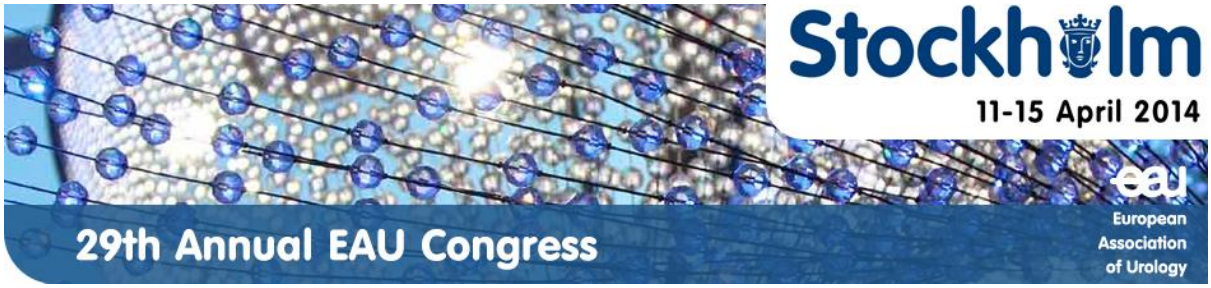

European Association of Urology 29th Annual Congress, Stockholm

Press release, embargo – Sat 12th April 08.30 (CEST, Stockholm)

A quarter of men drop out of prostate cancer monitoring, casting doubt on safety of "active surveillance"

A long-term follow up of prostate cancer patients shows that the option of monitoring slow-growing prostate cancer may not be as safe as thought, due to a quarter of men dropping out of the monitoring programme.

Prostate cancer is the most common cancer in men, with a European incidence rate of 214 cases per 1000 men, outnumbering lung and colorectal cancer*. Research shows that with advancing age, most men are likely to have a cancer of the prostate, although for many the cancer will be so slow growing that it does not create a real problem. Recently there has been significant visibility given to the risk of prostate-cancer "overdiagnosis" – treatment when it is not justified by a serious health threat.

Given that treatment for prostate cancer involves either radiotherapy or major surgery, and that this can have significant side-effects, such as incontinence and impotence, there has been an increasing tendency to keep low-risk men under "active surveillance"; in other words not to treat the cancer immediately by surgery or radiotherapy, but to monitor the cancer regularly to see if it worsens. However, there have been very few studies showing how this surveillance works in real life.

Now a group of researchers from Baden in Switzerland have presented a long-term study to the European Association of Urology Congress in Stockholm which raises concerns regarding the safety of active surveillance. The study was based in a normal-sized hospital rather than in an academic medical centre, so is probably representative of how prostate cancer is followed up in the real world. This study followed 157 patients over a 13 period years active surveillance. After 13 years it was found that around a ¼ (28%) of all patients needed definitive treatment. Almost all of these men were cured from cancer. However, it was also found that about another ¼ (27%) of all patients did not show up to the recommended appointments – which actually is the key element of active surveillance.

These men did not reply to follow-up letters requesting ongoing check-up, thus dropping out of the active surveillance system.

As lead researcher Dr Lukas Hefermehl said

"The limitation of this study is that this is not a huge sample, but nevertheless it is one of the best "real-world" samples we have with long-term data. I strongly believe that active surveillance is a good option for men who follow the recommended controls. But from our results it looks like there must be a significant number of men lost to follow up who will eventually develop a progressive disease; many of these men may even eventually die of prostate cancer. As Urologists we still remain responsible for these patients".

The group also found that just 3 months after the initial diagnosis, 30 men (19%) refused a mandatory confirmation biopsy which could have ruled out a wrong interpretation of the first biopsy.

Dr Hefermehl continued:

We don't know exactly what the reasons are. It may be that once the patient was told that this cancer is probably "not immediately threatening" , he might downplay the importance of another test. On the other hand some men might have real concerns about the risk of there being a more severe cancer. Or it may be to do with the risk of incontinence or impotence after treatment, the idea of having cancer, a sense that nothing will really happen to them or it may be due to another reason which we just don't know about".

But the fact is that overall these findings leave us with a practical and ethical dilemma; we often recommend that men go onto an active surveillance programme, but these results indicate that more than a quarter of men will disappear from the system. We strongly believe that this "patient factor" must be taken into account for future active surveillance protocols"

Commenting, Professor Manfred Wirth (Technical University of Dresden), Treasurer and Executive Member, Communication, of the European Association of Urology said:

"This is very interesting and potentially controversial work, which is based on clinical practice in the real world. It shows that we may need a clearer understanding of the psychological factors which might get in the way of effective follow up in these points."

ENDS

Notes for editors

Please mention the EUROPEAN ASSOCIATION OF UROLOGY CONGRESS in any press stories

This abstract is embargoed to match the time of a poster presentation at the congress.

For more information, please contact the EAU press officer, Tom Parkhill, via tom@parkhill.it or via telephone number **+39 349 238 8191**

Dr Lukas Hefermehl can be reached via lukas.hefermehl@gmail.com

The 29th EAU Congress takes place in Stockholm, Sweden, from 11th to 15th April, 2014. This is the largest and most important urology congress in Europe, with up to 13,000 expected to attend. Conference website: http://www.eaustockholm2014.org/en/home

*This statistic is taken from the EAU guidelines on Prostate Cancer, 2013 http://www.uroweb.org/gls/pdf/09_Prostate_Cancer_LR.pdf

Abstract

13 years of experience in active surveillance for prostate cancer: Malcompliance is a major concern in the long term
Hefermehl L.J., Disteldorf D., Talimi S., Groebli R., Lyttwin B., Lehmann K.Kantonsspital Baden, Dept. of Urology, Baden, Switzerland

INTRODUCTION & OBJECTIVES: Active Surveillance (AS) has become a standard treatment for a defined group of prostate cancer patients. Clinical parameters are used in a variety of similar protocols, which have been approved in large academic institutions with substantial financial and personal resources. However, non-clinical parameters such as patient compliance are strongly underrated but highly crucial parameters, especially in a form of therapy where close and continuous follow up (FU) is imperative. Furthermore, long term data for AS are still not well known, especially in a community hospital environment where a substantial number of AS patients is followed.

MATERIAL & METHODS: We conducted a prospective single-arm study starting in 1999 at our non-academic urologic institution. Inclusion and progression criteria as well as the FU schedule met general recommendations for AS. All patients were fully informed and gave written consent. If patients failed to appear they were contacted at least two times by post explaining the importance of follow up.

RESULTS: 157 consecutive patients have been included at a median age of 67(61-70) y between 1999 and 2013. Median FU was 36 (24-72) months (mo) 32 (20%) men showed progression after a median FU of 26 (19-35)mo. Progression free survival (PFS) was 65% in 146 mo. Of these 32 men 62% underwent radical prostatectomy (RP) and 34% had external beam radiotherapy (EBRT). 1 man required direct androgen deprivation therapy(ADT) and died consecutively. After RP 37% showed GS 7, 5% GS 8 and 10% GS 9. FU after RP was 52 (12-76)mo and 21 (15-51)mo after EBRT. Follow-up with no evidence of disease after treatment in these men was 43 (12-71) and 23 (15-50) mo respectively. 2nd line therapy was needed only in 1 man after RP and 1 after EBRT. 13-y Kaplan-Meier analysis revealed an estimated progression rate of 28%, lost to FU rate of 27%, overall survival of 94%, CSS of 99% and PFS of 98%. After 13y only 50% remained in the AS group. 17 (11%) men were lost to FU. Overall drop-out was 36%(57 men). If all patients would have followed all appointments the complete follow-up would have been a median of 67 months (43-118). Actual FU was 36 (24-72) months. Three months after the initial diagnoses 30 men (19%) refused the confirmation biopsy. Scheduled number of PSA measurements was 1891. Only 1142 were performed (missing 749, 40 %).

CONCLUSIONS: Even in a community hospital environment AS seams safe for selected patients if the protocol is followed. Secondary progression after definitive treatment is low. It needs to be stressed that in nearly one third of those who underwent definitive treatment the tumour was very aggressive. After 13 y ¼ of all patients will need definitive treatment and only ½ will continue AS. Lost to FU rate is considerable. Whenever a patient starts AS the possibility of malcompliance is often scotomized. Furthermore, with stable, non-progressive disease the risk of protocol violation increases and may lead to complete lost to follow up in some patients. However, if the patient does not follow the protocol the urologist sill remains responsible to a considerable amount. Hence, our 13 y experience raises critical thoughts concerning current AS protocols and underlines the consequence of malcompliance. We strongly believe that malcompliance is a major challenge for AS: This needs to be taken in consideration for future AS protocols an whenever AS is offered as a treatment option.