

## REPORT FROM SCANDINAVIAN PROSTATIC CANCER GROUP (SPCG)

SPCG has worked actively during the last two years. The group has been chaired by Teuvo Tammela and Peter Klarskov has worked as the secretary till the end of 2008 when he was replaced by Klaus Brasso. The Board consisting of ordinary members (two per country) and affiliated members has had annually at least two meetings. In addition, the investigators of the special studies have had their own meetings focusing on the special questions of that study. SPCG arranged Scandinavian Prostate Cancer Group Trial meeting for all investigators and study nurses in Johannesbergs Slott outside Uppsala in October 2008. One uro-oncologist from each Nordic country has worked as an affiliated member. This has offered oncological expertise and more opportunities to start new kinds of studies that require co-work between urologists and oncologists. The uro-oncologists have brought a lot of new ideas and new way of thinking into the group influencing the three newest studies (SPCG-12, SPCG-13 and SPCG-14). Other affiliated members have been the principal investigators of ongoing SPCG trials. See enclosed the list of members.

SPCG-11 Study (Effectiveness of Zometa treatment for prevention of bone metastases in high risk prostate cancer patients) started in 2004 as collaboration between SPCG and German Arbeitsgemeinschaft Urologische Onkologie (AUO) and with EAU. EAU coordinates the study and manages the database, while SPCG runs and monitors the Scandinavian part, which can also be analysed and reported separately after common analysis of the whole study. This gives autonomy thought to be important in this kind of collaboration. Main reason for collaboration was the high number (1500) of patients needed to reach the statistical power. Novartis is supporting the study by donating a grant to the SPCG Foundation. In SPCG 224 patients have been included.

SPCG-12 Study (An open randomised phase III trial of six cycles of docetaxel versus surveillance after radical prostatectomy in prostate cancer patients with high grade pT3 and Gleason  $\geq 3+4$  margin positive pT2/AdPro) focuses on adjuvant docetaxel treatment in patients undergoing radical prostatectomy but have poor prognostic factors. It is the only SPCG Study in which all the five Nordic Countries are participating. The study is done in close collaboration with uro-oncologists. The study started in 2005 and is close to reach the goal of 400 randomized patients. However, the number of randomized patients will be increased to reach surely the statistical power needed.

SPCG-13 Study (A Randomized phase III trial of six cycles of docetaxel versus surveillance plus hormonal treatment after radical radiotherapy in patients with intermediate or high-risk prostate cancer/AdRad) focuses similarly on adjuvant docetaxel treatment in patients treated with radiotherapy but have poor prognostic factors. The uro-oncologists have a leading role in this trial. The study started in 2006. Due to delays in recruitment the statistics have been re-evaluated and the number of the aimed patients has been decreased to 378.

SPCG-14 Study (A Randomized, Open Label, Multicenter, Phase III, 2-Arm Study of Androgen Deprivation +/- Docetaxel for Non metastatic Prostate Cancer Patients with a Rising PSA) recruits patients who have prostate cancer without metastases with rising PSA following curative treatment (RP or RT) and PSA  $> 10$  or PSA doubling time  $< 6$  months & PSA  $> 5$  and patients planned for antiandrogen treatment (castration) with PSA of 20-100 and PSA doubling time  $< 6$  months or Gleason score  $\geq 8$ . Antiandrogen treatment only is compared with antiandrogen treatment in combination with docetaxel. The primary endpoint is PSA progression free survival and the secondary endpoints are time to metastatic disease, cancer specific survival, overall survival and quality of life (FACT-P-T). The goal is include 215 patients per arm. The study has just started and recruited the first three patients.

The SPCG-5 Study (High-dose estradiol phosphate versus total androgen blockade) has been closed and the final evaluation has been published. Evaluation of other results of the study are still in progress, including quality of life, prognostic markers in hormone resistant prostate cancer and cardiovascular risk factors during treatment with parenteral estrogen in prostate cancer patients

SPCG-6 Study (A randomized, double-blind, parallel group trial comparing Casodex 150 mg once daily with placebo in patients with non-metastatic prostate cancer) has been closed. It produced more publications (18) and congress presentations (57) than any other SPCG Study. The most famous of the SPCG studies is, however, SPCG-4 (Expectation or radical prostatectomy on early prostate cancer) with three SPCG-6 reports published in N Eng J Med and two J Natl Cancer Inst. This study has made SPCG still more well-known globally among urologists.

SPCG-7 Study (Randomised trial of locally advanced prostate cancer. Antiandrogen treatment with or without radiotherapy) was started in 1996 and it recruited 880 patients in two arms. Its main results was reported recently in Lancet. The analysis showed that addition of radiotherapy gives a clear benefit over pure endocrine therapy in the treatment of local or locally advanced prostate cancer. In conjunction with SPCG-7 Study there is running a biopsy study. Two more papers have been published and the study is continuing.

Although SPCG studies last for a very long time most of them are completed and produce data which no other study groups have been able to produce. The long duration causes problems with sponsors which are not so willing to continue their support accordingly. The problems have, however, been succeeded to overcome so far. Although the economical situation of SPCG Foundation is a little bit better than it was a few years ago, due to the efforts made by the group, the future looks very challenging.

Most of the SPCG studies have been sponsored, at least partly, by drug companies, which seems to be important also in the future because there are no other realistic possibilities to find in the Nordic Countries all the money needed to cover the costs of clinical trials. The co-work with companies, however, necessitates that SPCG has a crucial role in planning protocols and has also an access to the database. On the other hand, the companies are not any more willing and permitted to support the investigator initiated trials as much as previously which, in association with the new EU directive, increases enormously the work load of the principal and coordinating investigators. This has made it more difficult to start and conduct good clinical trials. However, SPCG is most powerful in conducting clinical multicenter trials and I think this is what the group should also aim do in the future. Basic research can be included in these studies whenever possible. Another option is to develop collaboration with other study groups or the EAU which have more sponsoring from other sources. In this case the SPCG must make sure to have autonomy in order to keep identity of its own. In any case, it looks like SPCG will need this kind of collaboration in the future.

Tampere on May 31, 2009

Teuvo Tammela  
Chairman of SPCG

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