

NUF- BULLETINEN

SCANDINAVIAN ASSOCIATION OF UROLOGY



2 / 2009





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 **Abbott**
Oncology

FIN/168/11.2008

Editors' corner

Dear friends and colleagues,



NUF congress in Reykjavik in June was a success with 468 active participants. You can read a short report of miscellaneous matters from the happening in this issue. At the NUF home pages you can see hundreds of interesting pictures from the congress and the social events. First of all we want to welcome our new NUF president, professor Kimmo Taari, to our Bulletin team and to take care about the President's corner. In his first corner he will align his ideas for the next four years. Kimmo has always been very open for the Nordic co-operation. The arrangements for the next NUF meeting are already ongoing and it will be hold in the very beautiful lake district in Tampere 2011. It is chaired by professor Teuvo Tammela and we are expecting to have a high quality meeting with many attendees from all the Nordic countries.

Like Kimmo, the editors also think there is a need for Nordic co-operation. People from South Europe have very different climate, history, religion, culture and also different disease profile. For example we have much more prostate cancer patients. One form of the lively co-operation is the Nordic collaboration groups. Some of these are very active and productive, some of them less. The chairperson Elisabeth Farrelly represents the activities and the members of the newest group, the lower urinary tract dysfunction (LUTD), in this issue.

There are some colleagues who due to different motivations want to go to remote places to work. Urologist Matti Rauvala has been working under the Red Cross organization in many emergency areas. In this issue he tells us about his experiences to work in a small primitive village in Tanzania. One must admire those people who devote their free time and endanger their health for helping the other people. That is really something!

New medicines, operation techniques with the most fantastic novel equipments and other innovations are appearing all the time, some of them staying and the others quietly falling into the oblivion. Patients and doctors are asking or actually pressing for them and those responsible for the health economics are tearing their hair. Sometimes it is interesting to look backwards. The history of the treatment of prostate cancer is not very long but it has become very complicated these days, and must be individually tailored. Professor

Iversen has been involved in the secrets of prostate cancer for years and he if anyone is one of the best persons to illustrate with personal insight the present and the future of the issues related to the treatment of prostate cancer. Birdwatching and -photographing is a very fascinating and demanding hobby. Gunnar Aus is well known for his excellent presentations where the exciting moments of bird's life are captured in photos. The photos are alternating with scientific and work-related slides often concerning the matter at hand. In the section "Urologist and free time" you can read the breath taking lively story about an eagle in action with illustrations and the guidelines of bird photographing with many nice examples!

The editors wish you all a peaceful and relaxing Christmas time and a Happy New Year 2010.

Pekka and Sirpa



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EDITORIAL

Editor-in chief

Pekka Hellström, MD, PhD

Division of Urology

Department of Surgery

Oulu University Hospital

PO Box 22

FIN-90029 OYS, Finland

E-mail: pekka.hellstrom@ppshp.fi

Tel. +35883153598

Fax +35883152447

Co-editor

Sirpa Aaltomaa, MD, PhD, docent

Chief Urologist

Kuopio University Hospital

P.O. Box 1777

70211 Kuopio, Finland

Tel +358 44 7172250

Fax +358 17 173749

e-mail: sirpa.aaltomaa@kuh.fi

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EDIT / Grafica Reklame

Tagmosevej 11, DK-8541 Skødstrup

Tel./ fax: + 45 86 99 23 22

E-mail: lene@grafica-design.dk

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President's corner

by Kimmo Taari



Dear colleagues,

It is now my turn to write the President's corner. After eight years of hard work has Anders Mattiasson given up the post to Finland. Anders has lead our association with enthusiasm and in an excellent way. I give him humble and warm thanks for this work.

The 27th Congress of the Scandinavian Association of Urology and Urological Nurses in Reykjavik, Iceland, June 10-13, 2009 was a success. I give warm thanks to Gudjón Haraldsson, Congress Chairman and Guðmundur Geirsson, Chairman of the Icelandic Urological Association for arranging a fine meeting. We have reports from the meeting in this Bulletin and also plenty of pictures in our web site (<http://www.scaur.org/Pictures.html>).

The executive committee of our association is small; president, the general secretary and the treasurer. Although the new president is quite green, we have fortunately experienced colleagues in the board, namely Alexander Schultz as the general secretary and Börje Ljungberg as the treasurer. The executive committee has already had several stimulative meetings and the last one was held in Tampere in September. We had fruitful discussions with the organising committee of the next NUF congress. The forthcoming congress will be in Tampere in September (!) 2011 and the arrangements are in good shape. I know that Teuvo Tammela will organise a fine meeting.

What is the role of the Scandinavian Association of Urology? There has been some scepticism about the future of our association in the global world. Do we still need it and is there any more place for Scandinavian cooperation? This question has been asked many times during the past forty years as Jaakko Elo wrote in the short histo-

ry of the Scandinavian urology (<http://www.scaur.org/history/history.pdf>). I think our association still has an important role in Scandinavian urology. We need collaboration and we have strong working groups in different fields of urology. One of the main functions of our association is to support and activate the collaboration working groups. The national societies will nominate the members for the working groups and the association will give some financial support.

In the future, we need more basic teaching courses in different fields of urology e.g. urodynamics and laparoscopy. The association will give financial support also for these activities. This support maybe more and more important in the future if the economic depression and other regulations cause companies to restrict their support.

What is the role of the Scandinavian Association of Urology in Europe? The European Association of Urology is

very strong and we are all also members of it. Still we are Scandinavians and have many common features which are unique in Europe. Our surgical and urological education and also patient care and treatment is quite uniform in different Nordic countries. In urology we have a strong scientific tradition e.g. in SPCG and urothelial working groups. It is possible to conduct large multi-centre studies with common protocols in the Nordic countries. The clinical studies are usually of high quality and recognised all over the world. I think we should continue in this way and promote more multi-centre studies.

In short, we should also promote our journals Scandinavian Journal of Urology and Nephrology and NUF-Bulletinen.

With best wishes to all Scandinavian urologists and all friends of NUF.

*Helsinki November 2009
Kimmo Taari*



27th Congress of the Scandinavian Association of Urology, Reykjavik 10th-13th June, 2009

by S. Aaltomaa, P. Hellström & I. Perttilä, Pictures S. Aaltomaa & I. Perttilä

The 27th NUF meeting was held in exotic Reykjavik in favorable weather, no rain, only partly cloudy. There were 468 participants from 16 different countries attending the meeting; also many distant countries were represented. The arrangements were carefully done and convenient, everything seemed to work well. The main venue was in the hotel Hilton Nordica Reykjavik, which had appropriate rooms for the presentations and the exhibition. The exhibition was located just in front of the presentation rooms, easy to reach for everyone. And during the pauses, the exhibition was very crowded meeting place and lively discussion could be heard. The lunch was practically in boxes, which you could take where ever you wanted to enjoy your meal, in special lunch sessions, in the exhibition room or outside! Posters (n=25) were hanged in the presentation room available everyday during the congress.

On Wednesday 10th there were two parallel sessions running, in the morning; LUTD (lower urinary tract dysfunction) and laparoscopic urology. The rooms were situated next to each other, so it

was easy to switch from one to another if you wanted to. In LUTD session prostate enlargement, neurogenic bladder and stress urinary incontinence were the topics. In assessment of LUTS secondary to BPH Lars Malmberg handled the diagnostic procedures. The pressure-flow study is optional but the most useful investigation in counseling patients regarding the outcome of surgical therapies. Preoperatively proved obstruction means better outcome after TUR-P. On the other hand patients with low pressure and low flow urodynamics may benefit from TUR-P, however the probability is low. Poul Chr Frimodt-Möller presented the Menu how to treat LUTS secondary to BPH: The Appetizers are Alfa 1-blockers and 5-AR inhibitors. The Main Courses are TVP, TUR-P, TUI-P, laser-therapy, microwave therapy, TUNA. The Desserts are stents, catheters and clean intermittent catheterization. He also presented the PROSBASE database in the follow-up of these patients. After six (4-8) months symptom scores (DAN-PSS), incontinence, subjective evaluation, uro-flowmetry and residual urine are documented. Elisabeth Farrelly present-

ed the neurological base in the bladder function and what happens after the spinal cord injury in the lower urinary tract function. It's important to understand the correlation between the level of the neurogenic lesion and the disturbance of the detrusor and sphincter function. It helps to identify bladders with high pressure and potentially risk for kidney function and to follow up those patients with urodynamic studies. A less invasive routine follow-up with kidney ultrasound, and kidney function tests should be made for every spinal cord injury patient at least. Surgical treatment options in neurogenic bladder were presented by Hans Jörgen Kirkeby. The main goal is to preserve own bladder as far as possible. Incontinence and poor compliance of the bladder can be treated by botulinum A toxin injection therapy or by bladder augmentation (auto augmentation or Clam cystoplasty). Self intermittent catheterization through continent Mitrofanoff or Monti channel in the lower abdominal wall can be possible for those who cannot do it through urethra. Trygve Talseth showed in his presentation that in four different urodynamic studies post prostatectomy incontinence reveals in 8-59 % stress incontinence only but in 3-40 % detrusor overactivity only seems to be the reason. So far the Robotic assisted laparoscopic prostatectomy doesn't show any superiority in the continence results vs. open RRP. Ossi Lindell presented the different surgical treatment options in PPI. In mild and moderate cases there are periurethral bulging agents and slings (fixed and adjustable) but in severe cases the sphincter prosthesis is superior.

In the afternoon the program continued with the genital reconstructive surgery and with the kidney cancer. Aivar Bracka, a plastic surgeon from UK, gave two excellent presentations reporting his brilliant results of hypospadias surgery and other penile reconstructions.

Congress Venue hotel Hilton Nordica Reykjavik





Mirja Ruutu was very delighted hearing she had got the NUF honorary membership already in Århus 2007 - better know later than never. Jukka Sairanen shares the joy.



Iceland's Gudjon Haraldsson and the Finnish "talking machine" Christian "Palle" Palmberg

It is amazing how delicate reconstructions can be made if one is concentrated to and interested of the issue and has enough material to work on. Of course, skills in hands and good spatial recognition of shapes are needed. G. Läckgren reported the management of rare bladder extrophy cases in newborn. Realizing that there are maximally 5 new cases per year in Sweden and maybe 10 additional cases from other Nordic countries, the importance of centralization of these difficult cases is clear for everyone.

On Thursday 12th of June the program started by State of the art lectures of prostate cancer.

Gunnar Aus told about the implications of PSA screening in an overview. Antti Rannikko introduced the large European follow-up study for active surveillance patients having local prostate cancer. He encourages keeping in mind that the active surveillance is one option for patients in eager PSA screening era I. In the lunch symposium organised by PhotoCure the results of 2 recurrence studies using Hexvix[®] were presented. Gregers Hermann reviewed first time the results of the Danish recurrence study involving 233 patients randomised to white light (WL) or WL + blue light (BL) cystoscopy + TURB. 47 % of the patients in WL alone compared to only 31 % in BL experienced



Andres Mattiasson with his wife Elizabeth



To patients suffering from urgency.

Vesicare[®] (solifenacin) decreases the urgency episodes and increases warning time.¹

Ref. 1. Karam et al. Urology, Volume 73, number 1, January 2009, p. 14-18.
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Threesome Alexander Schultz, Andres Mattiasson and Gudjon Haraldsson, the top Vikings.

Hans Jørgen Kirkeby having as broad smile as the fellows in his tie



recurrence at 12 month's, the difference was significant between the groups. An important finding was that remnant tumour tissue after TURB in WL was seen in 33-41 % of patients with Ta or T1 tumours. False positive rate (all tumours) was 16 % (16-24) for WL and 25 % (16-34) for BL.

Professor Grossman presented the results of the large international multi-center recurrence study with 789 patients from USA and Europe. Hexvix^R

reduced 9 month's recurrence rate, 36 vs. 46 %, ITT (p=0.026) and PP (p=0.029). It also improved detection of Ta/T1 in 16.5 % of patients (p=0.0005) and 46 % of CIS tumours. The false positive rates were low for both groups (12 % for Hexvix^R and 10 % for WL). The safety profiles were identically good.

On last morning Georg Bjarnason (Iceland/Canada) gave an excellent review of the improved prognosis in the treatment of metastatic renal cell cancer patients during the last years. First he gave median progression-free survivals (months) for various treatments (treatment naive patients): best supportive care 2-3, INF- α alone 3-5, INF- α + IL-2 + 5-FU 5.3, temsirolimus 5.5, sorafenib 5.7, bevacizumab + INF- α 8.8, sunitinib 11.0. There are many trials of the first line therapy ongoing using different combinations of INF, bevacizumab, sunitinib, sorafenib, pazopanib, temsirolimus and everolimus. Progression-free survivals in treatment-refractory (cytokines, sorafenib or sunitinib) renal cell cancer vary from 3-5 (INF- α alone) to 15.7 months (axitinib). The rec-

ommendation for the first line therapy in good or intermediate risk patients (prognostic risk criteria given by Hudes et al. N Engl J Med 2007;356:2271-2281) is sunitinib or bevacizumab + INF and in poor risk patients temsirolimus. As a second line therapy sorafenib, pazopanib or everolimus can be used. Radical nephrectomy prior to medical therapy improves mean survival. Options for delayed operation are poor performance status of the patient, rapidly progressing large volume metastases and tumours which primarily seem to be inoperable. Targeted therapy is expensive and associated with significant toxicity. It is important to individualize the therapy and large clinical trials are needed.

Posters

Stilling & al. from Denmark (P54) showed that in the era of laparoscopy retrograde endopyelotomy still has a role in the treatment of primary and secondary pyeloureteral junction obstruction. 47 patients were treated and twenty-nine (66 %) experienced complete resolution and 10 patients (23 %) had significant improvement in symptoms. Five patients were failures and treated laparoscopically. No major complications were observed.

Skagemo & al (P65) designed the first randomized multi-center study to investigate if lactic acid bacteria given orally or intravaginally can reduce urinary tract infections. We are waiting for results.

Martins & al. from Portugal presented four interesting posters. The first (P60) illustrates an interesting technique



Kimmo Taari was selected as the new leader of NUF organization

where continent catheterizable neo-urachus-like tube is reconstructed from the abdominal skin (Rackley technique). Four patients were operated and all are performing self-catheterization without problem. The technique avoids the risks associated with an intra-abdominal bowel operation. In the second poster (P61) organ sparing surgery for penile carcinoma using disassembly technique is described. The glans with urethra is completely separated from corpora cavernosa. Glans is removed, urethra is spatulated and used for new glans construction. The third poster (P62) gives the results of 27 patients operated on for complex urethrovaginal fistulae us-

ing a Martius flap and its cutaneous variant. 22 patients healed uneventfully and 5 had minor complications. The fourth poster (P64) illustrates a single-stage dorsal onlay buccal mucosal grafting procedure through a perineal approach used in 11 patients. The graft was harvested from the lower lip and varied between 12 and 17 cm in length. One patient (11 %) experienced stricture recurrence.

Free papers

The number of free papers presented was 41.

A02, Gage et al. Of 535 radical prostatectomized patients 79 (13%) had tu-

mour negative prostate biopsies prior to later diagnosis of prostate cancer. They were relatively young men with non-palpable tumours and high PSA. The authors recommend that these kind of men should be re-biopsied.

A12, Fosså et al. In this large study patients with locally advanced or histologically high-risk localized prostate cancer were randomized to radiotherapy (RT) + hormonal therapy (HT) (N = 439) or only HT (N = 436). The cumulative prostate cancer-specific mortalities at 10 years were 11.9 % and 23.9 % respectively. The authors say that RT + HT should become standard treatment for these patients.



Table full of delicious food at the get together party



Aivar Bracka from UK gave two excellent presentations of reconstructive surgery

A13. Professor Iversen presented the results of 10 years follow-up of the CASODEX EPC program underlying that in localised disease, the risks of hormonal therapy with bicalutamide outweigh the benefits in delaying progression. In locally advanced disease there are benefits.

A14. Iversen et al. In this phase III randomised study GNRH antagonist degarelix was compared to leuprolide in the treatment of 610 patients with pros-

tate adenocarcinoma. Degarelix reduced serum FSH, LH, testosterone levels faster than leuprolide without testosterone surge and was at least as effective in maintaining serum testosterone at castrate level.

A30. Paananen et al. In this prospective comparative multicenter study organised by the Collaboration Group for Reconstructive Urology within the Scandinavian Association of Urology 78 men underwent radical cystectomy. In 66 patients the bladder was substituted by ileum and in 12 by colon. In enterocystomy and also clinically colon bladders were inferior to ileal substitutes.

General assembly was held on Friday, and after eight years of devoted service as the president of the NUF organization Andres Mattiasson said farewell to the post. Professor Kimmo Taari from Helsinki was elected as the new president. General secretary Alexander Schultz and treasurer Bör-Ljungberg continue their work in the board. The NUF collaboration groups and the editor-in-chief of NUF Bulletin gave their reports. The new hon-

orary members are professor Wiking Månsson from Lund and professor Steinar Karlsen from Oslo.

The traditional get together party was held at Reykjavik Art Museum.

The gala Dinner was held in Restaurant Broadway. The Icelandic show group, consisting of three women and three men, made funny tricks among guests before the dinner. During the dinner they showed excellent singing and dancing show leaving nobody cold. Last but not least orchestra played music and the dancing floor was crowded. There are hundreds of photos of the meeting attendees to look in the NUF homepages in the address <http://www.scaur.org/Pictures.html>.

We have to admire the Icelandic efficacy, it is amazing. Such a small group can arrange a relatively big meeting and with excellent skills! The next NUF meeting will be organized by professor Teuvo Tammela in Tampere in August 2011. Tampere is situated in the middle of the beautiful Finnish lake area worth visiting and knowing Teuvo, the scientific part of the meeting will be excellent.



Professor Teuvo Tammela has his hands full of work to prepare the next NUF meeting in Tampere 2011



Nikolaj Wessel and Viktor Berge enjoyed the get together party



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Therapeutic indications

Treatment of non-invasive urothelial bladder carcinoma:

- curative treatment of carcinoma in situ
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 - urothelial carcinoma limited to mucosa:
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 - Ta G3
 - urothelial carcinoma in lamina propria but not the muscular of the bladder (T₁)
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Nature and contents of container

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Therapeutic indications

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Nature and contents of container

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For further information:
www.fass.se
www.produktresume.dk



New collaboration group on LUTD within NUF

by Elisabeth C Farrelly – elisabeth.carlsson-farrelly@karolinska.se

A new collaboration group on Lower Urinary Tract Dysfunction has been formed within our Scandinavian Association of Urology. A former collaboration group on Urodynamics has been officially dissolved and finished its work.

The group on LUTD was formed in February 2008 at a most pleasant meeting in beautiful surroundings in Skåne, southern Sweden. Professor Anders Mattiasson had been able to organize a two-day meeting at the castle of Trolleholm, where the University of Lund has access to meeting facilities a limited number of times every year. This was a perfect environment for getting to know each other and for easy cooperation, so we were off to a great start!

With the help of Anders Mattiasson,

our group was constituted with the following members:

Elisabeth Farrelly,
Stockholm, Sweden, chairperson.

Lars Malmberg,
Lund, Sweden

Jens Sönksen,
Copenhagen, Denmark

Frank Schmidt,
Aarhus, Denmark

Per Espen Lähne,
Tönsberg, Norway

Gudmundur Geirsson,
Reykjavik, Iceland

Markku Leskinen
Seinäjäki, Finland

Ilkka Perttilä,
Helsinki, Finland

During 2008-2010 the group will focus on the fields of LUTD with BOO (bladder outlet obstruction), neurourology/ spinal cord lesions and CPPS/ IC (chronic pelvic pain/ interstitial cystitis). Our aim is to organize and promote educational activities within the Nordic countries, and we will also try to facilitate research communication and Nordic research cooperation in these fields.

Our first big undertaking was an educational course on the theme "Best practice in LUTD" at the NUF Congress in Reykjavik 2009, which turned out quite a success with great speakers from all our Nordic countries and a large number of attending colleagues. Thanks to all of you who turned out for this course, took part in the discussions and helped put LUTD issues firmly back on agenda of NUF!



Members of the group from the left: Gudmundur Geirsson, Ilkka Perttilä, Per Espen Lähne, Elisabeth Farrelly, Jens Sönksen, Markku Leskinen, Lars Malmberg.

Plans are now underway for a Nordic course on urodynamics during the first half of 2010. Again, there will be qualified speakers from the various Nordic countries, interactive discussions and case presentations. We will spend one – one and a half days on basic urodynamics, followed by one day on advanced urodynamics. The course will take place in Norway with the kind collaboration of Trygve Talseth at Rikshospitalet in Oslo.

During the spring of 2009, we have been asked to help on building a Nordic network in neurourology, as there seems to be a decreasing number of urology specialist in our countries who are active in this field. A starting discussion was held with a group Norwe-

gian urologists in training during the NUF-congress, and hopefully the urodynamics course will provide setting for a more formalised beginning of a network for sharing of ideas and new developments in this area.

An inventory of research areas in LUTD was done last year with interesting results:

Interstitial cystitis is a hot topic in several countries, ranging from basic molecular biology to understanding of symptoms and various forms of treatment.

Basic research in bladder muscular overactivity and the functions of the mucous membrane goes on in Lund, mainly..

Development of treatment in female and male incontinence is active in several countries. An epidemiological study of bladder dysfunction in spinal cord injury and risk factors for recurring UTI takes place in Stockholm.

BPH research is limited to very few studies managed by pharmaceutical industry.

Please feel free to contact members of the group with any queries, ideas, suggestions you may have on activities within our field! Our contact details will be found on the NUF website, under collaboration groups. We are looking forward to hearing from you!

NUF CLINICAL COURSE ON ADVANCED URODYNAMICS

Organised by NUF collaboration group on LUTD

26th February 2010 in Oslo, Norway
(arrival on 25th February)

Topics: Urodynamics in

- neurourology
- pediatrics
- male and female incontinence
- Round table, clinical cases

For further information visit <http://www.scaur.org/Courses.html>
or webpages of your national urological association.

Contact person: Elisabeth Farrelly · e-mail: e.farrelly@telia.com · tel: +46703865200



Som kirurg på savannen i Afrika

av Matti Rauvala, urolog, Rovaniemi

Rotary Doctor Bank Finland förmedlar finska läkare till flera sjukhus i Tanzania. Jag hade tillfälle att arbeta vid Ilembula Lutheran Hospital under december 2008 - januari 2009.

Ilembula är en by med ca 30 000 invånare som ligger i 1400 meters höjd 700 km från huvudstaden Dar es Salaam. Befolkningen är mest jordbrukare som odlar majs och bönor. Fattigdomen är påtaglig, folk bor i små hytter gjorda av lera och har inte mycket annat än trasiga kläder som egendom. Jordbruksmaskiner finns inte, några oxar kan träffas på åkrarna men mest sker jordbruket med hjälp av handredskap och hela familjen deltar i arbetet. Sjukhuset som ägs av kyrkan har ca 300

sängplatser med kirurgisk, medicinsk, gyn och obstetrisk samt barnavdelning, öppenvårdsmottagning och speciell mottagning för HIV-patienter.

Som rotary-doktor har man ganska fria händer angående själva jobbet vilket lär bero på att eftersom man inte får någon lön så har man inte heller så mycket förpliktelser. Då kan man utan dåligt samvete vid behov åka till närliggande större stad om man har ärende till bank eller behöver handla något annat än de allra vardagligaste förnödenheter som finns att få tag i själva byn Ilembula. Naturparken Ruaha ligger också inom rimlig avstånd och har högklassiga hotell och gått om vilddjur. I byn finns inte någon särskild nattliv, det finns inte TV eller radio vilket gör att man får

själv hitta på sin sysselsättning under fritiden. Savannen räcker långt om man vill promenera eller jogga, lokalbefolkningen är vänlig och ofta finns det också andra västerländska kollegor eller sjuksköterskeelever på plats och man kan hitta på något gemensamt tillsammans, om inte annat, bada bastu.

Det var naturligt att jag som kirurg trivdes bäst på kir-avdelning och operation. Dessutom blev det en del konsultationer på barn, ICU (intensive care unit) och OPD (out patient departement), men det var närmast omöjligt att ha själv mottagning på grund av språksvårigheter, utan nöjaktig kunskap på suahili. Det fanns inga tolkar och man kunde inte räkna med att en kollega eller sköterska alltid kunde ställa upp



Lokala kollegor på rond

För det mesta försöker man sköta frakturer konservativt. Matti med arbetsskamrater.

som tolk. Det fanns brist på sjuksköterskor och därför fick sköterskestudenter göra en stor del av deras jobb och alla kunde inte alls engelska så att någorlunda vettig kommunikation kunde vara möjlig. Det finns brist på så gott som allting, sjukhuset har inte råd att köra generatorm alltid när kommunal el inte finns tillgänglig vilket sker ofta. Vatten har man mycket bättre tillgängligt och för det mesta även varmt vatten. Nativröntgenbilder kan fås då det finns el, och vissa basala labundersökningar också, dock ganska opålitliga värden. Kemiska undersökningar görs inte, elektrolyter, eller t.ex. Kreatinin fås inte.

Ungefär hälften av sjukhusets patienter är HIV-positiva, vilket bör hela tiden



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Sjukhuset har egen snickare som tillverkar bl.a. kryckor.

hållas i minnet under operationer och vårdåtgärder. Operativ verksamhet kräver en hel del improvisation hela tiden, då instrumentariet är slitet och bristfälligt. Jag kunde finna dock en brukbar cystoskop som inte hade använts under sista åren och även en resektoskop, som vi dock inte fick att fungera. Hpl patienter hade alltså inte så mycket andra behandlingsalternativ än öppen

prostatactomi och prostatakarcinom kunde praktiskt taget diagnostiseras enbart med palpationsfynd. Histologiska prov togs nog, men det blev inte klart för mig, om man någonsin får svar på dessa. Urolithiasis träffade jag inte alls. (själv sagt inte heller symptomfri mikrohematuri eller erektil dysfunktion). Jobbet sker mycket jordnära och med enkla principer. Å andra sidan bör man fatta

en del svåra beslut, då man står där och vet att om man med en patient ingenting gör så gör ingen annan heller någonting, bara en bråkdel av patienter har råd att söka sig till mera avancerade kliniker som dock finns i landet.

Patienterna är mycket tålmodiga och kooperativa. Jag fick höra hur patienterna nog blir kvar och väntar till nästa



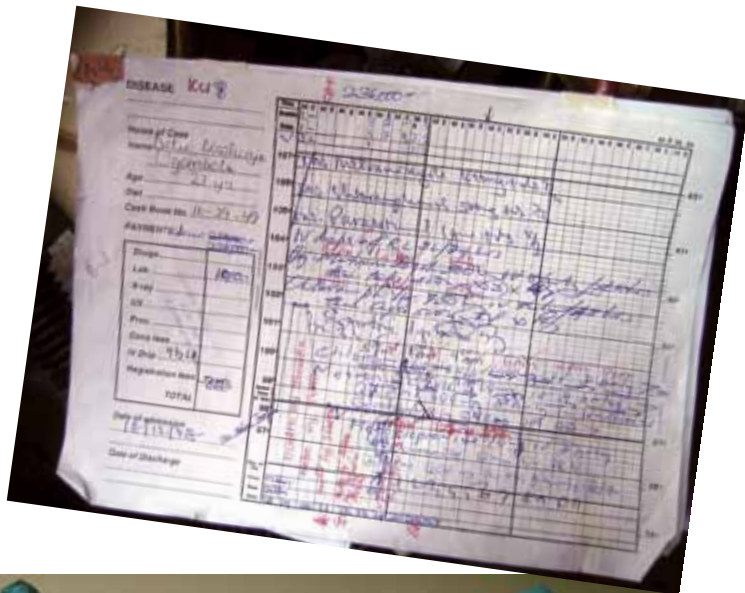
Vesicare® solifenacin succinate 5 mg or 10 mg, corresponding to 3,8 mg and 7,5 mg solifenacin. Pharmaceutical form: Film-coated tablets. Therapeutic indications: Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. Posology: Adults, including the elderly: The recommended dose is 5 mg solifenacin succinate once daily. If needed, the dose may be increased to 10 mg solifenacin succinate once daily. Children and adolescents: Safety and effectiveness in children have not yet been established. Therefore, Vesicare should not be used in children. Patients with renal impairment: No dose adjustment is necessary for patients with mild to moderate renal impairment (creati-

nine clearance > 30 ml/min). Patients with severe renal impairment (creatinine clearance ≤ 30 ml/min) should be treated with caution and receive no more than 5 mg once daily. Patients with hepatic impairment: No dose adjustment is necessary for patients with mild hepatic impairment. Patients with moderate hepatic impairment (Child-Pugh score of 7 to 9) should be treated with caution and receive no more than 5 mg once daily. Method of administration: Vesicare should be taken orally and should be swallowed whole with liquids. It can be taken with or without food. Contraindications: Solifenacin is contraindicated in patients with urinary retention, severe gastro-intestinal condition (including toxic megacolon), myasthenia gravis or narrow-angle glaucoma and in patients at risk for these conditions. Patients hypersensitive to the active substance or to any of the excipients. Patients undergoing haemodialysis. Patients with severe hepatic impairment. Patients with severe renal impairment or moderate hepatic impairment and who are on treatment with a potent CYP3A4 inhibitor, e.g. ketoconazole. Special warnings and precautions for use: Other causes of frequent urination (heart failure or renal disease) should be assessed before treatment with Vesicare. If urinary tract infection is present, an appropriate antibacterial therapy should be started. Vesicare should be used with caution in patients with: clinically significant bladder outflow obstruction at risk of urinary retention. Gastrointestinal obstructive disorders. Risk of decreased gastrointestinal motility. Severe renal impairment (creatinine clearance ≤ 30 ml/min), and doses should not exceed 5 mg for these patients. Moderate hepatic impairment (Child-Pugh score of 7 to 9), and doses should not exceed 5 mg for these patients. Concomitant use of a potent CYP3A4 inhibitor, e.g. ketoconazole. Hiatus hernia/gastro-oesophageal reflux and/or who are concurrently taking medicinal products (such as bisphosphonates) that can cause or exacerbate oesophagitis. Autonomic neuropathy. Safety and efficacy have not yet been established in patients with a neurogenic cause for detrusor overactivity. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. The maximum effect of Vesicare can be determined after 4 weeks at the earliest. Interaction with other medicinal products: Concomitant medication with other medicinal products with anticholinergic properties may result in more pronounced therapeutic effects and undesirable effects. An interval of approximately one week should be allowed after stopping treatment with Vesicare, before commencing other anticholinergic therapy. The therapeutic effect of solifenacin may be reduced by concomitant administration of cholinergic receptor agonists. Solifenacin can reduce the effect of medicinal products that stimulate the motility of the gastro-intestinal tract, such as metoclopramide and cisapride. Solifenacin is metabolised by CYP3A4. Simultaneous administration of ketoconazole (200 mg/day), a potent CYP3A4 inhibitor, resulted in a two-fold increase of the AUC of solifenacin, while ketoconazole at a dose of 400 mg/day resulted in a three-fold increase of the AUC of solifenacin. Therefore, the maximum dose of Vesicare should be restricted to 5 mg, when used simultaneously with ketoconazole or therapeutic doses of other potent CYP3A4 inhibitors (e.g. ritonavir, nelfinavir, itraconazole). Intake of Vesicare showed no pharmacokinetic interaction of solifenacin on combined oral contraceptives (ethinylestradiol/levonorgestrel). Intake of Vesicare did not alter the pharmacokinetics of R-warfarin or S-warfarin or their effect on prothrombin time. Intake of Vesicare showed no effect on the pharmacokinetics of digoxin. Pregnancy and lactation: The potential risk for humans is unknown. Caution should be exercised when prescribing to pregnant women. The use of Vesicare should be avoided during breastfeeding. Effects on ability to drive and use machines: Since solifenacin, like other anticholinergics may cause blurred vision, and, uncommonly, somnolence and fatigue, the ability to drive and use machines may be negatively affected. Undesirable effects: Vesicare may cause anticholinergic undesirable effects of (in general) mild or moderate severity. The frequency of anticholinergic undesirable effects is dose related. The most commonly reported adverse reaction with Vesicare was dry mouth. It occurred in 11% of patients treated with 5 mg once daily, in 22% of patients treated with 10 mg once daily and in 4% of placebo-treated patients. Very common (≥1/10): Dry mouth. Common (>1/100, <1/10): Blurred vision, constipation, nausea, dyspepsia, abdominal pain. Uncommon (>1/1000, <1/100): Urinary tract infection, cystitis, somnolence, dysgeusia, dry eyes, nasal dryness, gastrooesophageal reflux diseases, dry throat, dry skin, difficulty in micturition, fatigue, peripheral oedema. For more information see registered SPC 05.08.2008, Astellas Pharma a/s, DK-2600 Glostrup, Denmark.



dag om man lämnar mottagningen då det ännu finns patienter kvar där. Klagomål angående själva vård är väldigt sällsynta, dock är patienterna på det sättet misstänksamma att största del har nog sökt hjälp först hos en lokal "doctor" vilket kan ses på små ärr som är väldigt vanliga och visar tydligt var det onda sitter. Även om man ofta blir frustrerad och ledsen med all fattigdom och brister som är så stora så får man naturligtvis också uppleva av och till goda resultat och lyckliga tacksamma patienter. Även det uppskattas att man är med och diskuterar och filosoferar med kollegorna om sjukdomar och olika behandlingsalternativ och kommer därmed med en västerländsk synpunkt in i processen. Självt får man också en hel del nya synpunkter och upplevelser som nog varar resten av livet och kan vara nyttiga om man så vill. Att åka ut med Rotary läkarbank är tämligen lätt sätt att komma till en helt annan värld och kanske också få känna sig nyttig på ett eller annat sätt.

På intensivvården finns all patientdata samlat på en sida



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Prostate cancer in Denmark – personal reflexions

*by Peter Iversen, Department of Urology, Rigshospitalet,
Division of Clinical Sciences, University of Copenhagen.*

Only a week ago, I returned from two spectacular weeks of vacationing in South Africa - hunting on the banks of the Limpopo River and diving (locked up in an underwater cage) with great white sharks in the Atlantic Ocean. Despite all the excitement and near-death experiences, the trip also gave me time to think about life in general and the professional life in particular. I won't bore you with tedious philosophical and trivial existentialist reflexions. Still, my thoughts about the events, often completely by chance, that shaped my until now 33 years in urology inevitably involved considerations about how the entire prostate cancer scenario evolved in my country during this relatively short period of time.

Entering urology

Medical school didn't happen by accident. My grandfather was a general physician, my father was a surgeon, and there wasn't much doubt as to my future profession when I finished high school. During the last half of medical school I taught renal physiology and endocrinology at the Institute of Physiology in Copenhagen. The institute also hosted my first attempt with experimental research which was on the role of extra-vascular macro-proteins in the rat kidney. Therefore, following graduation in the summer of 1976, it felt natural to pursue my interest in the urinary tract by entering urology.

Hvidovre Hospital was brand new in 1976. The department of urology, moving from the old Kommunehospital, was led by Hans-Georg Iversen, a great clinician and an enthusiastic and extremely skilled transurethral resectionist. I had a wonderful time in the department and stayed there until 1980 except for little more than a year in ne-

phrology. Inspired and stimulated by Rolf Iversen Hansen (three "Iversen" in the same department!) I developed an interest in urodynamics, which became my research focus for some time. However, I also saw patients with prostate cancer, and I clearly remember Hans-Georg Iversen prophetically telling me that prostate cancer in the years to come would dominate the field of urology. How right he proved to be!

Prostate cancer – the seventies

However, in the seventies prostate cancer was not a "big" disease in Denmark. Although an incidence of almost one thousand new cases per year and a significant mortality/incidence ratio of approximately 0.7 clearly underlined that prostate cancer was not a toothless lion, patients were only treated when symptomatic and metastatic and then with bilateral orchidectomy, estrogens or the new drug, Estracyt. "Incidental" prostate cancer identified unexpectedly at transurethral resection was considered harmless and was not treated or followed if non-metastatic. Still, while prostate cancer patients were relatively scarce in our outpatient clinic, severely symptomatic castration-resistant patients filled the beds in our wards, sometimes for very long periods of time.

Madison, Wisconsin

In 1980 Hans Wolf, at that time one of the two chiefs of urology in Hvidovre, arranged a fellowship in Madison, Wisconsin, where he himself years before had worked with Paul O. Madsen. The whole thing was pure luck: I wasn't offered the position because of any special talent – I was the only one to volunteer, when senior and more qualified colleagues refused the offer. Privileged with a wife who was excited about the

idea, we left Denmark in May with our two daughters and all our belongings in four suitcases for what turned out to be some of the best years of our life.

In Madison I joined the laboratory's experimental research in urinary tract infection and also conducted a number of urodynamic studies in BPH-obstructed war veterans in collaboration with Reg C. Bruskewitz. Not only were the 21 months in Madison very productive - I also had the privilege to meet with a long list of well-known American urologists who came to Madison as visiting professors: Goodwin, Skinner, Tangho, Utz, Prout, Hodges (who worked with Huggins), Paulson, and Whitmore – none of them more charismatic than Whitmore, the Gary Grant of urology, who made a huge impression. We often discussed prostate cancer management in Madison. Paul O. Madsen had been part of the VACURG (Veterans Administration Urological Research Group) and their famous prostate cancer studies in both localised and advanced stages. Although he was (and still is) convinced that radical prostatectomy is only rarely indicated, the operations were performed in the department. Still, the person who really stimulated my interest in prostate cancer was Professor Thomas Stamey from Stanford. Stamey was originally engaged in female urinary incontinence. Later, his research focus shifted towards urinary tract infections including prostatitis, an interest shared by Paul Madsen's laboratory. Paul was kind enough to introduce me to Stamey at the AUA annual meeting in 1981. At the same time Stamey was asked by a group of American colleagues to review the whole subject of prostate cancer. He accepted, spent a 3 months sabbatical leave of absence in a monastery at Lake Como in Italy and wrote a fantastic and inspir-

ing monograph about prostate cancer – the first of a long series authored by invited guests and published by Stanford University as Monographs in Urology. At the very end of my fellowship I read his monograph and was completely intrigued by the enigmatic epidemiology and all the controversies so elegantly presented and discussed by Stamey in his very personal and original style. Years later, I was honoured when Stamey invited me, Søren Torp-Pedersen, Jan Adolfsson and Jan-Erik Johansson to contribute with a monograph on the Scandinavian view on localised prostate cancer.

DAPROCA and SPCG

Following my return to Denmark December 1981 I spent a couple of years finishing my basic surgical training. Back in urology, I became involved in one of the phase II trials with Zoladex, and in 1986 we initiated the first DAPROCA (Danish Prostatic Cancer Group) study of maximal androgen blockade (Zoladex+flutamide) versus surgical castration. Assisted by a statistician, I served as a coordinator and did all data handling and analysis. DAPROCA 86 became one of the first mature randomised studies of maximal androgen blockade and was presented at numerous international meetings. As a result, we became closely involved in the meta-analysis eventually published by Fritz Schröder – the European Mr. Prostate Cancer, whom I respect and admire tremendously.

Strongly supported by my Danish senior colleagues, Finn Rasmussen, Torben Krarup, Flemming Lund, and Valdemar Hvidt, I became a junior member of SPCG in 1987. At the time the group was supported by Leo Pharmacia personalised by Agne Rüdens-tam and powered by giants like P.O.

Hedlund, Per Åge Højsæter and Olof Alfthan, all of whom I came to consider as friends as well as mentors. The many years spent with SPCG have been a lot of fun and a tremendous learning experience. As we are all aware, the group has initiated, completed, and published a number of landmark trials, and it continues to be very active under the current chairmanship of Teuvo Tammela.

Changing scenario

The famous Örebro-study supported our conservative management of localised prostate cancer, but the increased use of PSA for early detection made it increasingly difficult to maintain the strategy. In 1995, with the help of Knud V Petersen in Jönköping (now in Århus) and after educational trips to Mayo Clinic, Vancouver, Miami, and Rotterdam, we started offering radical prostatectomy in Rigshospitalet. From a slow start, RP is now performed in great numbers in six Danish departments – four of them now equipped with Da Vinci robots. The results of the SPCG-4 study have only accelerated the development, and our operative activity is now almost comparable to the Swedish...! Also, more and more patients are offered EBRT for localised and locally advanced tumours.

The entire prostate cancer scenario has changed dramatically since the seventies: Mostly due to increased awareness and the use of PSA, the incidence has more than tripled and more than 4000 new cases are anticipated in 2009. When the rise in incidence is dominated by early low-risk tumours, the prevalence, which best reflects the actual burden on the health care system, grows almost exponentially. Age at diagnosis is falling; the stage distribution is much more favourable than before, and many more

patients are offered attempted curative therapy. The number of outpatient visits in Denmark because of prostate cancer has risen by a factor 5 from 1997-2008, and many pathology departments are struggling to keep up with the rapidly increasing burden of endless prostate biopsies and prostatectomy specimens.

What have achieved so far? Survival is increasing and the mortality/incidence ratio is decreasing. These facts may be interpreted by less knowledgeable individuals as criteria of success. However, increased detection and lead-time bias explain it all – and the crucial endpoint, prostate cancer - specific mortality, has not changed. On the other hand, thousands of men live their lives stigmatised with a malignant diagnosis, and many endure the well-known side effects of curative treatment.

Screening

We have to be patient – some will argue. We can't expect a major drop in mortality right away considering the long natural history of prostate cancer, they'll say. Well, it's about time for a fall in mortality...! Even though available epidemiological evidence and SPCG-4 in combination demonstrate a significant over-diagnosis and – treatment, we have already moved further. The European screening study has demonstrated PSA-based screening for prostate cancer to result in a statistically significant 20% reduction in the risk of disease specific mortality after approximately 9 years. A similar American study showed no difference and is almost forgotten...! It was an eye-opener to take part in the prestigious American Association of Genito-urinary Surgeons (AAGUS) annual meeting this year. Except for a few (and very courageous) members, the

predominant perception among these American leaders in urology was that the European screening study proved PSA-based screening to be beneficial...! Nobody discussed the significant over-treatment – 48 underwent some kind of treatment in the screening group for each saved for prostate cancer mortality. Even though this can improve with increased follow-up and better selection for biopsy and treatment, the data in my mind clearly emphasizes the key-problems we have with early prostate cancer – a very long natural history and a dramatic high prevalence of small and insignificant lesions.

Chemoprevention

Men not found to have prostate cancer in screening may now be offered chemoprevention with 5-alpha-reductase inhibitors. The PCPT and REDUCE trials have in slightly different populations of men without prostate cancer demonstrated a significant reduction in the risk of prostate cancer at biopsy after 7 and 4 years, respectively, of 24.8% and 23%. Many unanswered questions persist – is the concern about high risk cancer completely buried? Who, when, how long, acceptance of side effects, and who will pay, are all issues that need to be addressed. The 10.000 dollars question remains whether a reduction in biopsy-detected prostate cancer is a meaningful surrogate endpoint that will eventually translate into reduced mortality. So chemoprevention with 5-alpha-reductase inhibitors is not a settled issue. Do we use a new modality until proven harmful, or do we withhold it until proven beneficial?

Focal therapy

Arguing that not all patients with localised prostate cancer need a traditional radical prostatectomy or conventional radiotherapy and driven by an ambition to minimize side effects associated with curative treatments, the concept

of focal therapy has received a lot of attention recently. Both cryotherapy and HIFU provide the technology to treat only part(s) of the prostate and both modalities have therefore experienced a renaissance parallel to the increased interest in focal therapy. Is this another example of technology (and industry) leading the science? All available evidence, including our own database on more than 1100 RP's, demonstrates that clinically significant prostate cancer typically is multifocal and most often bilateral. Conventional biopsy-strategies are therefore insufficient and template-biopsies with up to 90 biopsies are advocated to more accurately map the tumour. A lot of critical questions must be answered: Will "focal" therapy really result in QoL-benefits? How will patients be followed for recurrence – can PSA be considered reliable after focal therapy and up to 90 biopsies? Is not the ideal candidate for focal therapy an individual who shouldn't be treated at all in the first place – or at least be offered active surveillance?

Concerns

As it appears, I have my own personal bias when it comes to screening, chemoprevention, and focal therapy. However, I welcome every attempt to change my views based on evidence and wise arguments. My personal concern is that we to some extent are missing the target. Surgeons, radiation oncologists, manufacturers of robots, cryo-, HIFU-, and radiotherapy equipment all have their individual motives for focusing a lot of effort on therapy for localised disease. Why not – we have all been taught that cancer should be treated as early as possible – and we have the full support of cancer societies and patient groups. However, the epidemiology of prostate cancer is different from most other solid tumours, and chemoprevention, screening, and early treatment is bound to be associated with inevitable and

significant over-diagnosis and –treatment. This fact represents a major ethical problem – and who should decide what may be regarded as an acceptable and affordable over-diagnosis/over-treatment? Physicians? Politicians? Patient groups? It is quite a challenge that we're facing!

Carpet bombing versus smart bombs

The therapeutic strategies for early disease may be compared with carpet bombing with many innocent victims. To stay with the analogy, the ideal way to reduce mortality/morbidity from prostate cancer is the "smart bomb", a precision therapeutic instrument selecting and curing those at high risk for morbidity and mortality. Unfortunately, we are not there yet. However, even though endocrine therapy remains as the most important treatment for advanced disease, a lot of new targeted therapeutic modalities are underway. I don't find it overly optimistic to hope for major breakthroughs in the treatment of advanced disease in the near future. Bringing all these new targeted therapies into our clinical routine requires a close collaboration within our specialty in order to conduct the necessary large clinical trials.

Prostate cancer continues to evoke discussion and controversy, and when given the opportunity I couldn't help myself presenting you with some of my concerns and personal biases. Now, don't think that I spent my entire vacation in South Africa thinking of prostate cancer. I most certainly did not. But on the other hand one could ask: Why travel 11.000 km to experience the excitement of hunting and swimming with sharks. When your interest is prostate cancer – you have all the excitement you need...

Bird photography – why do it?

by Gunnar Aus, Department of Urology
Sahlgrens University Hospital, Göteborg, Sweden.



The day has reached its end and we have placed our boat in position outside Husøy. We are on the Arctic circle in Traena community, 33 nautical miles from the Norwegian mainland. A moderate swell is rolling in from the North Atlantic, a reminder of yesterday's gale. In front of us there a narrow sound between two smaller islands, behind us the open sea.



We do know that the eagles have seen us; nearly nothing will escape the extremely sharp eyes of these magnificent birds. One of our newly caught fishes, weighting about a kilo, is thrown out and lands with a splash. An overambitious seagull tries to catch the fish but has no chance to swallow a fish of this size. Suddenly is one of the large eagles (2-2,5 meters between the wing tips is LARGE) in the air heading against us. After a turn over our heads it goes down for the fish. Always against the wind, always. Just before touch-down it lifts the white tail feathers (who wants to get wet?), focus the eyes on the fish and the large, very sharp, claws are ready.....



The camera sounds like a machine gun in its effort to catch the moment. Picture after picture are stored on the memory card. This is a onetime event with no second chance so everything has to be in order. After a few second is everything over. The strong eagle lifts the fish from the water without any noticeable effort and with a few strong wings is it back on the cliff with the catch. By this time of the year is the young eagle almost a young adult but still needs help with feeding and gratefully accept the fish that is offered for supper this evening.

The sound is quiet again and we are enjoying what we just have experienced, the boat slowly rising and falling in the long Atlantic swell. Slowly we are returning back to the harbor hoping for that our pics on the memory cards will turn out to be as good as our memories.

Moments like the one illustrated above is one explanation for why bird photography is a lovely excuse to get away from the hospital. The combination of being close to nature together with the challenge of getting good pictures of the often less cooperative birds makes it a worthwhile effort for every photographer.



The stork stepping.



The puffin with nesting material



But, it is not always possible to make the trip to remote areas in order to get the very special experience. Also a walk close by home can get you memorable experiences and good pictures. There are no real rules how a good bird picture should look like but here I have listed a few thoughts that might make your pictures stand out from the crowd.

1. Get down, either on your knees or, even better, flat on the ground. Dirty clothes can be washed but good photo opportunities cannot be remade..... Try to photo the bird from its own height for better impact.
2. Avoid placing your bird in the center of the frame. Nearly everything else will create more tension and thus more interest in your photo.
3. Dare to experiment! Digital photography is free (well, you have to have a camera....) so make all those funny things you can think of. Zoom in the lens at the same time you are taking the photo with a slow shutter speed. Try to follow the bird in flight with a slow shutter speed. Use your flash to find out about fine details. Use long exposures for creative blurry pictures. Convert your photos to black and white. It is only your fantasy that is the limit of what is possible.
4. So, dear urological friends, the scheme is set for the next weekend. Find your old binoculars; bring your camera and a flask of tea or coffee and GET OUT! Happy shooting.



The flock of eiders in the sunset



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Eligard® 7.5 mg, 22.5 mg and 45 mg, powder and solvent for solution for injection

Composition: After reconstitution of the powder with the solvent the deliverable amount is 7.5 mg, 22.5 mg and 45 mg of leuporelin acetate. **Indication:** Treatment of hormone dependent advanced prostate cancer. **Posology:** Eligard® 7.5 mg, administered every month subcutaneously. Eligard® 22.5 mg, administered every three months subcutaneously. Eligard® 45 mg, administered every six months subcutaneously. **Contraindications:** Hypersensitivity to leuporelin acetate, other GnRH agonists or to any of the excipients. Patients who previously underwent orchiectomy (Eligard® does not result in further decrease of serum testosterone in case of surgical castration). As sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases. Women and pediatric patients. **Special warnings and special precautions for use:** Leuporelin acetate causes a transient increase in serum concentrations of testosterone, dihydrotestosterone and acid phosphatase during the first week of treatment. This can lead to a transient worsening of symptoms (additional administration of an antiandrogen beginning 3 days prior to Eligard therapy and continuing for the first 2 to 3 weeks of treatment should be considered). Cases of ureteral obstruction and spinal cord compression, which may contribute to paralysis with or without fatal complications, have been reported with GnRH agonists. Patients with vertebral and/or brain metastases, as well as patients with urinary tract obstruction, should be closely monitored during the first few weeks of treatment. If spinal cord compression or renal impairment develops, standard treatment of these conditions should be instituted. Patients with hormone insensitive tumors will not benefit from further therapy with Eligard®. Decreased bone density has been reported in men who have had orchiectomy or who have been treated with a GnRH agonist. Antiandrogen therapy significantly increases the risk for fractures due to osteoporosis. As in some patients changes in glucose tolerance have been reported, diabetic patients should be monitored more frequently. **Undesirable effects:** Adverse reactions seen with Eligard® are mainly subject to the specific pharmacological actions of leuporelin acetate, namely increase and decrease in certain hormone levels. The most commonly reported undesirable effects are hot flushes, malaise and fatigue, and transient local irritation.

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Dosage: Zometa must not be mixed with calcium or other divalent cation-containing infusion solutions, such as Lactated Ringer's solution, and should be administered as a single intravenous solution in a line separate from all other drugs.

For 'prevention of skeletal related events in patients with advanced malignancies involving bone', the recommended dose is 4 mg, given as an intravenous infusion of no less than 15 minutes every 3 to 4 weeks.

For 'treatment of HCM', the recommended dose is 4 mg given as a single intravenous infusion of no less than 15 minutes. No dose adjustment in patients with mild to moderate renal impairment. Patients without hypercalcaemia should also be administered an oral calcium supplement of 500 mg and 400 IU vitamin D daily.

Contraindications: Pregnancy, breast-feeding women, patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates or any of the excipients in the formulation of Zometa.

Warnings/Precautions: Patients, must be assessed prior to administration of Zometa to assure that they are adequately hydrated. Monitoring of serum levels of calcium, phosphate and magnesium. Serum creatinine should be evaluated prior to each dose. In view of the potential impact of bisphosphonates on renal function, and the lack of extensive clinical safety data in patients with severe renal impairment with Zometa, its use in this population is not recommended. Dose reduction in adult patients with pre-existing mild to moderate renal impairment. If renal function has deteriorated, the dose should be withheld. Limited clinical data in patients with severe hepatic insufficiency; no specific recommendations can be given for this patient population. The use of Zometa in pediatric patients has not been studied. Osteonecrosis of the jaw has been reported predominantly in adult patients with cancer receiving bisphosphonates, including Zometa. The majority of reported cases have been associated with dental procedures such as tooth extraction.

Interactions: Zoledronic acid shows no appreciable binding to plasma proteins and does not inhibit human P450 enzymes in vitro, but no formal clinical interaction studies have been performed. Caution is advised when bisphosphonates are administered with aminoglycosides, since both agents may have an additive effect, resulting in a lower serum calcium level for longer periods than required. Caution is asked when used with other potentially nephrotoxic drugs. Attention should also be paid to the possibility of hypomagnesaemia developing during treatment. In multiple myeloma patients, the risk of renal dysfunction may be increased when i.v. bisphosphonates are used in combination with thalidomide.

Adverse reactions: *Very common (>10%):* hypophosphataemia.

Common (1 to 10%): anaemia, headache, conjunctivitis, nausea, vomiting, anorexia, bone pain, myalgia, arthralgia, generalised pain, renal impairment, fever, flu-like syndrome (including fatigue, rigors, malaise and flushing), blood creatinine and blood urea increased, hypocalcaemia.

Uncommon (0.1 to 1%) for example: thrombocytopenia, leucopenia; hypersensitivity reactions, local reactions at the infusion site, chest pain.

ZOMETA® 
 zoledronic acid

Protect what is essential

 **NOVARTIS**
 ONCOLOGY

Novartis Finland Oy
 Metsänneidonkuja 10
 02130 Espoo
 Finland

Tel +358 10 6133 200
 Fax +358 9 855 0003
 www.novartis.fi

Novartis Sverige AB
 Box 1150
 SE-183 11 TÄBY
 Sweden

Tel +46 8 732 32 00
 Fax +46 8 732 32 01
 www.novartis.se

Novartis Norge AS
 P.O. Box 237 Økern
 0510 Oslo
 Norway

Tel +47 23 05 20 00
 Fax +47 23 05 20 01
 www.novartis.no

Novartis Healthcare A/S
 Lyngbyvej 172
 2100 København Ø
 Denmark

Tel +45 39 16 84 00
 Fax +45 39 16 84 01
 www.novartis.dk