2 / 2011

# NUF-Bulletinen

SCANDINAVIAN ASSOCIATION OF UROLOGY

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# Editors' corner

*by Sven Löffeler and Karol Axcrona*

Yet another NUF congress, which had taken place in Tampere in Finland in August 2011 is history, and we can look back on a scientifically rewarding meeting. The organizers had clearly put lots of effort into putting together the program and their toils have certainly been worth the while. EAU and AUA meetings are certainly larger and more glamorous, but there is no substitute for exchanging experiences and opinions amongst colleagues who come from the same background and who share a similar view of the daily urological practice. NUF certainly provides a forum where one can meet many like-minded urologists and the more informal and familial setting gives lots of room for invaluable in-depth discussions. Hopefully, there will be many more such meetings ahead in the years to come. However, if we want to continue the story of success, it is important to keep up high attendance rates, also in times of diminishing funding from industrial players. It was a bit unsettling to see so few colleagues from Denmark, and particularly Sweden, who had found their way to Tampere and one can only hope that this was a temporary lapse. In this issue Mikkel Fode from Denmark gives us his summary of the Tampere meeting.

An important task discussed and decided upon by the General Assembly was to start a new initiative in order to get more residents in urology involved in NUF. Mikkel Fode, Denmark, and Sven Löffeler, Norway, were charged with the task and the first resident-work-shop will be held in Copenhagen in January 2012. The results of these discussions will be discussed in the next NUF bulletin. It's been more than three years since we last had a look at the different training programs for the Nordic countries and we thus take a new look at the subject in this issue of the bulletin. Since Iceland does not have an independent training course, their contribution is lacking.

Further, Elisabeth Farrelly takes us to a Rehab Station in Stockholm and its unique interdisciplinary approach in addressing the needs of complex neurological patients. We have also included a first report from the newly established Norwegian Skagerrak Bladder Cancer Group which makes interesting reading. And last, but not least, honorable Professor Hans Hedlund, who retired this year after many years of dedicated service at Rikshospitalet, Oslo, gets his well-deserved farewell bid.

We wish all our colleagues a happy and successful 2012!

*Sven and Karol*

# In Issue

*Bulletinen no. 2, 2011*





PHOTO

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EDITORIAL



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# President's corner

*by Kimmo Taari*

## Dear colleagues, NUF Congress 2011

NUF Congress was held on 24-27 August 2011 in Tampere. The program was truly interesting and the whole congress was a success gathering together 505 participants. Overall 68 presentations were held.

The main topics covered prostate cancer, invasive bladder cancer and lower urinary tract functional disorders. There were parallel topics, such as lower urinary tract dysfunction, complications after urological surgery and SPCG 30th Anniversary Meeting. The collaboration groups were very active in preparing these topics. There were at least eight sponsored symposia with several top guest lectures. Besides, the urological nurses had their own sessions parallel to the main program.

I warmly thank Teuvo, Maria, Mika, Juha and the whole organising committee in Tampere for their effort.

General Assembly was held on 29th August 2011 and the minutes are ready on our home page (www.scaur.org). Here are some selected points:

- Our economy is in good shape. The membership fee for the next two years will be the same, SEK 100.
- Scandinavian Journal of Urology and Nephrology will have a new Editor-in-Chief Per-Uno Malmström. He will start at the beginning of 2012. We warmly thank the retiring Editor-in-Chief Jan Adolfsson for his great work in developing Scand J Urol Nephrol.
- One of the main functions of our association is to support the collaboration working groups. The most active groups are urothelial cancer, reconstructive, SPCG, LUTD and stone groups. Two groups were decided to close, namely the laparoscopy group and the ablative treatment group. They have had no activity during the last years. A new group was started, the RCC group and Börje Ljungberg asked every national society to nominate two members for the group.
- Lisbeth Nerstrøm Salling (salling@rh.dk) from Denmark was elected new General Secretary. Christian Beisland from Norway was elected new Accountant. Steen Walter, Steinar Karlsen and Martti Nurmi will step down as members of the electoral committee and new members will be appointed by the national societies.
- I warmly thank Steen Walter, Steinar Karlsen and Martti Nurmi for their work in the electoral committee. Very special thanks are given to Alexander Schultz, who is now retired from the laborious post as our General Secretary.
- We warmly welcome a new honorary member to our association: professor Anders Mattiasson.

NUF Congress 2013 will be held in Sandefjord, Norway, on 21-24 August. The congress president is Sven Løffeler and the organising committee has already been very active.

I wish A Happy New Year to all Scandinavian urologists and all friends of NUF.

*December 2011*
*Kimmo Taari*

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# Urological training in Norway

*by Dag Gullan, Radiumhospitalet*

Urology is a surgical sub-speciality in Norway. As such there is a requirement for completion of general surgical training in addition to 3 years of recognized training from nationally accredited urology units. Until recently general surgery demanded a minimum of 6 years of practice from nationally accredited departments. Last year the requirements for general surgery were revised in order to modernize training and more properly meet the demands of an increasingly sub-specialized and centralized surgical environment. Applicants now need only 3 years of general surgery.

There are 6 mandatory courses for urology and 10 for general surgery. For urology this comprises a total of 120 hours covering transurethral surgery; urological oncology, uro-dynamics/neuro-urology; infection; uro-lithiasis; and trauma.

Accredited urology units are divided into group 1 and group 2 status. Group 1 units are restricted to university hospitals and each trainee must complete 1 ½ years of training in such a unit. The remaining accredited units have group 2 status.

Specialist trainees are required to perform an extensive range of procedures within urology and general surgery. The newly revised general surgery list is somewhat less demanding than earlier. It includes obligatory procedures relating to vascular, gastro-intestinal and thoracic surgery. In addition to this each trainee must perform a substantial number of major surgical procedures of their own choice.

The operative list for urology includes transurethral procedures, stone treatment, laparoscopic and open surgical procedures. Ultrasonographic examination of the prostate, bladder and kidney are required as well as performance of uro-dynamic investigations.

Research activity is not required. Training in the aforementioned group 1 university hospital units should offer research exposure.

With 2 years of foundation training immediately post-medical school, 3 years of general surgery and 3 years of urology, candidates can expect to use a minimum of 8 years before attaining specialist status.

# The Danish Residency Program in Urology

*by Hanne Kobberø, President, Association of Young Danish Urologists.*

To be eligible for the Danish Residency Program in Urology, it is required to have a medical degree (six years in Denmark), a one year basic clinical training position followed by a one year introductory position in Urology. The purpose of the introductory year is for the doctor, to develop basic urological skills, and for the department to evaluate the doctor's skills both surgically and medically. The evaluation is used if the resident chooses to apply for a residency in urology.

The Residency Program takes five years. The resident is trained in two different urological departments. One highly specialized and one with more basic urology. One of the departments serves as a base for the resident. All residents are trained and evaluated according to "The seven medical roles" listed below.

1: Medical expert, which includes clinical skills, para clinical skills and surgical skills.
2: Communication
3: Collaboration
4: Leadership/Administration
5: Promotion of health
6: Academics
7: Professional attitude

During the five years, the resident is required to follow a wide range of courses. These include:

Courses on different aspects of urology both in knowledge and surgical skills and research courses.

Broad surgical courses with other specialties

Courses in leadership, administration and collaboration

The resident is also required to visit collaborating departments from other specialties, (Gynecology, Oncology, Radiology) for different periods of time to learn basic skills that are needed to improve understanding and collaboration between the different specialties.

All acquired skills during the five year period are documented and send to the Department of Health for final certification.

The Danish healthcare system is undergoing a major transition these years with larger and more specialized units and doctors, but also financial cutbacks. Therefore the requirements listed above are under constant pressure and change. This is a challenge in the education of the individual resident and a constant focus of attention for both the Danish Urological association and the Association of Young Danish Urologists.

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| **Clinical management of neuropathic bladder dysfunction in SCI patients** | *Thomas Glott, Norway* |
| **Lower urinary tract function and dysfunction - New insights** | *Anders Mattiasson, Sweden* |
| **Contemporary management of painful bladder** | *Jørgen Nordling, Denmark* |

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# Urology training in Sweden

*by Ylva Huge, Urologists.*

In 2008, urology was made a branch speciality. This has been a controversial issue to the Swedish Society of Urology and much work has been invested in making urology a separate speciality once more.

There is an ongoing discussion of whether urology will get its positions as a separate specialty back. It is our impression that there will be a change, and we have high expectations that there will be a decision regarding this in June 2012.

Under the current system, the minimum length of training is seven years. Compulsory rotations are surgery and anaesthetics. This means that to be eligible to become a certified urologist you must first be a certified surgeon.

The common knowledge base with the branch specialties requires mastering surgical pathophysiology, basic surgical techniques, initial trauma handling, acute surgical illnesses in adults and children, basic nutritional treatment, basic pain management, basic surgical intensive care, and the effects of anaesthetics.

Urology specific competence requirements are defined by eleven objectives, which include the ability to handle acute injuries and illnesses in the kidneys and urinary tracts, as well as knowledge of inflammation and infection in the urinary tracts and the male genitalia. Additionally, urologists must also possess the ability to evaluate and handle lithiasis in the urinary tracts, as well as functional disorders and obstructions in the lower urinary tracts. Furthermore, knowledge of endourological investigation and treatment of other illnesses in the upper urinary tract is required. Urological tumour illness is a large field of illness, which urologists are required to have knowledge of how to evaluate and treat. Additionally, the ability to evaluate and treat symptoms and illnesses in men's genitalia, as well as knowledge of illnesses associated with male sexuality, is required. Beyond that, being able to handle symptoms and illnesses in the urinary tracts and the genitalia of male children is required.

Almost exclusively, these objectives require a separate course, but the definition of what qualifies as a course is vaguely defined.

Urologists do not perform renal transplantations; therefore general knowledge of the subject is sufficient.

Paediatric urology is performed by surgeons, but knowledge of how to initially recognize and treat symptoms and illness in the urinary tracts and genitalia of male children is necessary.

To become a urologist, a surgeon must be able to independently perform the following practical procedures: Bladder evacuation, scrotal exploration (suspicion of testicular torsion or scrotal trauma), TRUS-guided biopsy, pelvin lymphadenactomy, surgical castration, Cystoscopy and TUR-B; orchidectomy, testicular biopsy, ESWL treatment, semirigid uretheroscopic stoneextraction and biopsy, placement of double J-stent, incision ob abscess, Transurethral surgery, surgery in hydrocele spermatocele and phimosis and vasoresection.

In addition to these procedures, surgeons also need to have good knowledge and experience of a number of procedures.

If the systems of specialist training were to change, the specific urological procedures required are likely to remain more or less the same. The major change would be that less time would be spent on general surgical training and thus reducing the minimum time for training to five years.

# Overview of urological training program in Finland

*Teemu Murtola, M.d., Ph.D., University of Tampere, School of Medicine and Tampere University Hospital, Department of Urology*

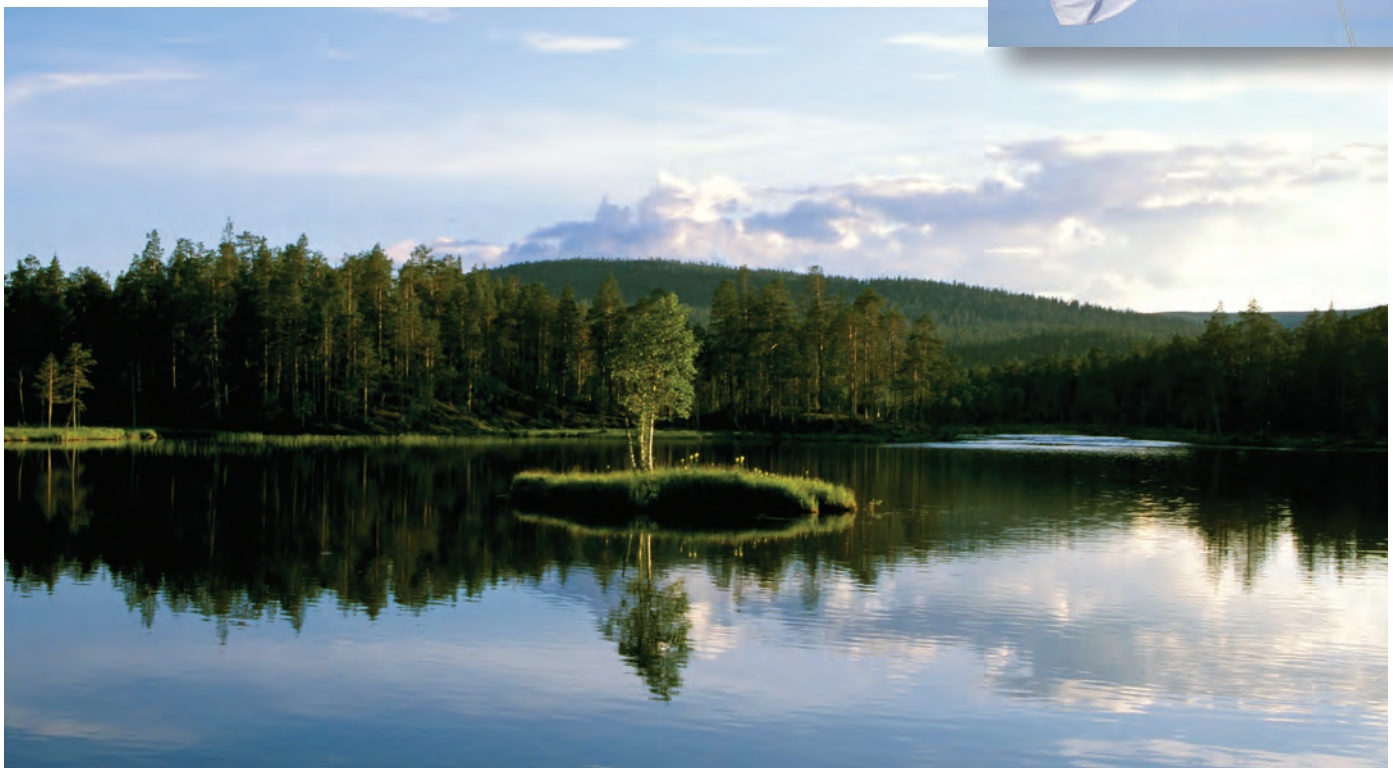
The specialization program is generally divided into two separate phases. The first is carried out in one of the country's central hospitals, which do have most surgical subspecialties adequately available. During this period the trainee will work on each subspecialty 3-6 months at a time; this time includes working in hospital wards, managing patients at the outpatient clinics and assisting or, when the abilities allow, performing operations on the field of that subspecialty.

The aim is to provide the trainee with basic surgical skills and overall understanding of different aspects of care regarding surgical patient, such as pre-operative conditioning and management during post-operative period. The duration of the basic skills training is two years and three months. This part of the training also includes nine months of working in primary care, usually in a health centre. This is usually done prior to central hospital training.

There is no set list of operations that a trainee must master before completing the basic training. Generally it is expected that the trainee can handle the simpler operations within each subspecialty, such as uncomplicated appendectomy or basic fixation of a bimalleolar ankle fracture. On the field of urology the trainee is expected to be able to perform cystoscopy and small operations such as circumcision and vasectomy.

The latter part of training is carried out in any of the five university hospitals in Finland. During this phase the trainee concentrates on the selected surgical subspecialty, expanding theoretical knowledge into specialist level and widening the operative skills. The typical operations expected to learn for a urological trainee are TURP and TURB, open prostate adenoma enucleation, open nephrectomy, and scrotal operation such as hydrocele and spermatocele repair. The duration of this training phase is three years. Most of it is carried out in a university hospital, but depending on the discretion of the training supervisor (professor of urology), up to one year of this period can be carried out in a central hospital. The period ends in a specialist examination, which consists of writing tasks on the field of the specialty.

During each phase the trainee is entitled to weekly teaching meetings. The amount of required theoretical training are 60 h during basic training phase and 80 hours during specialization phase. These are achieved by attending national and international meetings and by attending training courses selected by the trainee and his mentor.



# YDU, Association of Young Danish Urologists

*by Hanne Kobberø, President, Association of Young Danish Urologists.*

The association was founded in the early eighties as an independent initiative among young urologists.

The original name of the association was DUSC, Danish Urological Science Club, and its purpose was to create an independent forum for young doctors with a special interest in urology in order to improve and increase the scientific activity, the level of information among future and current urologists, the national collaboration between urological departments, and to offer a natural supplement to the education of urologists. Furthermore the club could participate in discussions on education and on changes in the residency program along with the Danish Urological association. Finally the club represented the Danish residents in urology in the European Society of Residents in Urology (ESRU). In 2010 the association changed its name to YDU, Association of Young Danish Urologists, however, the concept was maintained.

Currently YDU arranges two annual national meetings with academic content, presentation of different urological departments, and both social and professional networking. At the same time YDU is arranging supplementary courses and lectures for the already existing residency program in urology. YDU is also participating actively in an initiative to strengthen the Scandinavian collaboration further.

YDU is an independent association with its own board; however, a membership of the Danish Urological Association is required to become a member of YDU. Currently YDU has 98 members.

The board work in YDU is volunteer work and our annual meetings and courses are sponsored by the pharmaceutical industry. In addition the sponsorships also include two editions of Campbell-Walsh´s Urology per meeting and travel grants for young urologists for congresses in both Scandinavia and Europe.

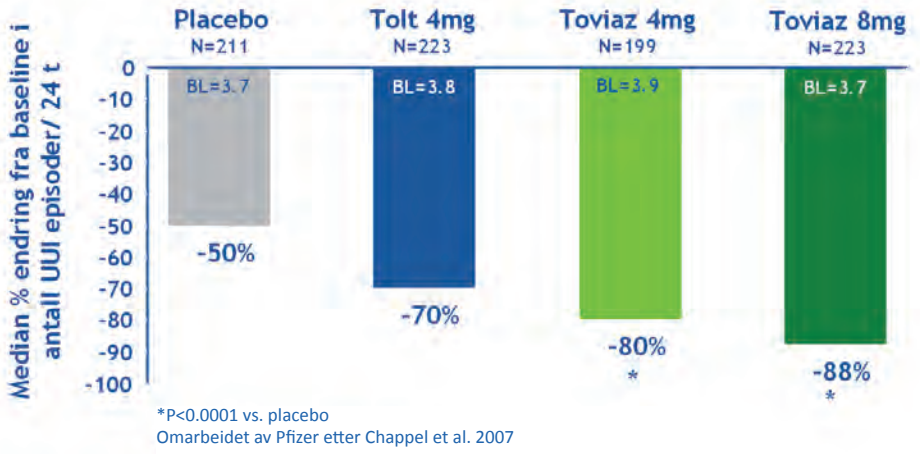
There is a continued wish in YDU to strengthen international contacts. This requires a united and strong national organization, which the YDU board regards as one of its most important jobs to maintain.

E2010-1232

# Effektivt antimuskarin[1]

- **Fleksibel dosering: 4 mg og 8 mg[2]**
- **En gang daglig[2]**


## UUI-episoder[1]




*P<0.0001 vs. placebo
Omarbeidet av Pfizer etter Chappel et al. 2007

Toviaz depottabletter «Pfizer» Muskarinreseptorantagonist. ATC-nr.: G04B D11 **DEPOTTABLETTER 4 mg og 8 mg:** Hver depottablett inneh.: Fesoterodinfumarat 4 mg, resp. 8 mg tilsv. fesoterodin 3,1 mg, resp. 6,2 mg, hjelpestoffer. Fargestoff: Indigotin (E 132), titandioksid (E 171).**Indikasjoner:** Symptomatisk behandling av urgeinkontinens og/eller hyppig vannlating og økt vannlatingstrang som kan forekomme hos pasienter med overaktiv blære. **Dosering:**Voksne: Anbefalt startdose er 4 mg 1 gang daglig. Basert på individuell respons kan dosen økes til 8 mg 1 gang daglig. Maks. daglig dose er 8 mg. Til pasienter med normal nyre- og leverfunksjon, som får samtidig behandling med potent CYP 3A4-hemmer, bør maks. daglig dose av fesoterodinfumarat være 4 mg 1 gang daglig. Ved samtidig administrering av en moderat CYP 3A4-hemmer bør individuell respons og toleranse evalueres før doseøkning til 8 mg. Skal svelges hele. Kan inntas uavhengig av måltid. Fullstendig behandlingseffekt er sett etter 2-8 uker og virkningen bør derfor evalueres etter 8 ukers behandling. Barn: Sikkerhet og effekt er ikke dokumentert. **Kontraindikasjoner:** Urinretensjon. Alvorlig ulcerøs kolitt. Toksisk megacolon. Ukontrollert trangvinkelglaukom. Myasthenia gravis. Alvorlig nedsatt leverfunksjon («Child-Pugh» C). Samtidig bruk av potente CYP 3A4-hemmere ved moderat til kraftig nedsatt lever- eller nyrefunksjon. Ventrikkelretensjon. Overfølsomhet for fesoterodin eller noen av de andre innholdsstoffene, peanøtter eller soya. **Forsiktighetsregler:** Bør brukes med forsiktighet ved betydelig hindret blæretømming med fare for urinretensjon (f.eks. klinisk signifikant forstørret prostata pga. benign prostatahyperplasi). Forsiktighet også ved obstruktiv sykdom i mage-tarmkanalen (f.eks. pylorusstenose), gastroøsofageal refluks og/eller samtidig bruk av legemidler som kan føre til eller forverre øsofagitt (f.eks. orale bisfosfonater), nedsatt gastrointestinal motilitet, autonom nevropati og kontrollert trangvinkelglaukom. Forsiktighet må utvises når fesoterodin forskrives til eller opptitreres hos pasienter som forventes å ha økt eksponering for aktiv metabolitt: Nedsatt lever- og nyrefunksjon, samtidig administrering av potente eller moderate CYP 3A4-hemmere, samtidig administrering av potente CYP 2D6-hemmere. Ved kombinasjon av disse faktorene forventes ekstra økning i eksponeringen. Doseavhengige antimuskarine bivirkninger vil sannsynligvis oppstå. Individuell respons og toleranse bør evalueres før doseøkning til 8 mg 1 gang daglig. Organiske årsaker til overaktiv blære skal utredes før behandling. Forsiktighet skal utvises ved risiko for QT-forlengelse (f.eks. hypokalemi, bradykardi og samtidig administrering av legemidler som er kjent for QT-forlengelse) og ved relevante tidligere hjertesykdommer (f.eks. myokardial iskemi, arytmier, medfødt hjertesvikt). Dette gjelder spesielt ved samtidig bruk av potente CYP 3A4-hemmere. Forsiktighet må utvises ved bilkjøring eller bruk av maskiner pga. mulige bivirkninger som f.eks. uklart syn, svimmelhet og søvnighet. Bør ikke brukes ved sjeldne arvelige problemer med galaktoseintoleranse, en spesiell form for hereditær laktasemangel (lapp-laktasemangel) eller glukose-galaktosemalabsorpsjon. **Interaksjoner:** Samtidig behandling med andre legemidler som har antimuskarine eller antikolinerge egenskaper (f.eks. amantadin, trisykliske antidepressiver, enkelte nevroleptika) kan resultere i uttalte terapeutiske effekter og bivirkninger (f.eks. forstoppelse, munntørrhet, søvnighet, urinretensjon). Fesoterodin kan redusere effekten av legemidler som stimulerer motiliteten i mage-tarmkanalen, som f.eks. metoklopramid. Maks. fesoterodindose bør begrenses til 4 mg ved samtidig bruk av potente CYP 3A4-hemmere (f.eks. atazanavir, klaritromycin, indinavir, itrakonazol, ketokonazol, nefazodon, nelfinavir, ritonavir (og alle ritonavirforsterkede PI-regimer) sakinavir og telitromycin). Det forventes økt eksponering av aktiv metabolitt ved samtidig bruk av moderate CYP 3A4-hemmere (f.eks. amprenavir, aprepitant, diltiazem, erytromycin, flukonazol, fosamprenavir, grapefruktjuice, verapamil), men mindre økning enn den som er sett med potente CYP 3A4-hemmere. Samtidig administrering av potente CYP 2D6-hemmere kan gi økt eksponering og bivirkninger og dosereduksjon til 4 mg kan være nødvendig. Induksjon av CYP 3A4 kan føre til subterapeutiske plasmanivåer. Samtidig bruk med CYP 3A4-indusere (f.eks. karbamazepin, rifampicin, fenobarbital, fenytoin, johannesurt) anbefales ikke. **Graviditet/Amming:** Overgang i placenta: Ukjent. Risiko ved bruk under graviditet er ikke klarlagt. Gravide bør ikke behandles med fesoterodin. Overgang i morsmelk: Ukjent. Bruk under amming bør unngås. **Bivirkninger:** Munntørrhet er mest vanlig (1/10). Hyppige (>1/100): Gastrointestinale: Magesmerter, diaré, dyspepsi, forstoppelse, kvalme. Luftveier: Tørr hals. Nevrologiske: Svimmelhet, hodepine. Psykiske; Søvnløshet. Syn: Tørre øyne. Urogenitale: Dysuri. Mindre hyppige: Gastrointestinale: Abdominalt ubehag, flatulens, gastroøsofageal refluks. Hud: Utslett, tørr hud. Hørsel: Vertigo. Lever: Økning i ALAT og GGT. Luftveier: Faryngolaryngeal smerte, hoste, nesetørrhet. Nevrologiske: Smaksforstyrrelse, somnolens. Sirkulatoriske: Takykardi. Urogenitale: Urinretensjon (inkl. følelse av resturin, sykelig trang til vannlating), urinhesitasjon, urinveisinfeksjon. Øvrige: Utmattelse, generelle lidelser. Etter markedsføring: Tilfeller av urinretensjon hvor kateterisering har vært nødvendig, vanligvis i løpet av den 1. behandlingsuken. Primært sett hos eldre mannlige pasienter (>65 år) som tidligere har hatt benign prostatahyperplasi. **Overdosering/Forgiftning:** Symptomer: Fesoterodin er administrert sikkert i doser opptil 28 mg/dag. Overdosering kan føre til alvorlige antikolinerge virkninger. Behandling: Ev. ventrikkelskylling og medisinsk kull. Symptomatisk behandling. Se Giftinformasjonens anbefalinger G04B D. **Oppbevaring og holdbarhet:** Oppbevares ved høyst 25°C, i originalpakningen. **Pakninger og priser:** 4 mg: 28 stk. (blister) kr 432,40. 84 stk. (blister) kr 1227,30. 8 mg: 28 stk. (blister) kr 432,40. 84 stk. (blister) kr 1227,30 **Refusjon:** Refusjonsberettiget bruk: Motorisk hyperaktiv nevrogen blære med lekkasje (urge-inkontinens).

Refusjonskode:

| ICPC | | Vilkår nr | ICD | | Vilkår nr |
|---|---|---|---|---|---|
| U04 | Urininkontinens | - | N39.4 | Annen spesifisert urininkontinens | - |

Vilkår: Ingen spesifisert.

**Sist endret:** 27.09.2010

**Referanse:**
1. Chapple C, Van Kerrebroeck P, Tubaro A, Haag-Molkenteller C, Forst HT, Massow U, Wang J, Brodsky M. Clinical Efficacy, Safety, and Tolerability of Once-Daily Fesoterodine in Subjects With Overactive Bladder. Eur Urol. 2007. Oct; 52 (4): 1204-12.
2. SPC Toviaz Juni 2010

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# NUF Tampere, 2011

*by Mikkel Fode, Department of Urology, Herlev Hospital, Denmark*

I had the good fortune to be able to both attend and present some work at the 2011 conference of the Scandinavian Society of Urology in Tampere, Finland. My group left for Tampere the day before the conference and already at the lay over in Helsinki we knew it was going to be a good trip as we enjoyed a reindeer burger and a beer in the airport. When we arrived in Tampere we were pleasantly surprised as the Finnish weather showed itself from a very pleasant and warm side, which was to last all week. The conference itself also turned out to be great event – both scientifically and socially.

## Scientific Program

The congress started on the 24th of August and the first thing on the agenda was a live surgery course with an artificial sphincter in a female patient. After this I attended an excellent symposium created by the LUTS group of the Scandinavian Association of Urology. This covered a range of topics including new understandings of the pathophysiology of LUTS, neural issues, lifestyle factors, and how to think about "healthy voiding". It also dealt with treatments in the form of lectures on pelvic floor training and surgery and a point/counter-point discussion about TUR-P vs. the Green




science as well as clinical aspects were included. The standards of the presentations were generally high and the day included a Finnish presentation on "Smoking and Urinary Storage Symptoms in Women" by Dr. Riikka Tähtinen, which later went on to win for best presentation.

The final day began with state-of-the-art lectures on Bladder Pain Syndrome and neuromodulation by Jørgen Nordling and Stefan de Wachter. This was followed by lectures on bladder cancer and during the lunch break Photocure and Orion Pharma held their symposiums – again at a very high standard. The conference ended with 4 more sessions with new Scandinavian research – again at a standard the Society can be proud of. All together there were 505 registered participants. There were 68 accepted papers, all presented either as 13 minutes oral presentations, or as posters with a 8 minutes oral presentation and discussion.

## Social programme

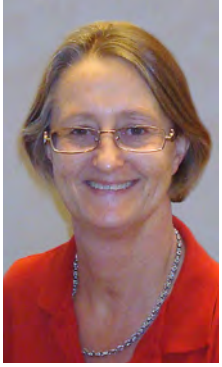
Regarding the social program the NUF conference was a packed event – the first night there was a get together reception at the conference hall and the second night a reception at the impressive Tampere City Hall with a speech from the mayor and entertainment from a Finnish men's choir. The third day was the gala dinner and the night ended in a party with both dancing and socializing. Especially the gala dinner stuck with me partly because of unusual events for formal dinners such as dancing during dinner, very dirty jokes and a magician for entertainment. The night was very enjoyable and after the dinner venue closed a large group from the party continued on to the bars of Tampere. Along with the good times these social events was also a great chance to get to know colleagues from all of Scandinavia. When I was a medical student I was first attracted to urology because of the friendly and open people I met in this field. This is also the reason I enjoy it when I get to spend time with my Danish colleagues – especially out side of normal work hours. Therefore I had looked forward to the opportunity to meet urologists from the rest of Scandinavia, and I was not disappointed as the people I met turned out to be as open and friendly as my Danish colleagues.

I feel certain that the encounters will lay the ground for friendships and future collaborations across borders in Scandinavia.

## Urologists in training

On the second day of the conference a brainstorming session about "journal improvements" for young urologists was scheduled – unfortunately this even was largely overlooked and only a few people showed up. Generally I experienced some talk among the younger urologists about a decreasing knowledge about and interest in the Scandinavian Society of Urology.

However, during the general assembly this was addressed in that the president of the Danish Urological association Claus Dahl and the newly elected NUF Bulletin editor Sven Löffeler suggested, a meeting between 2 representatives from each of the young urologist organisations to discuss ideas on how to improve Nordic collaboration. The general assembly approved this initiative. During one of the social events of the conference I was approached about this idea, and we are now arranging such a meeting in Copenhagen in early 2012. It is our hope that this will be the start of a group of Scandinavian Urologists in Training under the Scandinavian Association of Urology. The main ideas are, in time, to create joint Scandinavian courses and education as well as future Scandinavian research projects and clinical exchange. We also hope that the group can help to strengthen the Scandinavian Association of Urology by increasing awareness and interest in the association among the younger colleagues.



# Welcome to rehab station stockholm!

*by Elisabeth Farrelly, consultant urologist Södersjukhuset, Stockholm and Rehab Station Stockholm*

It looks like an old military base, with some modern bungalows added here and there. The front parking lot is constantly busy with private cars, taxis and vans pulling in and out, and people are coming and going in wheel-chairs, using walking aids or just their two feet.

Majestic old trees around the buildings sway their autumn-coloured leaves and some remaining birds chirp on the branches.

We are in the "City National Park" in Solna, just north of Stockholm and only a stone´s throw away from the home of crown princess Victoria and prince Daniel.

Inside the buildings, the reception area looks like something out of a modern advertising company and to the left is a pool table in the waiting area. Downstairs is the restaurant and a large fireplace, increasingly popular during dark evenings.

## Welcome to Rehab Station Stockholm!

This is a rehabilitation hospital and research institute, which is the home of unique collaboration between neurology, rehabilitation medicine, urology and several other medical specialities.

Rehabilitation is offered, since 1987, for patients with spinal cord injury, orthopedic injuries, multiple sclerosis, stroke and general neurology in the form of day rehab courses or inpatient stays. Through contracts with counties in Sweden and access for foreign insurance holders, domestic as well as foreign patients from many countries are welcomed.

For spinal cord injury, the Stockholm area has an established programme of care ("vårdkedjan för spinalskadade"). The programme involves a chain of medical care institutions as well as a defined amount of money to cover for each individual´s medical needs during the first years.

Typically, a person who suffers a spinal cord injury will be treated in neurosurgery or orthopedics for stabilization of the injury, then in the inpatient neuro-rehab unit at the Karolinska University Hospital.

Next stop will be inpatient rehabilitation at Rehab Station Stockholm (RSS), where focus is heavily on training and preparing for life outside the institutions, returning to one´s own home and becoming mobile between home and training facilities.

After return to home, the SCI-patient continues rehabilitation at the Spinalis clinic, also situated at RSS. The day rehab programme will now focus on mobility for all areas of daily life, on getting to know and controlling the "new" body functions, and on preparations for return to work or other daily activities. The Spinalis clinic has the responsibility for day rehabilitation and life-long outpatient follow -up. Structured re-rehab periods are offered when indicated, for instance after long infection periods, plastic or urologic surgery.

## At Spinalis is also where consultants from other specialities come into the scene.

The Spinalis clinic was started in 1991 and invited all SCI-patients in Stockholm for a comprehensive medical check-up. Since then, about 95% of patients in the regional prevalence group are registered and attend yearly visits.

It quickly became evident that referrals to other specialist clinics such as urology, all too often resulted in the patient being pushed around like a pinball. This was a very time-consuming process with meagre results in terms of improvement of daily life. Instead, a process was started where the patients would have only one centre to visit – the Spinalis clinic – and specialists would come there. The first regular consultancy contract was established with Urology at the Karolinska University hospital, and other specialities have followed eventually.

For several years now, the Spinalis clinic has had access to two regular neuro-urologists. My colleague Daniela Volz from Karolinska and myself from Södersjukhuset take turns every other

week at the Thursday urology clinic in Spinalis/ RSS.

Our function is to go through patient cases with the nurses, neurologists and rehab specialists at Spinalis, to see patients and to serve as "hot-lines" to our respective hospitals.

A regional follow-up programme for neurogenic bladder dysfunction post SCI was drawn up by ourselves and colleagues in collaboration between RSS and the Karolinska University Hospital some years ago and is our daily guide. The programme outlines important points for follow-up in all levels and grades of spinal injury, as well as for adults with myelomeningocele.

A typical Thursday clinic at Spinalis will include a morning conference with nurses and rehab doctors, then patient visits and telephone calls and finally, results of various radiology and lab tests to go through.

Some common patient visits may be

- a young person who suffered a traumatic spinal cord injury some months ago. Discussion of urodynamic findings, prognosis of bladder function over the next few years, available and recommendable methods of bladder management
- an adult patient with myelomeningocele, who has increased urinary incontinence since 1-2 years. Urodynamics and a urethrocystosopy have been done. Discussion of available surgical options.
- a patient with paraplegia for several years. Previously continent with anticholinergics and CIC, but now for some time increased spasticity and increased urinary leakage. Discussion on examinations to be done and treatment options such as botulinum toxin.
- a patients with recurring urinary tract infection in spite of CIC and anticholinergic treatment.

What check-ups need to be done, and which prophylactic measures can be taken?

- follow-up of increased cystatin-C and creatinine values found at yearly medical check-up, which is performed by neurologist or rehab specialist. Discussion on bladder management, alternatives, relevant urodynamics and radiology to be done.

Urodynamics can be performed at Spinalis, just down the corridor from the consultants room.

For urethrocystoscopy and for botulinum toxin treatment, patients are referred to our respective hospitals. Continuity is an important part of the formal and moral contract with the Spinalis clinic, and the urology consultant is always responsible when SCI-patients are admitted to one of our hospitals for any planned treatment or surgery.

The urology clinic at Spinalis takes place once a week, year round, and is the most frequent consultancy. A plastic surgery clinic takes place once a month and a hand surgeon visits every two months and provides a direct link to Reconstructive Hand Surgery in Gothenburg.

Other specialities with more or less formalized links to Spinalis/RSS are psychiatry, colorectal surgery, orthopedics (for spinal deformities, shoulder problems and other long term complications), rehabilitative neuro surgery (for surgery of cyst formations at level of injury in spinal cord).

Research at Rehab Station Stockholm is very active with an established research unit under the Karolinska Institute. Academic dissertations over the years have covered medical complications in chronic SCI, fertility and sexuality, pain, spasticity, cardiovascular disease prevention after SCI, and many other areas. A large inventory of urinary tract complications in this patient group is also underway.

One of the unique features of Rehab Station and the Spinalis clinic is that true interprofessional collaboration is possible. Deliberations with physiotherapists, occupational therapists and neurology colleagues take place easily over the lunch table.

This provides for an open, mind-challenging atmosphere that I wish every urologist would have the opportunity to experience!

It is my firm belief that urologists today need to understand more about physiology, neurophysiology and rehabilitative processes in the pelvis and lower urinary tract.

This is certainly important, not only in spinal cord injury or multiple sclerosis, but also in the rehabilitation process after any type of comprehensive surgery such as for prostate cancer and bladder cancer.

# Thank you Sweden

*by Alexander Schultz*

In 1996, Bjørn Klevmark retired as Professor and chief of urological department at Rikshospitalet in Oslo. The department had focused on neurourology and reconstructive urology, as the main fields of interest, for many years.

So the search went in for a replacement of Klevmark. One who could bring the department even more knowledge in these topics, to further establish it as a centre of competence in neurourology and reconstruction in Norway. Rumours went around, that Hans Hedlund had been seen chasing a woman in Stavanger! So may be he would like to put up his Wigwam in Norway?

Luckily he took the bait, and was appointed Professor and head of department from 1996. A position he has held up to his retirement in September this year.

Hans is well known from his experimental in vitro studies on human prostatic and erectile tissue, carried out in a group led by Karl Erik Andersson in Lund. This work led to an accelerating international research on voiding dysfunction and erectile dysfunction. Hans has contributed to numerous published studies on various neuro-urological problems.

In 2010 he received the European Society of Sexual Medicine's Award of excellence!

Hans is open-minded, and easily gets in good contact with whoever he meets. When taking up his position at Rikshospitalet, he soon won the respect as an excellent professional and the affection as a warm and kind person, both from the staff and the patients. In a department dealing with neurourology, there are always a number of patients, with rather special mentalities. Hans has a special way of looking after these odd personalities, and they just love him! One should not, however, end up with the impression that he is some sort of Santa Claus! On the contrary, he is strong-minded and energetic! He has a voluptuous temperament! Many telephones have been smashed, when the conversation took a wrong direction! (A habit he brought from Sweden, I learned when visiting his former department in Lund).

Hans is a great guy, and it has been a privilege to work with him for the last 15 years! He will be missed by colleagues, nursing staff and patients alike!

Hans Hedlund has been an excellent example of the benefit we have from close collaboration between the Nordic urologists!

*On behalf of the staff at Urological department, OUS-Rikshospitalet*
*Alexander Schultz*

*Hans Hedelund da han mot-to European Society of Sexu-al Medicine's Award of excel-lence k*

*Hans Hedelund da han kom til Norge*

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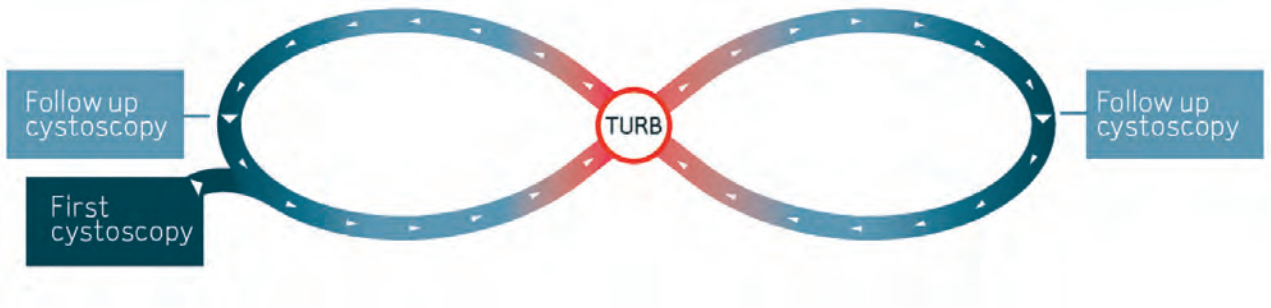
# The only thing worse than having cancer... ...is having it twice

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PRESCRIBING INFORMATION HEXVIX (hexaminolevulinate)
***Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.***
Hexvix 85 mg, powder and solvent for solution for intravesical use.
PRESENTATION Pack of one 10ml glass vial containing 85mg of hexaminolevulinate as 100mg hexaminolevulinate hydrochloride as a powder and one 50ml polypropylene vial containing solvent. After reconstitution in 50ml of solvent, 1ml of the solution contains 1.7mg hexaminolevulinate which corresponds to a 8mmol/l solution of hexaminolevulinate.
INDICATIONS This medicinal product is for diagnostic use only. Detection of bladder cancer, such as carcinoma in situ, in patients with known bladder cancer or high suspicion of bladder cancer, based on e.g. screening cystoscopy or positive urine cytology. Blue light fluorescence cystoscopy should be used as an adjunct to standard white light cystoscopy, as a guide for taking biopsies.
DOSAGE AND METHOD OF ADMINISTRATION Hexvix cystoscopy should only be performed by health care professionals trained specifically in Hexvix cystoscopy. The bladder should bedrained before the instillation. Adults (including the elderly): 50ml of 8mmol/l reconstituted solution is instilled into the bladder through a catheter. The patient should retain the fluid for approximately 60 minutes. Following evacuation of the bladder, the cystoscopic examination in blue light should start within approximately 60 minutes. Patients should be examined with both white and blue light to obtain a map of all lesions in the bladder. Biopsies of all mapped lesions should normally be taken under white light. Only CE marked cystoscopic equipment should be used, equipped with necessary filters to allow both standard white light cystoscopy and blue light (wavelength 380–450nm) fluorescence cystoscopy. Children and adolescents:There is no experience of treating patients below the age of 18 years.
CONTRAINDICATIONS Hypersensitivity to the active substance or to any of the excipients of the solvent. Porphyria. Women of child-bearing potential.
WARNINGS AND PRECAUTIONS Repeated use of Hexvix as part of follow-up in patients with bladder cancer has not been studied. Hexaminolevulinate should not be used in patients at high risk of bladder inflammation, e.g. after BCG therapy, or in moderate to severe leucocyturia. Widespread inflammation of the bladder should be excluded by cystoscopy before the product is administered. Inflammation may lead to increased porphyrin build up and increased risk of local toxicity upon illumination, and false fluorescence. If a wide-spread inflammation in the bladder becomes evident during white light inspection, the blue light inspection should be avoided. There is an increased risk of false fluorescence in the resection area in patients who recently have undergone surgical procedures of the bladder.
INTERACTIONS No specific interaction studies have been performed with hexaminolevulinate.
PREGNANCY AND LACTATION No clinical data on exposed pregnancies are available. Reproductive toxicity studies in animals have not been performed.
UNDESIRABLE EFFECTS Most of the reported adverse reactions were transient and mild or moderate in intensity. The most frequently reported adverse reactions were bladder spasm, reported by 3.8% of the patients, bladder pain, reported by 3.3% of the patients and dysuria, reported by 2.7% of the patients. Other commonly reported adverse reactions are: headache, nausea, vomiting, constipation, urinary retention, haematuria, pollakuria and pyrexia. Uncommonly reported adverse reactions are cystitis, sepsis, urinary tract infection, insomnia, urethral pain, incontinence, white blood cell count increase, bilirubin and hepatic enzyme increase, post-procedural pain, anaemia, gout and rash. The adverse reactions that were observed were expected, based on previous experience with standard cystoscopy and transurethral resection of the bladder (TURB) procedures.
OVERDOSE No case of overdose has been reported. No adverse events have been reported with prolonged instillation times exceeding 180 minutes (3 times the recommended instillation time), in one case 343 minutes. No adverse events have been reported in the dose-finding studies using twice the recommended concentration of hexaminolevulinate. There is no experience of higher light intensity than recommended or prolonged light exposure.
INSTRUCTIONS FOR USE AND HANDLING Hexaminolevulinate may cause sensitisation by skin contact. The product should be reconstituted under aseptic conditions using sterile equipment.
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1. Stenzl A et al. J urol 2010; 184: 1907-1913
2. Hermann 66 et al. BJU int (published online)

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# Skagerak bladder cancer group (SBG)

*by Erik Skaaheim Haug, Espen Kvan, Terje Wold, Leif Hunderi and Stein Egil Øverby*

*Skagerak bladder cancer group (SBG) - approaching quality in bladder cancer treatment in a Norwegian region*

Unlike Sweden, in Norway a national registry on bladder cancer has so far been more an ambition rather than a reality. Most efforts on uro-oncological diseases in Norway have been spent on prostate-cancer. Dr Rolf Wahlqvist and colleagues in the Norwegian Urological Cancer Group published the first national guidelines on bladder cancer in 2005. However, so far there has been no evaluation of its implementation.

In autumn 2010 five urological departments from 3 different hospital trusts (Sørlandet sykeshus, Sykehuset i Vestfold and VestreViken) located along the western coast of the Oslo-fjord decided to establish a work-group on bladder cancer. The hospitals cover a population of approximately 780.000 in 4 different counties (Aust-Agder, Vest-Agder, Buskerud and Vestfold). The goal of the work-group was to improve treatment of bladder cancer by:

- establishing identical quality registers in each hospital with standardized entry of data on procedures and results, with comparison of data and results on a regular basis
- establishing and implementing common guidelines based on best practice principles
- exchanging knowledge and experience by fellowship visits

Due to strong regulations on quality registries in Norway involving more than one hospital, together with the understanding that each hospital should have the full privilege and control over its own data, Skagerak offers a network of cooperating local quality-registries rather than a regional registry. By joining the group the different departments commit to common rules and conventions for data treatment, and to reporting their collected data. The registries are procedure-based and –due to the fact that there is little patient mobility and no real private competition in the region- close to being population based.

As a first presentation of SBG two abstracts were submitted to the Urological symposium in Norwegian Surgical Associations' Autumn meeting. The first abstract presented the principles and methods applied in SBG. It was also specified that in the last 1, 5 years 65 TUR and 6 cystectomies were performed per 100.000 inhabitants in the region with a variance of respectively 51 - 81 and 4-9 in the different counties. The mean age of patients undergoing TURB was 73,6 years and 70,4 years for patients undergoing cystectomy. Of the 3625 days in hospital for all procedures, 60% could be attributed to TURB- patients and 40% to cystectomy-patients.

In the second abstracts preliminary results from an analysis of 759 TURB-procedures showed that 43,3% were performed for primary treatment (range 41,2-46,9%), 10,3% were secondary TURB (re-resection) (range 5,1-17,6%) and 46,4% were procedures for recurrent tumor (range 41,4-53,7%). Interestingly, among patients operated for recurrent tumor, 36,2% of the patients were pT0 in the specimen investigated by the pathologist. Only 10% of all evaluable patients received postopera-


*Stein Øverby, Mark Soloway and Sven Löffeler (left to right) on a little cruise on the outer Oslo Fjord before the bladder cancer meeting in Tønsberg (3)*


tive instillation of Mitomycin C, and in contrast to the supplier's sales-numbers that indicate a 34% use of PDD, coding for the procedure was only found in 12% of the patients. These findings indicate that there are quality issues to address both in our practice and in our registering of data.

Another important goal of SBG is the regular organizing of meetings with in-depth review of different aspects of bladder cancer. The primary focus groups of these meetings are fellows and residents. An invitation from Photocure ASA to arrange a local meeting with Mark Soloway from Miami in connection with his Nordic tour in august 2011, was considered a splendid opportunity for our first meeting. Dr Soloway, well known for his enthusiastic and pedagogic lectures turned out to be a perfect choice for the event. After just recently finishing the ICUD-EAU International consultation on Bladder Cancer, Soloway gave the audience in Tønsberg a first class lecture with lots of firsthand information from the extensive final report, which he had been closely involved with as editor-in-chief and which was newly presented at the EAU in Vienna. Besides taking the audience through a broad sample of different case-discussion of this challenging disease, there was also time for a short discussion on the topic of active surveillance in prostate cancer.

Dr Soloway also insisted on taking the audience to a guided tour of the construction site of a replicate of the famous wiking ship of Oseberg (the original was built in 820AD), after realizing that the construction was taken place just outside the hotel. Dr Soloway found the project so fascinating that he was more than inclined to come back to Vestfold in 2013 for the NUF-meeting in Sandefjord, to see its completion.

In our busy urological daily-life, it is not often that we manage to accomplish our ambitions in scientific work and quality-assessment. In the Skagerrak Bladder cancer group we have found a common platform that with reasonable effort from the participating physicians, can provide us with opportunity to improve the quality of the treatment we are providing to bladder cancer patients and to strengthen our relations as urologist and colleagues.

*Fom left to right Espen Kvan, Leif Hunderi, Terje Wold, Mark Soloway, Erik Skaaheim Haug and Stein Øverby*

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Gjentatte kurer skal ikke gis på grunn av risiko for tap av benmasse. Det er vist at hormonerstatning (daglig dose østrogen og progesteron) har redusert tap av benmasse og vasomotoriske symptomer hos kvinner som får goserelin mot endometriose. *Forbehandling før endometriereseksjon:* 2 implantater gis med 28 dagers mellomrom. Inngrepet utføres innen 2 uker etter tilførsel av det andre implantatet. *Forbehandling til in vitro-fertilisering:* Så snart endogen hormonpåvirkning er oppnådd ved hjelp av Zoladex®, gjennomføres stimulering av eggløsning og uthenting av egg i samsvar med normale rutiner. *Nedsatt nyre- og leverfunksjon:* Dosejustering er ikke nødvendig hos pasienter med nedsatt nyre- eller leverfunksjon. *Eldre:* Dosejustering er ikke nødvendig hos eldre pasienter. **Barn:** Goserelin er ikke indisert for bruk til barn. For korrekt administrering av Zoladex-sprøyten, se brukerveiledningen som følger pakningen. **Kontraindikasjoner:** Kjent alvorlig overfølsomhet overfor virkestoffet eller noen av innholdsstoffene. Graviditet og amming. **Advarsler og forsiktighetsregler:** Goserelin 3,6 mg er ikke indisert for bruk til barn fordi sikkerhet og effekt av behandlingen ikke er kjent for denne pasientgruppen. Pasienter med kjent depresjon og pasienter med hypertensjon skal overvåkes nøye. Humørsvingninger, inkludert depresjon er rapportert. **Menn:** Hos pasienter spesielt utsatt for å utvikle ureterobstruksjon eller paraplegi bør bruk av goserelin vurderes nøye, og pasientene følges nøye opp den første måneden av behandlingen. Det bør vurderes bruk av et anti-androgen (f.eks. cyproteronacetat 300 mg daglig i 3 dager før og 3 uker etter behandlingsstart med goserelin) ved start av GnRH-analog behandlingen, da dette er rapportert å forebygge mulige skader av initial økning i serumtestosteron. Oppstår det paraplegi eller nedsettes nyrefunksjon som følge av ureterobstruksjon, bør spesifikk behandling av disse komplikasjonene igangsettes. Bruk av GnRH-agonister kan forårsake reduksjon av benmasse. Foreløpige data tyder på at bruk av bisfosfonater i kombinasjon med en GnRH agonist kan minske reduksjonen av bentetthet hos menn. Spesiell forsiktighet er nødvendig i forhold til pasienter med ytterligere risikofaktorer for osteoporose (f.eks. ved kronisk alkoholmisbruk, røykere, pasienter på langtidsbehandling med antikonvulsiva eller kortikoider og ved familiær osteoporose). En reduksjon i glukosetoleransen er sett hos menn som får GnRH-agonister. Dette kan vise seg som diabetes eller redusert glykemisk kontroll hos dem som har diabetes mellitus fra før. Det bør derfor overveies å overvåke blodsukkeret. **Kvinner:** *Brystkreftindikasjon.* Redusert bentetthet: Bruk av GnRH-agonister kan forårsake reduksjon av benmasse. Etter to års behandling av tidlig brystkreft var gjennomsnittlig tap av benmasse 6,2 % og 11,5 % i henholdsvis lårhals og lumbalcolumna. Tap av benmasse er vist å være delvis reversibelt ved oppfølgingen ett år etter avsluttet behandling. Begrensede data viser en forbedring på 3,4 % og 6,4 % i henholdsvis lårhals og lumbalcolumna sammenlignet med baseline. Foreløpige data tyder på at bruk av goserelin i kombinasjon med tamoksifen ved brystkreft kan minske reduksjonen av bentetthet. **Godartede indikasjoner:** Tap av benmasse: Bruk av GnRH-agonister kan forårsake reduksjon av benmasse med omtrent 1 % per måned i en 6 måneders behandlingsperiode. For hver 10 % reduksjon i benmasse øker risikoen for brudd med ca 2-3 ganger. Tilgjengelige data tyder på at noe remineralisering kan forventes etter endt terapi hos en stor del av pasientene. Hormonell tilleggsmedikasjon (daglig dosering av østrogen og progesteron) har vist seg å kunne minske reduksjonen av benmasse og vasomotoriske symptomer hos kvinner som behandles med goserelin for endometriose. Det foreligger ikke dokumentasjon for bruk til pasienter med etablert osteoporose eller pasienter med risikofaktorer for osteoporose (f.eks. kronisk alkoholmisbruk, røykere, langtidsbehandling med legemidler som reduserer benmassen, f.eks. antikonvulsiva og kortikoider, familiær osteoporose, dårlig ernæring, f.eks.anoreksi). Da reduksjon i bentetthet antakelig er mer skadelig for disse pasientene, bør behandling med goserelin vurderes på individuell basis og bare igangsettes dersom fordelene med behandlingen oppveier risikoen. Ytterligere tiltak bør vurderes for å forhindre tap av benmasse. **Bortfallsblødning:** I starten av goserelinbehandlingen kan enkelte kvinner få vaginalblødninger av varierende varighet og intensitet. Vaginalblødning oppstår vanligvis den første måneden etter oppstart av behandlingen. Slike blødninger skyldes sannsynligvis østrogenbortfall og forventes å stanse spontant. Dersom blødningen fortsetter, må årsaken undersøkes. Det mangler kliniske effektdata for behandling av godartede gynekologiske tilstander med goserelin 3,6 mg i mer enn 6 måneder. Bruk av goserelin kan forårsake en forhøyet tonus i livmorhalsen og forsiktighet bør utvises ved dilatasjon av denne.Når goserelin 3,6 mg administreres som del av et behandlingsopplegg for in vitro-fertilisering, skal dette bare skje under overvåking av en spesialist innenfor området. Som for andre GnRH-agonister har det vært rapportert ovarielt hyperstimuleringssyndrom (OHSS) når Zoladex® 3,6 mg har blitt gitt i kombinasjon med gonadotropiner. Stimuleringssyklus bør overvåkes nøye for å identifisere de pasientene som risikerer å utvikle OHSS. Ved slik risiko bør humant koriongonadotropin (hCG) ikke gis. Ved in vitro-fertilisering bør Zoladex® 3,6 mg brukes med forsiktighet hos pasienter med polycystisk ovariesyndrom da en økt tendens til follikkeldannelse kan foreligge. Fertile kvinner skal bruke ikke-hormonelle prevensjonsmetoder i hele behandlingsperioden med goserelin, og helt til menstruasjonen er tilbake etter avsluttet behandling. Behandling med goserelin kan føre til positive utslag på dopingtester. **Interaksjon med andre legemidler og andre former for interaksjon:** Ingen kjente interaksjoner. **Graviditet og amming:** *Graviditet:* Goserelin skal ikke brukes ved graviditet fordi bruk av GnRH-agonister er forbundet med en teoretisk risiko for abort og fosterskader. Fertile kvinner bør undersøkes nøye før behandling iverksettes for å utelukke graviditet. Ikke-hormonell antikonsepsjon bør anvendes inntil menstruasjonen kommer tilbake (se også advarsel vedrørende tid til menstruasjon i pkt.4.4). Graviditet skal utelukkes før goserelin 3,6 mg implantat brukes ved fertilitetsbehandling. Når goserelin brukes ved denne indikasjonen er det ingen kliniske holdepunkter for en sannsynlig sammenheng mellom goserelin og senere skader på fosterutvikling, graviditet eller nyfødte. *Amming:* Det er ukjent hvor mye av goserelinacetat som går over i morsmelk. Det er ikke klarlagt om barn som ammes kan skades. Goserelinacetat skal ikke brukes under amming. Påvirkning av evnen til å kjøre bil og bruke maskiner: Legemidlet antas normalt ikke å påvirke evnen til å kjøre bil eller betjene maskiner. **Bivirkninger:** De vanligst rapporterte bivirkningene av goserelin er: nedsatt libido, erektil dysfunksjon, hetetokter, hyperhidrose, vulvovaginal tørrhet i skjeden, endringer i brysttørrelse, reaksjoner på injeksjonsstedet (rødhet, smerte, hevelse, blodutredelser). Forekomst av bivirkninger er rangert etter følgende frekvensinndeling: *Svært vanlige* ≥1/10, *vanlige* ≥1/100, <1/10, *mindre vanlige* ≥1/1000, <1/100), *sjeldne* ≥1/10.000, <1/1000 og *svært sjeldne* <1/10.000, ukjent (frekvens kan ikke estimeres fra tilgjengelige data). **Bivirkninger av goserelin 3,6 mg presenteres ved hjelp av MedDRA organklassesystem:** ***Godartede, ondartede og uspesifiserte svulster (inkludert cyster og polypper):*** *Svært sjeldne (menn & kvinner):* Tumor i hypofysen. *Ukjent (kvinner):* Degenerasjon av uterine fibromyomer hos kvinner som har dette. ***Forstyrrelser i immunsystemet:*** *Mindre vanlige (menn & kvinner):* Overfølsomhetsreaksjoner mot legemidler. *Sjeldne (menn & kvinner):* Anafylaktisk reaksjon. ***Endokrine sykdommer.*** *Svært sjeldne (menn & kvinner):* Blødning i hypofysen. ***Stoffskifte- og ernæringsbetingede sykdommer:*** *Vanlige (menn):* Nedsatt glukosetoleranse.[1] *Mindre vanlige (kvinner):* Hyperkalsemi. ***Psykiatriske sykdommer:*** *Svært vanlige (menn & kvinner):* Nedsatt libido.[2] *Vanlige (kvinner):* Humørsvinginger, inkludert depresjon. *Svært sjeldne (menn & kvinner):* Psykose. *Ukjent frekvens (menn):* Humørsvinginger, inkludert depresjon. ***Nevrologiske sykdommer:*** *Vanlige (menn & kvinner):* Parestesi. *Vanlige (menn):* Trykk på ryggmargsnerven. *Vanlige (kvinner):* Hodepine. ***Hjerte- og karsykdommer:*** *Svært vanlige (menn & kvinner):* Hetetokter.[2] *Vanlige (menn & kvinner):* Endret blodtrykk.[3] *Vanlige (menn):* Hjertesvikt.[6] ***Hud- og underhudssykdommer:*** *Svært vanlige (menn & kvinner):* Hyperhidrose.[2] *Vanlige (menn & kvinner):* Utslett.[4] ***Sykdommer i muskler, bindevev og skjelett:*** *Vanlige (menn):* Skjelettsmerter.[5] *Vanlige (kvinner):* Artralgi. *Mindre vanlige (menn):* Artralgi. ***Sykdommer i nyre og urinveier:*** *Mindre vanlige (menn):* Ureterobstruksjon. ***Lidelser i forplantningsorganer og brystsykdommer:*** *Svært vanlige (menn):* Erektil dysfunksjon. *Svært vanlige (kvinner):* Vulvovaginal tørrhet. Endring i brysttørrelse. *Vanlige (menn):* Gynekomasti. *Mindre vanlige (menn):* Ømhet i brystene. *Sjeldne (kvinner):* Ovariecyster. *Ukjent frekvens (kvinner):* Bortfallsblødning. ***Generelle lidelser og reaksjoner på administrasjonsstedet:*** *Svært vanlige (kvinner):* Reaksjoner på injeksjonsstedet (f.eks. rødhet, smerte, hevelse, blodutredning). *Vanlige (menn):* Reaksjoner på injeksjonsstedet (f.eks. rødhet, smerte, hevelse, blodutredning). ***Undersøkelser:*** *Vanlige (menn & kvinner):* Tap av benmasse.

**1.** En reduksjon i glukosetoleransen er sett hos menn som får GnRH-agonister. Dette kan vise seg som diabetes eller redusert glykemisk kontroll hos dem som har diabetes mellitus fra før. **2.** Dette er farmakologiske effekter som sjelden krever seponering av behandlingen. **3.** Dette kan arte seg som hypotensjon eller hypertensjon, og er av og til observert hos pasienter som får goserelin. Endringene er vanligvis forbigående og opphører enten under behandlingen eller etter avsluttet goserelinbehandling. **4.** Disse er generelt milde, og forsvinner som oftest uten at behandlingen seponeres. **5.** I begynnelsen av behandlingen kan pasienter med prostatacancer oppleve økte forbigående skjelettsmerter som håndteres utifra symptombildet. **6.** Observert i en farmakoepidemisk studie av GnRH-agonister som ble brukt i behandling av prostatakreft. Det viser seg at risikoen øker når behandlingen blir brukt i kombinasjon med antiandrogen.

**Erfaring etter markedsføring:** Det er rapportert et antall tilfeller av endring i antall blodlegemer, forstyrret leverfunksjon, lungeemboli og interstitiell lungebetennelse i forbindelse med bruk av goserelin. I tillegg er det rapportert følgende bivirkninger hos kvinner som behandles for godartede gynekologiske tilstander: Akne, endring i kroppsbehåring, tørr hud, vektøkning, økning i serumcholestrin, ovarialt hyperstimuleringssyndrom (ved samtidig bruk av gonadotropiner), vaginitt, utflod, nervøsitet, søvnforstyrrelser, tretthet, perifert ødem, myalgi, kramper i underben, kvalme, oppkast, diaré, forstoppelse, mageproblemer, endringer i stemmeleie. I starten kan pasienter med brystkreft oppleve en midlertidig økning i symptomer (f.eks. tumorsmerte) som håndteres utifra symptombildet. I sjeldne tilfeller har kvinner med metastaserende brystkreft utviklet hyperkalsemi. Dersom symptomer på hyperkalsemi oppstår (f.eks. tørste) må pasienten undersøkes for eventuelt å utelukke hyperkalsemi. I sjeldne tilfelle kan behandling med GnRH-agonister føre til menopause. Hos noen kvinner vil menstruasjonen ikke komme tilbake etter avsluttet behandling. Hvorvidt dette er en effekt av behandling med goserelin, eller et uttrykk for kvinnenes gynekologiske tilstand er ikke kjent. **Overdosering:** Det er begrenset erfaring med overdosering hos mennesker. I de tilfeller hvor Zoladex® utilsiktet er blitt gitt for tidlig i forhold til neste dose eller i for høy dose, har ingen klinisk relevante bivirkninger vært observert. Dyreforsøk tyder på at høyere doser ikke har noen annen effekt enn den tilsiktede terapeutiske effekt på konsentrasjonene av kjønnshormoner og på kjønnsorganer. Eventuelle utslag av overdosering behandles symptomatisk. **Pakninger og priser:** (pr 10.09.2010): 1 stk. (ferdigfylt sprøyte) kr 1372,60. 3 stk. (ferdigfylt sprøyte) kr 4047,70. **Refusjon:** Refusjonsberettiget bruk: Prostatacancer i avansert stadium hvor kirurgisk kastrasjon er uønsket eller ikke kan gjennomføres. Avansert cancer mammae hos pre- og perimenopausale pasienter, egnet for hormonell behandling. Symptomatisk behandling av endometriose. Forbehandling ved endometriereseksjon. *Refusjonskode:* ICPC X76 Ondartet svulst bryst (K) X99 Endometriose Y77 Ondartet svulst prostata ICD C50 Ondartet svulst i bryst C61 Ondartet svulst i blærehalskjertel N80 Endometriose. Vilkår ICPC X76 og Y77, ICD C50 og C61: Behandlingen skal være instituert i sykehus, sykehuspoliklinikk eller av spesialist i vedkommende disiplin.

*Basert på godkjent preparatomtale 18.06.2010.*

*1. Fernandez del Moral P, Dijkman GA, Debruyne FMJ et al. Urology 1996;48:894–900.*

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