12 Improving Prostate Cancer Treatment

Situation

Prostate cancer ranks third among male cancers in Japan (2010 figures) and the incidence is growing.[1] The most strongly associated risk factors are age, ethnicity, family history, hormones, and obesity, among others.[2] According to data for 2004, prostate cancer is expected to increase and surpass gastric cancer into second place among Japanese males by 2020.[3] Moreover, prostate cancer is already the second most common cause of cancer deaths in American males since 1997. In Japan, the disease still ranks sixth in cancer deaths,[1] but the incidence is expected to increase even more by 2025.[4]

Because the morbidity and death rates start increasing from the age of 50 while individuals are still working,[1] future economic losses are considered to be significant. Therefore, countermeasures should be sought.

Current Policy

Recently, a new pathological concept for castration-resistant prostate cancer (CRPC) is being used. Prostate cancer is originally characterized by slow progression and is considered controllable to some extent up to the initial castration. Once resistance is observed, however, the prognosis worsens rapidly and unmet medical needs exist for these patients.

Three drugs with overseas track records were introduced to Japan in 2014. These drugs are expected to improve the prognosis of patients with CRPC dramatically. Currently, there are nearly 30,000 patients with CRPC and both the number and the incidence are increasing. Early CRPC is often found in men in their 50s to 60s who still working, and they can continue to support society while they are receiving treatment, if the efficacy and symptoms permit.

In 2009, the US FDA proposed in the Journal of Clinical Oncology that emphasis be placed on PROs (Patient Reported Outcomes) for the entire cancer therapeutic area.[5] PROs report the status of the patient's health directly from them without interpretation by a clinician or any other party.[6] PROs can be used to analyze patients' assessments of their QOL, and this makes medical care from the patient's point of view even more important. It is clear from the 2013 report about prostate cancer that physicians and patients do not share similar perceptions about the peripheral symptoms of prostate cancer, such as pain and fatigue, and that the gap between their positions has not been narrowed yet.[7] Prostate cancer data reported in journals have been discussed mainly on the basis of "PSA (prostate-specific antigen)." In addition, in recent years, the importance of evaluation by diagnostic imaging relating mainly to bone lesions, alleviation of symptoms relating mainly to pain, and evaluation relating to QOL has been pointed out.[8]

In consideration of the important therapeutic goal of maintaining the quality of daily life of prostate cancer patients, it is important to improve PRO-conscious communication between patients and physicians. Because patients with this disease increase in numbers in their 50s — people who are still working and making social contributions — treatments with less impact on daily life are important to both patients and the Japanese economy.

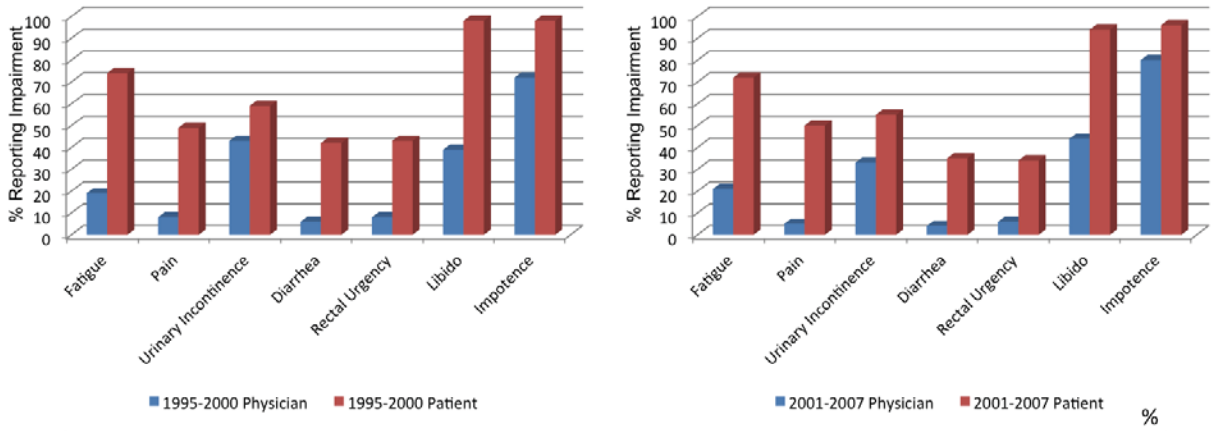
Recommendations

- Promote proven treatments that enable the maintenance of quality of daily life in order to improve outcomes for prostate cancer, in particular castration-resistant prostate cancer.
- It is important from the perspective of PROs to promote the importance of QOL evaluation in consideration of not only PSA measurements, but also of imaging and symptom assessments and patient opinions.
- Recommend the perspective of PROs for future clinical study endpoints and for guidelines on the use of cancer medications.
- Establish a mechanism to adopt PROs in actual clinical settings.
- Ask disease specific questions during a physician's medical examination.
- Recommend communication with cancer-certified pharmacists and nurses.

References

1. Gan-pro.com http://www.gan-pro.com/public/cancer/urol.html
2. International Agency for Research in Cancer (IARC). EPIC Study. The Prostate Cancer Working Group. http://epic.iarc.fr/research/cancerworkinggroups/prostatecancer.php
3. Shinoharashinsha Publishers Inc. Akira Oshima/Cancer Statistics-Affection, Death, Prognosis 2004
4. Shinoharashinsha Publishers Inc. Cancer Statistics 2012
5. Contains Nonbinding Recommendations, December 2009
6. US Department of Health and Human Services, Food and Drug Administration. Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims; Dec. 2009, p6.
7. THE JOURNAL OF UROLOGY® Vol. 189, S59-S65, January 2013
8. Cookson M., et al. Castration-resistant prostate cancer: AUA Guideline. 2014 The Journal of Urology 190(2); 429-438

12. Perception Gaps of QOL between Patients and Doctors has yet to be improved. "QOL Improvement Appealed by Patients" should be considered as one of treatment goals



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		Fatigue	Pain	Urinary Incontinence	Diarrhea	Rectal Urgency	Libido	Impotence
1995-2000	Physician	19	8	43	6	8	39	72
	Patient	74	49	59	42	43	98	98
2001-2007	Physician	21	5	33	4	6	44	80
	Patient	72	50	55	35	34	94	96

Source: Differing Perceptions of Quality of Life in Patients With Prostate Cancer and Their Doctors
THE JOURNAL OF UROLOGY Vol. 189,January 2013

12. PRO Measures used in Prostate Cancer

Cancer-Specific Instruments
1. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
2. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Prostate Module (EORTC QLQ-PR25)
3. Functional Assessment of Cancer Therapy – General Version (FACT-G)
4. Functional Assessment of Cancer Therapy – Prostate Version (FACT-P)
5. FACT Advanced Prostate Symptom Index (FAPSI-8)
6. Prostate Cancer Treatment Outcomes – Questionnaire (PCTO-Q)
7. University of California-Los Angeles Prostate Cancer Index (UCLA-PCI)
8. Expanded Prostate Index Composite (EPIC)
9. Prostate Cancer-Quality of Life (PC-QoL)
10. Patient Oriented Prostate Utility Scales (PORPUS-P and PORPUS-U)

Reference: Morris C., Gibbons, E., Fitzpatrick, R. A structured review of Patient-Reported Outcome Measures for men with prostate cancer. Report to the Department of Health 2009. Patient-reported Outcome Measurement Group, Department of Health, University of Oxford, pp. 35-37.