Keynote Forum

6th World Congress on

Masaru Sakamoto, J Nurs Res Pract,
ISSN : 2632-251X, Volume 06

WOMENS HEALTH AND MIDWIFERY

July 11, 2022 | Webinar

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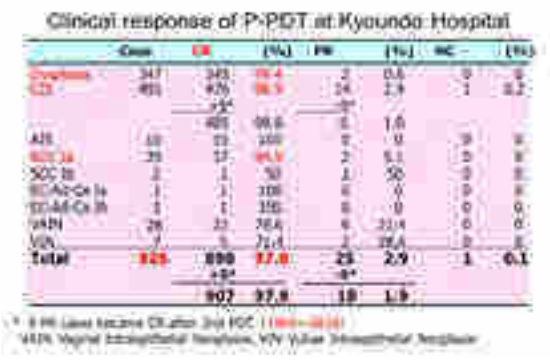
Received date: 08. 05. 2022 | Accepted Date: 12. 05. 2022 | Published Date: 25. 07. 2022

Application of the next generation L-PDT with talaporfin sodium (Laserphyrin) for Cervical Intraepithelial Neoplasia (CIN)

We have treated more than 900 cases of CIN and uterine cervical cancer using PDT with Photofrin (P-PDT) (Sakamoto, et al. In: Cryosurgery and Colposcopy, Nova Science Publishers, p127-144, 2016). PDT is considered to be a treatment modality with higher fertility sparing capacity than cone resection as uterine preservation therapy for CIN3. P-PDT has high efficacy for CIN and has low obstetric risks such as premature delivery after P-PDT. However, the side effect of photosensitivity is strong and the hospitalization period is long, so P-PDT has not reached standard treatment. In order to investigate the safety and effectiveness of L-PDT using semiconductor laser and Laserphyrin with less half-life in blood, we started Phase I/II study of L-PDT after registration to UMIN.

Methods: After approval of the ethical committee, phase I/II study of L-PDT was performed on 43 cases of CIN2-3 with IC. Phase I study was performed to investigate safety and the optimal dose of laser irradiation. Three cases were performed for each step of 50, 75 and 100 J/cm2. Phase II study was performed to further investigate safety and effectiveness of L-PDT with recommended dose of 100 J/cm2. [Results]Intra-tumor accumulation of Laserphyrin was confirmed by Fluorescence microscopy. Dose Limiting Toxicity was not observed. The main side effects were lower abdominal pain of G1-2 and fever of G1-2. Photosensitivity of G1 within 15 days was seen only in 3/43 cases (7%). Histological disappearance of CIN2-3 was observed in 41/43, 42/43 cases at 3, 6 months after L-PDT, respectively.

Conclusion: Although temporary lower abdominal pain and fever were observed in L-PDT, photosensitivity was hardly seen unlike P-PDT, suggesting safety. CR rates 3 and 6 months after L-PDT were 95 and 98%, suggesting efficacy. These data suggested L-PDT would become the next generation PDT for CIN as uterine preservation therapy.



Recent Publications:

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4. Harano N, Sakamoto M, Fukushima S, Iwai S, Koike Y, Horikawa S, Suzuki K, Narui C, Matsuoka K, Ozeki R, Iwaya K, Umayahara K, Tanaka T, Okamoto A. Clinical Study of Sentinel Lymph Node Detection Using Photodynamic Eye for Abdominal Radical Trachelectomy. Current Oncology. 2021; 28(6):4709-4720. https://doi.org/10.3390/curroncol28060397.

Biography

Masaru Sakamoto is the Professor of the department of Obstetrics and Gynecology, the Jikei University School of Medicine, graduated from Tokyo Medical University and qualified as a medical doctor from the Japan National Board of Medicine in 1982. He was qualified as a specialist of OB/GYN in 1988. After he obtained his PhD degree, he worked at the Department of Gynecology of Sasaki Foundation Kyoundo Hospital as a medical staff in 1988. He studied abroad as a researcher at Prof. Gray Lab. in Lawrence Livermore National Laboratory, USA in 1990. He moved to the Gray Lab. at the University of California San Francisco, USA, in 1991. He came back to the Kyoundo Hospital in 1992. He was qualified as a specialist of clinical cytology in 1996. He became a co-inventor of Comparative Genomic Hybridization, which was registered as U.S. Patents, in 1999. In 2000, he became Principal Investigator of the National Research Project of Ministry of Health and Welfare until 2004. In 2005, he became Medical Director of the Department of Gynecology of Sasaki Foundation Kyoundo Hospital (-Present). In 2006, he was qualified as a specialist of Laser Surgery and Medicine. In 2007, he was qualified as a specialist of Gynecologic Oncology. In 2015, he became Vise-President of Sasaki Foundation Kyoundo Hospital (~Present). He was also promoted to be the Professor of the Department of OB/GYN at the Jikei University School of Medicine in 2017.

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