Long-Term Followup of a Randomized Study of Locally Advanced Prostate Cancer Treated with Combined Orchiectomy and External Radiotherapy versus Radiotherapy Alone

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Purpose: In a randomized study we compared the combination of orchiectomy and radiotherapy to radiotherapy alone as treatment for locally advanced prostate cancer. Patients who were treated only with radiotherapy initially underwent castration therapy at clinical progression, providing the opportunity to compare immediate vs deferred endocrine intervention.

Materials And Methods: In this prospective study 91 patients with locally advanced prostate cancer were randomized to receive external beam radiotherapy (46) or combined orchiectomy and radiotherapy (45) after surgical lymph node staging. Survival rates were calculated.

Results: During 14 to 19 years of followup 87% of the patients in the radiotherapy group and 76% in the combined orchiectomy and radiotherapy group died (log rank $p = 0.03$). Prostate cancer mortality was 57% and 36%, respectively (log rank $p = 0.02$). The difference in favor of combined treatment was mainly caused by lymph node positive tumors. For node negative tumors there was no significant difference in the survival rates.

Conclusions: Immediate androgen deprivation should be considered instead of deferred endocrine treatment started at clinical progression for prostate cancer with spread to regional lymph nodes. While awaiting evidence from randomized trials, one should consider full dose radiotherapy for local control of locally advanced prostate cancer even when it is lymph node positive.

Editorial Comment

This paper gives the long-term results of a simple but well-done trial: immediate or deferred hormone ablative treatment in patients undergoing external beam radiation therapy (ERBT) after surgical lymph node staging.

The answer is clear-cut: immediate hormone ablative therapy is better than deferred therapy with regard to survival. This difference was most predominant in lymph node positive patients. In conclusion, these data and other papers strongly support the use adjuvant endocrine treatment in radiotherapy against prostate cancer.

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NEUROUROLOGY & FEMALE UROLOGY

Transurethral Radiofrequency Energy Collagen Micro-Remodeling For the Treatment of Female Stress Urinary Incontinence

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Aims: This prospective, randomized, controlled clinical trial was performed to demonstrate the 12 months safety and efficacy of transurethral radiofrequency energy (RF) collagen micro-remodeling in women with stress urinary incontinence (SUI).

Materials and Methods: Women with SUI, bladder outlet hypermobility, and leak point pressure (LPP) ≥ 60 cmH₂O were randomized to RF micro-remodeling or “sham treatment.” Adverse events (AEs) were recorded. Incidence of ≥ 10 point incontinence quality of life (I-QOL) score improvement, a magnitude of improvement with a demonstrated responsiveness to patient satisfaction with treatment and to $\geq 25\%$ reduction in both incontinence episode frequency and stress pad weight, served as a subjective outcome measurement. Change in mean LPP served as an objective outcome measurement.

Results: 110 women underwent RF micro-remodeling and 63 underwent virtually identical “sham treatment” (with the exception of RF delivery). The 12 months RF micro-remodeling safety profile was statistically no different than that of sham treatment (a brief bladder catheterization). Seventy-four percent of women with moderate to severe baseline SUI experienced ≥ 10 point I-QOL score improvement at 12 months ($P = 0.04$). Women who underwent RF micro-remodeling demonstrated LPP elevation at 12 months, while sham treated women demonstrated LPP reduction ($P = 0.02$).

Conclusions: Non-surgical, transurethral RF micro-remodeling is a safe treatment for women with SUI. In women with moderate to severe SUI, this novel therapy resulted in statistically significant improvement in quality of life of a magnitude associated with patient satisfaction with the treatment. Women who underwent RF micro-remodeling demonstrated a statistically significant elevation in mean LPP at 12 months.

Editorial Comment

In a well-constructed scientific study, the authors describe and analyze a technique to address female stress urinary incontinence utilizing radiofrequency energy to denature collagen in multiple microscopic sites causing a change in the compliance of the tissue. This anatomic change will theoretically reduce the inappropriate opening of the bladder neck and proximal urethra with stress maneuvers much in the manner of the sub urethral support of a sling. The technique utilizes less energy than that used by radiofrequency tissue ablation for renal masses and/or gynecological conditions. During the study, the authors used the Incontinence Quality of Life questionnaire (I-QOL) to grade the patient’s incontinence (as opposed to pad weight test) as well as urodynamics including leak point pressure determination. These metrics did make it a little challenging to note if any of the patients were absolutely dry post procedure. Nevertheless, treated patients were able to exhibit a statistically significant increase in leak point pressure at the 12-month follow-up period as opposed to those patients who underwent a sham treatment thus indicating a measure of efficacy (1). This study does speak volumes to the effect of placebo therapy for at the 12-month period almost 50% of both treated and sham groups had a ≥ 10 point I-QOL score improvement. The authors do clearly highlight the safety and tolerability of this procedure and denote that radiofrequency micro remodeling clearly responds to the incontinent patients who will settle for improvement as opposed to cure in a trade-off for having a minimally invasive procedure. Similar patient desires with regards to injectable therapy have been noted in this journal (2).

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Vaginal Discharge and Bleeding in Girls Younger than 6 Years

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Purpose: Persistent unexplained vaginal discharge or bleeding in the pediatric population may be the only manifestation of a serious underlying medical or social problem. Therefore, these symptoms require careful and complete evaluation to identify the primary pathology accurately. We retrospectively reviewed charts of patients who presented for evaluation of persistent vaginal discharge or bleeding to determine if noninvasive imaging was a sensitive means of screening for gynecological pathology.

Materials and Methods: The records of 24 girls younger than 6 years who presented with vaginal discharge or bleeding were reviewed retrospectively. All patients were evaluated with noninvasive imaging, a pelvic examination while under anesthesia, vaginotomy and cystoscopy.

Results: Noninvasive imaging was useful in identifying 5 of 7 vaginal foreign bodies. However, noninvasive imaging identified only 2 of 6 malignancies. These malignancies consisted of rhabdomyosarcoma (3 patients) and endodermal sinus tumor (3). Two girls also had benign vaginal mullerian papillomas that were not identified by noninvasive imaging. Noninvasive imaging did not aid in the diagnosis of sexual abuse.

Conclusions: Based on these data, we recommend that all girls younger than 6 years who present with persistent vaginal discharge or bleeding be evaluated with pelvic examination while under anesthesia, to be followed by vaginotomy and cystoscopy if no readily identifiable pathology is found by simple genital examination alone, regardless of the results of noninvasive imaging studies.

Editorial Comment

The authors reviewed the efficacy of non-invasive imaging (including abdominal x-ray, ultrasound, CT scan and MR of the pelvis) in the population of females younger than 6 years old who presented to their clinic with vaginal discharge and bleeding as opposed to a physical examination with potential endoscopy under anesthesia; in addition, notation was made of the diagnoses found after evaluation. The patients had for the most part already been treated with antibiotic therapy prior to presentation to the authors. The study found that approximately half of the patients with vaginal discharge had a vaginal vault foreign body while one-third of the patients had no identifiable cause of the discharge. Of the patients with vaginal bleeding, almost half had a vaginal malignancy while approximately 15% had a foreign body within the vagina. The authors thus highlight the difference of potential diagnosis of vaginal discharge versus vaginal bleeding in this young population. Based on their findings, the presentation of vaginal bleeding in a female younger than 6 years old should engender an evaluation without hesitation under anesthesia since there is a high likelihood of the presence of malignancy.

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