface

The Education Committee of JGOG is taking an active part in improving therapy for gynecologic cancer as well as in educating gynecologic oncologists. Management of gynecologic cancer is accomplished by comprehensive medical care including surgery, anticancer agents, radiation, and multi-field health care staff engaged in palliative and other treatments.

It is, therefore, important for the determination of therapeutic strategy that health care staff should fully understand the standard therapy based on an ethical code before they communicate with each other. This point is also essential to clinical trials aimed at developing a new therapeutic

method. The Education Committee educates medical care staff involved in gynecological malignancy therapy and enlightens the public. This Committee has 5 major targets of its activities: largely, leading physicians in gynecologic cancer therapy, younger physicians specialized in gynecologic cancer therapy, medical service staff participating in clinical trials, citizens, and JGOG members.

1. Overseas dispatch

Overseas dispatch was initiated to train leaders responsible for education of clinical oncologists. In 1999, five physicians were sent for the first time to ASCO held in Atlanta, U.S.A. and the M.D. Anderson Cancer Center, Houston, Texas. This train-

ing program was administered every year later on to dispatch physicians to conferences related to clinical oncology as well as to cancer centers. A total of 78 physicians were dispatched for a total of 16 times until 2009 when some of them visited Germany. They, thus, learned up-to-date medical knowledge and technology, mingling with local clinical oncologists. JGOG members who join the program enjoy the advantage that they spend precious time on directly experiencing state-of-the-art clinical medicine and research. I believe that dispatched physicians were very sensible of their rewarding responsibility for taking the leadership in gynecologic cancer therapy in our country.

2. Educational seminar

Educational seminar was started in 2007 for the purpose to educate younger gynecological oncologists who were well versed in chemotherapy for gynecologic cancer as well as clinical study and were able to take a lively part worldwide in these fields. This seminar of 3 days and 2 nights enrolls about 20 younger gynecological oncologists, who plan clinical trials to develop new improved therapeutic methods in light of current standard therapy after they attend lectures on medical statistics and ethical standards, both of which are required to design and execute such trials. They create concept sheets of clinical study receiving advice from clinical oncologists and medical statistics specialists who are active in the first line. It is literally cordial man-to-man guidance since the number of participants is same as that of Faculty and Administration Office staff who advise and coach participants. The project has a good reputation for participants' developing their ability considerably. It is very reassuring that some of seminar participants have become advisers to younger oncologists at later seminars.

3. CRC education project

Clinical trials are conducted by a team system composed of a lot of medical service professionals and medical statistics specialists. Clinical research coordinators (CRCs) of the system play a very important role for ensuring reliability of clinical trials. JGOG dispatched a total of 281 medical service professionals of various types to the 1st to 10th CRC education seminars. I am confident that seminar participants are actively involved in execution of clinical trials and their quality improvement at their institutions.

4. Support to citizens' open lectures

One of 3 citizens die from cancer in these days, so that Japanese people are now very interested in cancer. JGOG holds JGOG citizens' open lectures for citizens to educate and enlighten about pathophysiology, therapy, and prognosis of gynecologic cancer. Specifically, active members make an application to JGOG for an open lecture, followed by judgment by JGOG, which gives support if applicable. This support was provided to a total of 35 lectures from November of 2003 to June of 2010.

5. Gynecologic cancer conference

JGOG cosponsors conferences mostly locally sponsored by active members for the purpose to improve quality of clinical trials that are intended to establish new evidence for gynecologic cancer therapy. The 1st ovarian cancer conference was held in Morioka in 2004. The conference was held every year later in Kurashiki and Kagoshima. The 4th conference held in Sapporo was retitled as "Gynecologic Cancer Conference" and the conferences were continuously held nationwide until today in Utsunomiya, Yonago, or Matsuyama, growing as a JGOG project. Conference themes have been clinical trials, chemotherapy, surgical treatment, radiotherapy, and pathological diagnosis, covering various fields of oncology.

Afterword

JGOG appreciates the great significance of educational projects to contribute to the progress and improvement of domestic gynecologic cancer therapy. I wish the members to steadily understand and cooperate with JGOG.

Education, Publication and Public Relations



Public Relation Committee

Kazushige Kiguchi, M.D., Ph.D. Chairperson, Public Relation Committee

Article 1 of the rules of the Public Relation Committee states to the following effect: "The Japanese Gynecologic Oncology Group (JGOG), a nonprofit organization, carries out publicity activities for the purpose to obtain an understanding of citizens on gynecological malignancy therapy and to call out to researchers and clinicians for participation in JGOG activities, particularly clinical studies. Another purpose is to provide a place for holding information in common among the members in order to facilitate JGOG activities." At present, the Public Relation Committee has 7 members engaged in publicity activities. The Committee has launched a Web site to timely inform the members of ongoing clinical studies and various JGOG activities. The Web site posts state-of-the-art information, that is

as friendly and easy to understand as possible for ordinary citizens to deepen their knowledge as well as understanding on gynecological cancer therapy. Web site notified about 70 newly arrived pieces of information since 2007 until today. Their contents are listed below.

- (1) A list of the participating registered institutions
- (2) The achievements of JGOG: Reports of results of completed clinical trials. Each report is linked to Pub Med etc., so that its contents are easily accessible.
- (3) The study protocols: you can download the protocols of ongoing clinical trials.
- (4) The points of JGOG clinical trials: These points are updated 2-3 times a

year. I beg many of you to join JGOG clinical trials.

- (5) The Chemotherapy News: The past issues of the Newsletter that have been published since 2000 appear.
- (6) The articles, rules, and detailed regulations of JGOG: Besides its article, rules, and detailed regulations, the auditing manual, the written request form for running an article on the Web site, and the operative procedure manuals appear.
- (7) Notification: The Data Center Newsletter, Periodical Monitoring Report on GCIG/JGOG3017 and JGOG2043, notice to invite the physician members to send in entries for the JGOG CRC education projects, and various important information have been posted since 2003.

As mentioned above, the Web site is full of important information which must be very useful for the viewer, so that I would appreciate many of the members visiting the Web site to make the best use of it. On the other hand, creation of an Annual Report, membership list management (pri-

vate information management) and security management (passwords have been set up), revision of the leaflet to introduce JGOG (in Japanese and English), a JGOG Newsletter for foreign countries, creation of English Web site of JGOG, and drawing up PowerPoint® files including a glossary

for clinical trials accessible only by the members logging in the members' site are under consideration in the Public Relation Committee. I will continue to make every effort to reflect members' candid opinions and requests on the Web site.

Education, Publication and Public Relations



Chemotherapy News Editorial Committee

Toshiko Jobo, M.D., Ph.D. Chairperson, Chemotherapy News Editorial Committee

The Chemotherapy News is a quarterly Japanese report issued by JGOG to be distributed to its members. Its contents are decided after discussion by the Editorial Committee composed of 9 editors, covering all fields related to gynecological malignant tumors such as chemotherapy in particular, surgical operation, radiotherapy, and clinical trials. "A special feature series" carries articles written by top oncologists in each field on recent major topics that gynecological oncologists should pay attention to. The recent topics were "Updates on HPV vaccine," "Revision of FIGO staging for gynecological cancer," "Cytodiagnosis of the peritoneal cavity and prognosis of endometrial cancer," "Translational research," and "New

chemotherapy for ovarian mucinous adenocarcinoma." The section of "Members' views" asks for submission of articles on activities of JGOG, reports of domestic or overseas conferences, and tips for daily clinical practice. This section carried "The trend and management of juvenile uterine cervical cancer," "Launching of JGOG International," "An audit of clinical trials," "Chemotherapy for platinum-resistant recurrent ovarian cancer," "Approval of government-unapproved drugs," and "Fertility-sparing surgery for ovarian cancer" for the last one year.

It is an important role of this Newsletter to inform the members of recent trends of JGOG as well as the current situations of

clinical trials. Accordingly, non-physician JGOG members are requested to write for the Newsletter. Although the newsletter is not an academic publication, the latest information on clinical oncology is provided by experts of each field. I believe that such information is very helpful for JGOG members involved in clinical medicine.

We make it our motto to "keep contents high-level and sentences easy." We will try hard to make contents of the Newsletter rich not only to improve mental attitude of JGOG members but also to advertize JGOG activities to non-member gynecologists as well as ordinary people.

Introduction to JGOG Clinical Research

Randomized phase II trial of paclitaxel plus carboplatin therapy versus irinotecan plus cisplatin therapy as first line chemotherapy for clear cell adenocarcinoma of the ovary: Japanese Gynecologic Oncology Group study; JGOG3014

Satoshi Takakura, M.D., Ph.D.
The Jikei University Hospital



Paclitaxel plus carboplatin is generally considered to be the "gold standard" regimen for treatment of epithelial ovarian carcinomas. Little data is available, however, on the use of this regimen in patients with clear cell adenocarcinoma of the ovary (CCC).

Combination chemotherapy with irinotecan hydrochloride plus cisplatin has been reported to be effective for primary and recurrent or resistant CCC. JGOG conducted a randomized phase II study to compare CPT-P with TC in patients with CCC.

Patients (n=99) with CCC were randomly assigned to receive either 60 mg/m² irinotecan hydrochloride on days 1, 8, 15 plus 60 mg/m² cisplatin on day 1 every 28 days (CPT-P arm, n=49) or 180 mg/m² paclitaxel on day 1 plus AUC 6 mg/mL x min carboplatin on day 1 every 21 days (TC arm, n=50). One patient in the CPT-P arm refused to allow submission of the case report form to the data center. Therefore, the full analysis sets (FAS) for the CPT-P and TC arms were 48 and 50 patients, respectively. After central pathology review, 5 cases were excluded due to wrong cell type. One of them was in the CPT-P arm and 4 were in the TC arm. Therefore, an analysis [for] per protocol set (PPS) was performed for 47 patients in the CPT-P arm and 46 patients in the TC arm. The median follow-up time for this trial was 31.6 months.

The percentages of patients receiving the scheduled 6 cycles of chemotherapy in the CPT-P and TC arms were 70.8% and 72.0%, respectively. Although toxicity was well tolerated in both arms, the toxicity profile of each arm differed. Grade 3 or worse thrombocytopenia occurred more frequently in the TC arm than in the CPT-P arm (Odds ratio, 0.14; 95% CI, 0.03 to 0.65; p = 0.0077). Grade 2 or worse peripheral sensory neuropathy occurred more frequently in the TC arm (Odds ratio, 0.19; 95% CI, 0.05 to 0.72; p = 0.0015). Although the difference was not statistically significant, grade 3 or worse gastrointestinal toxicities were more frequent in the CPT-P arm.

Clinical response was assessed in the 13 patients in the PPS with clinically measurable disease. There were 2 CR, 2 NC and 4 PD among the 8 assembled patients in the CPT-P group, and the overall response rate was 25% (95% CI, 3.2 % to 65.1 %) in the CPT-P group. There were one CR, one PR, and 3 PD among the 5 assembled patients in the TC group, and the overall response rate was 40 % (95% CI, 5.3 % to 85.3 %). No significant difference was observed in overall response rate between the two treatment groups.

PFS was compared for all patients in PPS and FAS. No significant difference was observed between the two treatment groups (PPS: p = 0.9089 by the log-rank test; FAS: p = 0.9035 by the log-rank test), and the relative risk of disease progression in the TC group as compared with that in the CPT-P group was 1.034 (95% CI, 0.583 to 1.835) in PPS and 0.964 (95% CI, 0.544 to 1.710) in FAS. Since there were more patients in the CPT-P arm (11 patients in PPS and FAS) than in the TC arm (2 patients in PPS; 4 patients in FAS) with larger residual disease greater than or equal to 2 cm, we performed a subset analysis by removing those patients, and then compared the PFS with patients without residual disease or with residual disease less than 2 cm. PFS tended to be longer in the CPT-P group, although the difference was not statistically significant (PPS: p = 0.2702 by the log-rank test; FAS: p = 0.3176 by the log-rank test), and the relative risk of disease progression in the TC group as compared with that in the CPT-P group was 1.465 (95% CI, 0.757 to 2.836) in PPS and 1.414 (95% CI, 0.730 to 2.739) in FAS. Furthermore, we compared PFS in patients with residual disease less than 2 cm. There was a strong tendency that PFS was longer in the CPT-P group, although the difference was not statistically significant (PPS and FAS: p = 0.056 by the log-rank test), and the relative risk of disease progression in the TC group was significantly higher than that in the CPT-P group [2.945 (95% CI, 1.052 to 8.246)] in PPS and FAS.

These results suggest that CPT-P has a potential therapeutic benefit that is greater than that of TC therapy for CCC. A phase III randomized trial is required to elucidate the efficacy of CPT-P combination chemotherapy in CCC. At present, the JGOG and the Gynecologic Cancer Intergroup (GCIIG) is performing an international cooperative randomized phase III trial of TC therapy versus CPT-P therapy as a first line chemotherapy for CCC (GCOG/JGOG 3017 ovarian trial), and the results are eagerly awaited.

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Introduction to JGOG Clinical Research

Randomized phase II study comparing docetaxel plus cisplatin, docetaxel plus carboplatin, and paclitaxel plus carboplatin in patients with advanced or recurrent endometrial carcinoma: Japanese Gynecologic Oncology Group study; JGOG2041

Daisuke Aoki, M.D., Ph.D.
Keio University Hospital



It is presently considered that cisplatin and doxorubicin are the key drugs for endometrial carcinoma. Cisplatin/doxorubicin (AP) combination therapy is also generally acknowledged to be the standard chemotherapy for advanced or recurrent endometrial carcinoma by GOG 107 study and EORTC 55872 study. On the other hand, taxanes are considered to be one of the effective classes of drugs for the treatment of endometrial carcinoma. In the

GOG 177 study, paclitaxel/doxorubicin/cisplatin (TAP) + G-CSF combination therapy was significantly superior to AP with regard to survival, however, from the perspectives of toxicity and tolerability, the conclusion that TAP could be the standard therapeutic choice was not supported. In this matter, combination chemotherapy approaches that include taxanes are presently under scrutiny as the standard regimen for endometrial carcinoma. This study

aimed to assess the efficacy and safety of treatment with taxane plus platinum in combination therapies for advanced or recurrent endometrial carcinoma.

Eligibility criteria of this study allowed for entry of patients with measurable disease derived from histologically confirmed stage III/IV or recurrent endometrial carcinoma and/or patients having had a treatment-free interval following cytotoxic chemotherapy, radiotherapy, or hormonal therapy of at least 6 months, 4 weeks or 2 weeks, respectively. Prior chemotherapy was permitted and there was no limitation to the number of prior chemotherapy regimens. The study planned to administer docetaxel (70 mg/m²) plus cisplatin (60 mg/m²) (DP), docetaxel (60 mg/m²) plus carboplatin (AUC 6) (DC), or paclitaxel (180 mg/m²) plus carboplatin (AUC 6) (TC) every 3 weeks until disease progression or adverse events prohibited further therapy. Patients were randomly allocated to 3 groups at a rate of 30 per group by the minimization method. The primary endpoint was the response rate, and the secondary endpoints were the frequency of adverse events, the treatment completion rate, and progression-free survival (PFS). An independent review committee assessed the tumor response for each patient according to RECIST.

Ninety patients were enrolled. Of the enrolled patients, 88 were eligible and consequently 29, 29, and 30 patients were randomly assigned to DP, DC, and TC, respectively. Regarding the frequency of the main toxicities, the following were observed: grade 3 and 4 neutropenia in 83.3, 90.0, and 76.6%; febrile neutropenia in 10.0,

6.7, and 3.3%; grade 3 and 4 thrombocytopenia in 6.7, 10.0, and 10.0%; grade 3 and 4 diarrhea in 13.3, 3.3, and 0% in the DP, DC and TC groups, respectively; and grade 2 or more neurotoxicity in 13.3% of the TC group. These toxicity profiles were not significantly different. Tumor response rates were 51.7% (0 CR, 15 PR; 95% C.I.; 32.5-70.6), 48.3% (4 CR, 10 PR; 95% C.I.; 29.4-67.5), and 60.0% (2 CR, 16 PR; 95% C.I.; 40.6-77.3) in DP, DC, and TC, respectively (P = 0.65). There was not statistically significant differences in the progression-free survival or the overall survival between each group.

This study designed the comparison between standard AP therapy and each taxane plus platinum regimen. This study concluded that the response rates of all taxane plus platinum regimens did not fall below 25% of the threshold response rate, based on the lower boundary of 26% for the 95% confidence interval (26%-43%) of the response rate for AP in the GOG 177 study. Among combination chemotherapy options involving taxanes and platinum for advanced or recurrent endometrial carcinoma, the results of the present study suggested that the 3 regimens of DP, DC, and TC may have efficacy and tolerability that surpass those of AP reported in the past. The efficacy was similar in each arm and their potential efficacy will allow us to choose an experimental arm for a phase III trial to confirm a survival benefit of taxane plus platinum for endometrial carcinoma.

(Published: Ann Oncol; 2010, Epub ahead of print)

Introduction to JGOG Clinical Research

The Utility of Neoadjuvant Chemotherapy using Irinotecan hydrochloride (CPT-11) and Nedaplatin (NDP) for the Bulky but Operable Cancer with the Uterine Cervix: Japanese Gynecologic Oncology Group study; JGOG 1065

Satoshi Yamaguchi, MD, PhD.
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Uterine cervical cancer study (JGOG1065) was performed to investigate neoadjuvant chemotherapy (NAC) for uterine cervical cancer (squamous cell carcinoma). Eligible criteria were: treatment-naïve patients with cervical cancer (squamous cell carcinoma) which could be treated with radical hysterectomy; in stages of Ib2-IIb; lesions that could be measured directly or by MRI; 20-75 years of age; and P.S. 0-1. The regimen for NAC was CPT-11+Nedaplatin, which achieved good response rates in the former JGOG cervical cancer studies. In consideration of its easy applicability to NAC in practical medicine, the treatment method could be changed to radical hysterectomy if patients achieved a PR after 1-3 courses of the regimen.

Sixty-eight patients were entered but 2 patients were ineligible. Therefore, 66 cases were analyzed as FAS subjects. Patient backgrounds: the median age, 47 years (22-71); stage Ib2 in 18 cases, IIa in 10 cases, and IIb in 38 cases; P.S. 0 in 61 cases and 1 in 5

cases; and tumor diameter ≤ 4 cm in 16 cases and > 4 cm in 50 cases. The therapeutic protocol was discontinued in 3 cases: refusal of therapy by the patient in 1 case; exploratory laparotomy alone in 1 case; and decision of inoperability in 1 case. The number of courses was 1 in 13 cases, 2 in 43 cases, and 3 in 10 cases. Initiation of the second course was postponed in 75.5% of cases, while start of the third course was postponed in 70%.

Grade 3-4 adverse events occurred as follows: neutropenia most frequently in 71.2%; leukopenia in 16.7%; thrombocytopenia in 7.6%; diarrhea in 6.1%; and ALT/SGPT elevation / appetite loss / vomiting / fever / ileus / neutropenia-induced infection / allergic reaction / vesicovaginal fistula in 1.5%. There was no serious event like death and no problem with safety.

The response rate as the primary endpoint was 75.8%: CR in 2 cases, PR in 48 cases, SD in 12 cases, PD in none, and evaluation failure in 4 cases. The average number of courses required until

response was 1.42: 1 course in 30 cases, 2 in 19 cases, and 3 in 1 case.

Regarding evaluation of surgical treatment outcomes, residual tumors and incomplete lymph node dissection as judged by the operating surgeons occurred in 6.4% (4/63), and cancer cell-positive stumps that were pathologically examined in the extirpated tumors were seen in 11.1% (7/63). The average blood loss was 998 ml, while the average surgical time was 294 minutes.

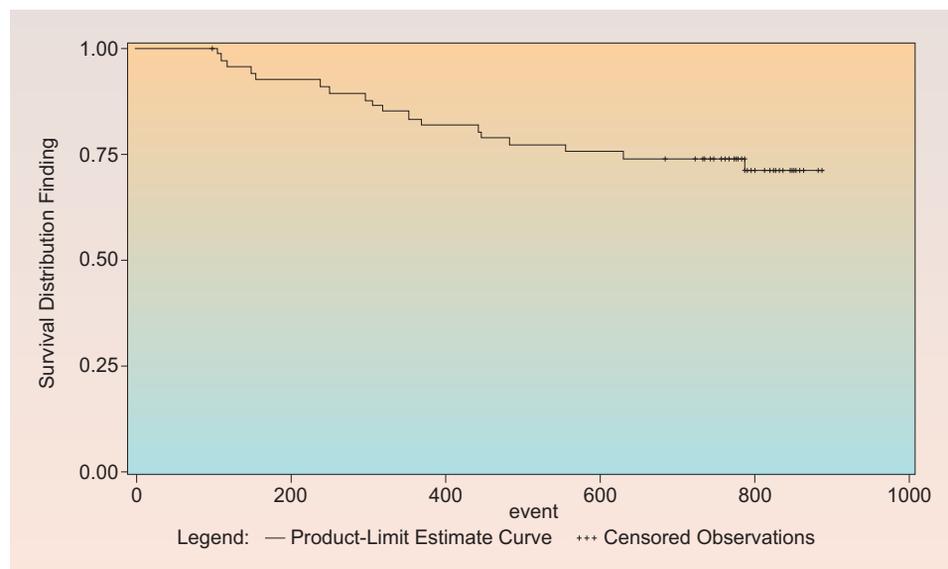
Pathological examination revealed the following: as to stromal invasion, negative in 6 cases, less than 50% in 21 cases, and 50% or greater in 36 cases; as to vascular invasion, negative in 32 cases, positive in 31 cases; as to lymph node metastasis, negative in 44 cases, positive in 19 cases; and as to histological response, G0 in 6 cases, G1a in 23 cases, G1b in 8 cases, G2 in 22 cases, and G3 in 4 cases.

Concerning operative complications, G3-4 intraoperative bleeding associated with surgery was seen in 3.2%, which seemed comparable to radical hysterectomy. Urinary retention occurred at G0 in 33.9%, G1 in 25.8%, G2 in 19.4%, and G3 in 21%. Concerning other complications, G1-2 lymphocele was observed in 27.4%, which tended to be higher compared to other studies.

Two-year progression-free survival rate was 73.8% (95% confidence interval was 0.613 – 0.829). This study did not lay down a rule for postoperative additional therapy, which was provided depending on the treatment plan of each institution as well as the attending physician's decision. Details of postoperative therapy were as follows: no additional therapy in 30 cases, RT/CCRT in

20 cases, and chemotherapy in 15 cases.

In conclusion, CPT-11+Nedaplatin is one of effective regimens for the treatment of uterine cervical cancer (squamous cell carcinoma) since this study showed that the regimen brought about the response rate of 75.8% in NAC for the cancer. This study itself could not determine whether NAC should be conducted nor whether NAC benefited prognosis since the outcomes were greatly influenced by inter-institutional differences in surgical treatment methods and also by the presence or absence of postoperative additional treatment. It is at least safe to say that the overall 2-year PFS was 73.8% in patients who were initially treated with CPT-11+Nedaplatin as NAC and underwent radical hysterectomy thereafter. This response rate was not bad taking it into account that 57.6% of the patients were in the stage of IIb and 75.8% of them had tumors >4 cm in diameter. However, validity of NAC was not confirmed nor denied by this study. There seem to be a lot of institutions that perform NAC in clinical practice or as clinical trial, so that we need to study furthermore.



2-year progression-free survival time (Kaplan-Meier method)

Editorial postscript



Kinkaku-ji (Golden Pavilion) in Kyoto

In order to provide citizens with better therapy for gynecological malignant tumors, we need to make an effort relentlessly to keep quality of therapy at a high level. To this end, it is important to carry out the education for enlightenment of not only physicians but also medical care professionals as well as patients. JGOG has carried out such education to medical care professionals engaged in therapy for gynecological malignant tumors. It has also been involved in enlightening teaching of ordinary citizens through the support to citizens' open lectures. Moreover, The Chemotherapy News is issued quarterly as part of the enlightening teaching project for medical care professionals. Accordingly, the JGOG International No.3 has run articles primarily on Education, and Publication and Public Relation which constitute the central pillar of JGOG projects ranking beside Clinical Research. On the other hand, this issue carries articles on JGOG3014, JGOG2041 and JGOG1065 also. In addition, I was happy to have received a letter of greetings from Soon-Beom Kang (President of KGOG), with which JGOG has most deeply collaborated. I express my cordial gratitude to Professor Soon-Beom Kang. I will continue to report activities of JGOG through the JGOG International.

Kazushige Kiguchi M.D., Ph.D.
Chairperson, Public Relation Committee



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