# Finasteride + Flutamide Might Improve Response in Men With Recurrent Prostate Cancer

*Combined Low-Dose Flutamide Plus Finasteride vs Low-Dose Flutamide Monotherapy for Recurrent Prostate Cancer: A Comparative Analysis of Two Phase II Trials With a Long-Term Follow-Up.*

Banez LL, Blake GW, et al:

*BJU Int;* February 23 (epub ahead of print):

In this study, finasteride plus flutamide resulted in better initial PSA response than flutamide alone in men with biochemically recurrent prostate cancer.

**Objective:** To compare finasteride plus flutamide versus flutamide alone in men with biochemically recurrent prostate cancer.

**Design/Methods:** This was a non-randomized phase II study which enrolled 56 men with biochemically recurrent prostate cancer. Men were sequentially assigned to their treatment arm. The first 36 were treated with combination low-dose flutamide plus finasteride while the subsequent 20 were treated with low-dose flutamide alone. Patients were treated for up to 84 months and responses were assessed based on changes in PSA.

**Results:** Men on combined therapy had a greater decrease in PSA with lower nadir PSA levels after correcting for their baseline PSA values. Men on combined therapy were more likely to have a complete response, ie, an undetectable PSA. There was a trend toward better progression-free survival for the combination treatment group on univariate analysis, but this was not statistically significant. Patients on the combination arm had a higher incidence of toxicity, though overall toxicity was mild and manageable.

**Conclusions:** Low-dose flutamide either alone or in combination with finasteride may be an alternative to traditional androgen deprivation therapies in men with biochemically recurrent prostate cancer, and phase III randomized trials of these regimens should be undertaken.

**Reviewer's Comments:** Every urologist has faced the problem of the man who has undergone therapy for his prostate cancer, but now the serum PSA has begun to rise, suggesting biochemical recurrence. The anxiety and stress this provokes in patients and their families can be profound. Often, the choice boils down to treat with androgen deprivation therapy (ADT) or observe. There is growing appreciation that ADT has significant morbidity that gets progressively worse with time, strongly arguing for alternative approaches in these men who are typically asymptomatic with respect to their cancer. Banez et al present a study that purports to show that a solution may be the use of low-dose flutamide with or without the addition of finasteride. Their report, while demonstrating low toxicity and an ability to lower PSA, unfortunately adds relatively little to our understanding of how to treat these men. This is mainly because it was not powered adequately to be called a phase II trial for either of its individual arms, and it was not randomized, making comparison across the 2 arms of this very small trial virtually impossible. Therefore, it would be inappropriate for the reader to conclude from this study that low-dose flutamide, with or without finasteride, is the appropriate routine next step in the management of men with biochemically recurrent prostate cancer. Rather, as the authors themselves point out, it will take a well designed, randomized trial comparing one or both of these strategies to traditional ADT to answer this question.

**Additional Keywords:** Biochemical Recurrence

**print tag:** () Refer to original journal article.

# Intermittent vs Continuous ADT for Advanced Prostate Cancer

*Intermittent Androgen Deprivation for Locally Advanced and Metastatic Prostate Cancer: Results From a Randomised Phase 3 Study of the South European Uroncological Group.*

Calais da Silva FE, Bono AV, et al:

*Eur Urol;* February 21 (epub ahead of print):

In this study, intermittent androgen deprivation was not associated with worse survival or disease progression compared to continuous therapy in men with advanced prostate cancer.

**Objective:** To test whether intermittent androgen deprivation therapy (ADT) is associated with better quality of life without compromising survival or disease progression in advanced prostate cancer.

**Design/Methods:** This was a prospective study of intermittent versus continuous ADT in men with advanced prostate cancer. Overall, 766 men received 3 months of cyproterone acetate (CPA) and luteinizing hormone-releasing hormone (LHRH) analog. The 626 men whose PSA fell <4.0 ng/mL or who achieved an 80% drop from baseline were randomized to continuous versus intermittent therapy. Primary end point was disease progression, while secondary end points included survival, toxicity, and prospective quality of life (QOL) assessments.

**Results:** Compared to continuous therapy, men on intermittent therapy did not have significantly increased risk of developing disease progression or dying. There was increased toxicity in the continuous therapy arm, but only small differences in QOL between the groups except for sexual function, which favored intermittent therapy. A competing risk analysis for the risk of death suggested that there was a trend toward increased prostate cancer deaths in the intermittent therapy group, which was offset by an increase in cardiovascular deaths in the continuous therapy group.

**Conclusions:** Intermittent ADT was not associated with a significant decrease in progression, survival, or QOL and may offer considerable cost benefits and improved sexual function compared to continuous therapy.

**Reviewer's Comments:** There has been an ongoing debate on whether intermittent ADT should be routinely considered as part of the management in men with advanced prostate cancer. Much of this is fueled by the growing appreciation of the substantial costs in terms of toxicity and the economics associated with ADT. The promise of intermittent ADT is to reduce both without compromising cancer therapy. This study joins several others in demonstrating that intermittent therapy is not associated with profound detriments in survival or progression compared to continuous therapy. However, bear in mind that because the trial was first started many years ago, the steroidal anti-androgen chosen, CPA, is one that is inferior to the more frequently utilized non-steroidal anti-androgens. This may explain why there was a trend toward more cardiovascular deaths in the continuous therapy arm in the competing risks analysis. It is possible that, had a non-steroidal anti-androgen been used, the increased cardiovascular deaths may not have been as profound and perhaps the intermittent ADT would have resulted in more deaths. This is purely speculative at this point, but does raise some important issues that need further testing. As a consequence, I agree with the authors' statement in the body of the paper that intermittent ADT is not quite ready to become the standard of care, but it is definitely something worthy of further study.

**Additional Keywords:** Advanced Prostate Cancer

**print tag:** () Refer to original journal article.

# When Going After the Stone, Don't Leave the Others Alone

*Combined Retrograde Flexible Ureteroscopic Lithotripsy With Holmium YAG Laser for Renal Calculi Associated With Ipsilateral Ureteral Stones.*

Cocuzza M, Colombo JR Jr, et al:
*J Endourol;* 23 (February): 253-257

The optimal time to address intrarenal calculi is at the time of ureteroscopic stone extraction of an ipsilateral ureteral calculus.

**Objective:** To evaluate the effectiveness of addressing intrarenal calculi at the time of ureteroscopic treatment of ureteral calculi.

**Design:** Retrospective multi-institutional study.

**Participants:** 63 patients with intrarenal and ureteral calculi treated over a 5-year period were compared to 39 patients with a ureteral calculus treated over the same time period.

**Methods:** Semi-rigid and flexible ureteroscopy was performed with holmium laser lithotripsy as the intracorporeal lithotripsy modality. A ureteral sheath was used in select patients (33%). A ureteral stent was left in place for 2 weeks. Follow-up imaging to define a stone-free result was conducted at 6 weeks with non-contrast computerized tomography.

**Results:** The mean ureteral stone size was 8 mm in both groups, while the mean intrarenal stone size was 11 mm. In total, 60% of the ureteral calculi were present in the distal ureter. Stone-free success rate was 81%, and was similar if the stone was located in the lower pole. Patients with multiple intrarenal calculi were less likely to be rendered stone-free (76%). Treating the intrarenal calculus increased the time of surgery by only 18 minutes. Complication rates were low in both groups (3%), with 1 patient in each group experiencing a minor ureteral perforation. Patients with renal stones <15 mm in size were 13 times more likely to be stone-free than patients with larger stones.

**Conclusions:** Simultaneous ureteroscopic treatment of intrarenal calculi <15 mm and obstructing ureteral calculi is safe and effective.

**Reviewer's Comments:** The authors are to be commended for the high stone-free rates obtained with the stringent criteria based on CT scan imaging. One might consider that it could be difficult to standardize instrumentation and technique across 3 continents and across a 5-year time period. This may impact the interpretation of results, especially if a larger bulk of the flexible ureteroscopies were conducted in the latter portion of the study period when the authors had more experience and better instrumentation. It would be helpful for the authors to define their criteria for using a ureteral access sheath. It is our practice to use it routinely during intrarenal stone extraction to improve stone-free rates and minimize the risk of ureteral injury. The authors importantly define the upper limit of stone size to tackle ureteroscopically as 15 mm. Beyond this size, one must inform patients of the risk of requiring staged ureteroscopies to be rendered stone-free. Another important consideration is that all patients were stented after the surgery. As 60% of these patients had distal ureteral calculi, they could have been offered the alternative of no stent if an intrarenal calculus was not treated at the same setting. Often, patients who have had significant stent discomfort in the past will elect to leave the intrarenal stone untreated so as to avoid the ureteral stent.

**Additional Keywords:** Calculi

**print tag:** () Refer to original journal article.

# Percutaneous Cystolithotripsy Superior to Transurethral Cystolithotripsy at TURP

*Percutaneous versus Transurethral Cystolithotripsy.*

Tugcu V, Polat H, et al:
*J Endourol;* 23 (February): 237-241

If the cumulative bladder stone dimension is >2.5 cm, a percutaneous approach is superior to transurethral in men requiring a simultaneous TURP for benign prostatic hyperplasia.

**Objective:** To compare transurethral cystolithopaxy (Cysto) to percutaneous cystolithopaxy (Perc) for stone extraction at the time of simultaneous transurethral resection of the prostate (TURP).

**Design:** Retrospective chart review.

**Participants:** 63 patients with prostate volumes >40 cc and bladder stones 2.5 cm in aggregate size were evaluated. The percutaneous approach was not attempted in obese patients or in those having prior abdominal surgery.

**Methods:** Pneumatic lithotripsy was performed through a 23F cystoscope in the Cysto group or through a 30F Amplatz sheath in the Perc group. Percutaneous access was obtained by bladder puncture under direct cystoscopic visualization followed by balloon dilation of the tract. TURP was then performed, using continuous flow through the 30F Amplatz sheath in the Perc group. At the end of the procedure, a 22 F 3-way catheter was utilized in the Cysto group, while 2 20F 2-way catheters were used in the Perc group--one as a urethral catheter and the second as a suprapubic catheter.

**Results:** The mean stone size of 5 cm in the Perc group was significantly larger than the mean stone size of 3 cm tackled in the Cysto group. Despite this, operating time for stone removal in the Perc group was shorter at 22 minutes compared to 40 minutes in the Cysto group. In the Cysto group, 8% of patients had residual stones requiring a second surgery and 8% of patients developed a urethral stricture.

**Conclusions:** Combined percutaneous cystolithopaxy and TURP is a safer, more effective, and more efficient approach to patients with larger bladder stones and benign prostatic hyperplasia.

**Reviewer's Comments:** The study is limited in its retrospective nature, but provides important support for the empiric approach utilized by the authors. It is clear that the transurethral approach carries a higher risk of urethral stricture, and this may be related to the duration of instrumentation during stone extraction or it may be related to the size and duration of postoperative catheterization. The authors emphasize the importance of stone extraction prior to TURP, as bleeding from the prostatic fossa may obscure the identification of residual stone. The authors also emphasize the importance of leaving the Amplatz sheath in place during the TURP, as premature removal of this may lead to extraperitoneal extravasation of irrigation fluid. Another advantage of a percutaneous approach not mentioned by the investigators would be the use of an ultrasonic lithotripter through a rigid nephroscope as a more efficient means of stone clearance. Lastly, it is important to note that these recommendations are specific for men; though less common, larger stones in women can be effectively addressed cystoscopically with a rigid nephroscope and ultrasonic lithotripter.

**Additional Keywords:** Benign Prostatic Hyperplasia

**print tag:** () Refer to original journal article.

# Dextranomer Implants May Mimic Ureteral Stones on CT Scan

*Appearance of Dextranomer/Hyaluronic Acid Copolymer Implants on Computerized Tomography After Endoscopic Treatment of Vesicoureteral Reflux.*

Cerwinka WH, Qian J, et al:

*J Urol;* 181 (March): 1324-1329

Dextranomer implants may appear as ureteral stones on CT, but unlike ureterolithiasis, they are rarely associated with hydronephrosis or isolated microscopic hematuria.

**Objective:** To describe the long-term appearance of dextranomer/hyaluronic acid copolymer (DHA) implants on computerized tomography (CT).

**Design/Methods:** A retrospective review was performed identifying patients who had undergone DHA injection for vesicoureteral reflux (VUR) and had subsequently had a CT scan for other reasons. Findings were compared to a cohort of 30 patients with ureterovesical junction (UVJ) stones, but no history of VUR or DHA injection.

**Results:** 33 implants were detected in 17 patients by CT scan. Twenty-one were low density (LD=median 22 HU) and 12 were high density (HD=median 193 HU). Age, grade of reflux, and volume of DHA injected did not correlate with density of the implant on CT. Only elapsed time between surgery and CT was associated with increasing implant density (mean time from surgery was 18 months for LD and 31 for HD). Two of 10 with urinalysis assessment tested positive for infection (blood, leukocytes, and nitrites), but none had isolated microscopic hematuria. Patients with UVJ stones had additional stones in 24%, hydronephrosis in 80%, and isolated microscopic hematuria in 95%.

**Conclusions:** DHA implants may resemble UVJ stones on CT scan. DHA implants are associated with a history of DHA injection, and absence of microscopic hematuria and hydronephrosis, differentiating them from ureterolithiasis.

**Reviewer's Comments:** This paper is extremely important for practicing urologists. Although most pediatric urologists have experienced this diagnostic dilemma, our adult counterparts have not. As these patients age, that will change. The most concerning issue is that DHA explants have been shown to have microcalcifications. Although no report of mucosal erosion and stone formation has been reported after DHA injection, our experience with this substance is really in its infancy. The idea that the density of the implant increases over time certainly looms in the distance as a potential problem. As with any new technology, long-term follow-up is imperative.

**Additional Keywords:** Appearance on CT

**print tag:** () Refer to original journal article.

# High Incidence of Late Effects of Pediatric Cancer Tx Warrants LTFU Care

*Long-Term Follow-Up Care for Pediatric Cancer Survivors.*

American Academy of Pediatrics Section on Hematology/Oncology, Children's Oncology Group:
*Pediatrics;* 123 (March): 906-915

Resources for the long-term follow-up care of survivors of pediatric cancers are readily available at www.survivorshipguidelines.org.

**Objective:** To present guidelines developed by the Children's Oncology Group (COG) for the primary care provider for high-quality, long-term follow-up (LTFU) care and supervision for survivors of pediatric malignancies.

**Methods:** The COG, a cooperative trials group supported by the National Cancer Institute, has >200 member institutions. Beginning in 2002, a multidisciplinary panel was formed which collected evidence for development of COG LTFU guidelines by conducting a complete search of the medical literature of the previous 20 years using Medline. A panel of experts created and revised the guidelines using a hybrid of evidence-based and consensus-driven approaches. The guidelines are designed for use in asymptomatic survivors presenting for routine health maintenance at least 2 years after completion of their therapy. They are not designed for disease-related surveillance.

**Results:** Several tools were developed, including tables incorporating organ system, chemotherapeutic agent, radiation therapy field, and surgery with potential late outcomes. The authors provide online resources to tailor care for survivors of pediatric malignancies at www.survivorshipguidelines.org.

**Conclusions:** Given the high incidence of late effects of cancer therapy, long-term follow-up care from knowledgeable providers is essential. These resources are readily available in the form of the COG-LTFU guidelines.

**Reviewer's Comments:** This article was included to remind urologists that our treatment of pediatric urologic tumors is only the beginning of the story. Survival in pediatric tumors is a contemporary phenomenon, as only 40 years ago almost all children died of their primary disease. Multimodal therapy and aggressive supportive care regimens have resulted in an overall cancer survival rate of around 80%. As a result, the long-term sequela of therapy is inevitable. With 2 of every 3 survivors developing at least 1 late therapy-related complication, and 1 of every 4 cases being severe or life threatening, it is important to recognize the long-term effects of primary urologic treatments and also the effects of other treatments on the urinary tract.

**Additional Keywords:** Follow-Up Guidelines

**print tag:** () Refer to original journal article.

# TVT-O Is Safe, Effective for Tx of Urinary Incontinence

*The TVT-Obturator Surgical Procedure for the Treatment of Female Stress Urinary Incontinence: A Clinical Update.*

Waltregny D, de Leval J:

*Int Urogynecol J Pelvic Floor Dysfunct;* 20 (March): 337-348

The TVT-O procedure has been shown to be safe and effective and is comparable in many patients to the standard retropubic approaches of mid-urethral sling placement.

**Objective:** To review current experience with the transvaginal tape obturator (TVT-O) approach for the management of urinary incontinence in women.

**Design/Methods:** This was a literature review with an analytic summary of experience with the TVT-O procedure since its inception, evaluating both initial feasibility and efficacy studies, as well as longer term studies and also to compare TVT-O to retropubically placed mid-urethral tapes.

**Results:** This is an extensive review of current experience with the TVT-O procedure to this point. Early feasibility and efficacy demonstrated that the TVT-O procedure was a safe and reasonably effective procedure. Both short- and intermediate-term results revealed that the procedure resulted in efficacy similar to other mid-urethral tapes in general populations. Three-year follow-up studies revealed that the majority of patients (>95%) had disappearance or improvement of stress incontinence using older follow-up criteria. This again was considered to be comparable to results of pain with retropubic approaches. Results were apparently persistent and stable from 1 to 3 years in these homogenous populations. To date, 10 randomized trials, 2 national registries, and multiple case reports exist, although much less than reported with retro-pubic approaches. There was a very small incidence of intraoperative and/or bladder injury noted in these trials. Overall incidence was 0.04% of bladder injury, 0.02% of urethral injuries, and 0.6% vaginal injuries. Specifically, no bladder or ureteral injury has been identified. Two cases of nerve complications have been associated with the TVT-O. Overall incidence of hematoma or bleeding is assessed at 0.26%. Rare cases of vesicovaginal fistula have been reported. Additionally, persistent chronic pain and discomfort have been reported in small numbers of women undergoing these procedures.

**Conclusions:** The authors concluded that the TVT-O procedure is safe and effective for the treatment of urinary incontinence, both in the short- and medium-term and that longer term data are needed.

**Reviewer's Comments:** TVT-O is a safe and effective procedure in multiple trials with short- and intermediate-term effectiveness. Long-term studies are needed.

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## Is Mechanism of Action of PDE-5 Different Than alpha -Blocker Tx for LUTS?

*Is There a Rationale for the Chronic Use of Phosphodiesterase-5 Inhibitors for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia?*

Roumegure T, Zouaoui Boudjeltia K, et al:

*BJU Int;* February 23 (epub ahead of print):

PDE-5 inhibitors affect LUTS related to BPH on multiple levels. The affect is greater on storage than on voiding symptoms.

**Objective:** To assess and analyze the role of phosphodiesterase-5 (PDE-5) inhibitors in the management of lower urinary tract symptoms (LUTS) typically attributed to benign prostatic hyperplasia (BPH) with or without erectile dysfunction (ED).

**Design/Methods:** This was meta-analysis review of 18 years of articles pertaining to the use of PDE-5 in men with LUTS attributable to BPH. The papers were selected based upon their subject matter and were analyzed based upon incorporated clinical data. Only data pertaining to humans were included in this analysis. Additionally, only the data pertaining to treatment of LUTS secondary to BPH were included in this analysis.

**Results:** Several modes of action have been identified and specified in the literature, including the role of PDE-5 inhibitors and nitric oxide/cGMP signaling, which may have a role in prostate tone. There may also be an addition of PDE-5 inhibitors in the regulation of inflammatory processes that may be contributory to BPH. Also, this class may affect, in a downward fashion, human stromal cell proliferation in the prostate via cGMP activity. Several randomized controlled trials have been identified that have assessed the effect of these agents on symptoms as well as flow rates and quality of life. All 3 generally available agents of this class have been compared to placebo from 6 to 12 weeks of trial duration. All 3 randomized controlled trials against placebo did demonstrate a significant effect on LUTS with magnitude of effect similar to what has been previously noted with alpha -blocker therapy for this condition. Studies comparing PDE-5 to alpha blockers directly, however, are not available. Study results imply a greater effect on storage symptoms than on voiding symptoms.

**Conclusions:** Several modes of action of PDE-5 therapy putatively exist. Large-scale studies are needed to compare this class to alpha -blocker therapy in order to understand the role of these agents in treatment of LUTS. The mechanism of action of these agents is possibly different than alpha -blocker therapy.

**Reviewer's Comments:** PDE-5 therapy shows effectiveness in lower urinary tract symptoms across trials and has several potential modes of action, with greater effect on storage.

**Additional Keywords:** LUTS

**print tag:** () Refer to original journal article.

# Pain From Injection Tx for Erectile Dysfunction Is Modest

*Patient-Reported Pain With Initial Intracavernosal Injection.*

Albaugh J, Ferrans CE:

*J Sex Med;* 6 (February): 513-519

In this study, there was a surprisingly high percentage of men who felt no pain with needle insertion or from the medication itself.

**Background:** Intracavernous injections are the most efficacious medical treatment option for erectile dysfunction (ED). Despite the efficacy, one large impediment is the negative reaction of men to the thought of a needle inserted into the penis. Pain from the injection can occur related to needle insertion or from the medication itself.

**Objective:** To determine the severity of pain associated with intracavernosal injections for ED. Both the pain associated with needle insertion and the medication were studied.

**Design/Methods:** This was a prospective study utilizing self-reported pain measures using a verbal 0 to 10 rating scale immediately after needle insertion and again after the medication began to take effect.

**Results:** 65 men (mean age, 60.9 years) participated. In total, 51 of 65 used monotherapy with prostaglandin, while the balance used either trimix or bimix. Of 65 patients, 40% reported no pain at all with the needle insertion. The mean pain rating was 0.80 out of a 10.0 scale. Of those patients who reported any pain, the mean pain rating was 1.3. Regarding pain from the medication itself, the mean rating was slightly elevated at 0.92. More than half of the patients did not report any pain from the medication. Of those who did experience pain, the mean pain rating was 2.6. A significantly larger proportion of post-radical prostatectomy (RP) men experienced pain from the medication (51.9 vs 23.7; $P$ =0.02) compared to those who had not had RP; pain was experienced by these men regardless of time since RP, ranging anywhere from 8 weeks to 33 months postoperatively, suggesting that this does not diminish with time.

**Conclusions:** There was a surprisingly high percentage of men who felt no pain with the needle insertion. In terms of medication pain, men with a history of RP reported the side effect of pain with the use of prostaglandin more often than men who had not undergone RP. This study provides evidence that, although patients may be nervous about the first injection, the majority of these men do not experience pain.

**Reviewer's Comments:** Although based on a convenience sample, this prospective study is unique in showing that participants experience little or no pain with needle insertion or from the injected medication itself. Knowing that the injections are not associated with significant pain can remove a crucial barrier to utilizing this option. This study also suggests that medication pain is more common in men post-radical prostatectomy, and thus, it might be advisable to start these men with lower doses of prostaglandin.

**Additional Keywords:** Patient-Reported Pain

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# RRP in Patients With IPP Safe, With Satisfactory Outcomes

*Anatomical Radical Retropubic Prostatectomy in Patients With a Preexisting Three-Piece Inflatable Prosthesis: A Series of Case Reports.*

Deho' F, Salonia A, et al:

*J Sex Med;* 6 (February): 578-583

In patients with an IPP, RRP can be performed safely without injuring the implant and the clinical outcome is satisfactory.

**Objective:** To evaluate the feasibility and safety of radical retropubic prostatectomy (RRP) patients who had previously undergone the placement of an inflatable penile prosthesis (IPP).

**Design/Methods:** In this series, 1580 consecutive patients underwent an open RRP. Of these, 12 had undergone a previous malleable prosthesis and 4 had had placement of an IPP. The latter 4 were evaluated for this retrospective chart review. Patients were treated systematically with preoperative vancomycin and gentamicin and urethral catheter placement. At the start of the procedure, the IPP was fully activated to reduce the volume of the reservoir that had previously been placed in the left retzius space in all cases. These procedures were performed through a midline incision. If exposed, the reservoir was coated in a Betadine-soaked sponge and displaced from the operative field and then replaced at the end. In no case was the reservoir disconnected or removed. Catheters were left in for 7 days and the day prior to removal, patients were given prophylactic quinolone antibiotics.

**Results:** The mean patient age was 66 years and a mean BMI of 25.2 1.8. All patients had an AMS 700 CX IPP using a 65 cc reservoir. All patients were able to use their prosthesis following the RRP and there was no evidence of change in function based on IIEF scores or other mechanical issues.

**Conclusions:** 4 proposed options exist in the surgical treatment for prostate cancer in men with penile prosthesis: (1) removing the reservoir during the procedure and replacing at another time; (2) relocating reservoir without opening it/breaking the sealed system; (3) performing a perineal prostatectomy instead; and (4) operating around the reservoir. In this study, the latter was chosen. By these authors experience, opening the pseudo capsule around the reservoir is a safe procedure and does not increase the risk of infection. Other authors reported a 50% infection rate if the reservoir was left in place.

**Reviewer's Comments:** Anatomic radical prostatectomy (open and perhaps robotic) can be performed safely in the presence of an existing IPP. Continence and surgical margins are unchanged and the device can be fully functional postoperatively with a low risk of infection.

**Additional Keywords:** IPP

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# Cheap Flaxseed Powder Seems to Improve Prostate, Overall Health

*Flaxseed Supplementation (Not Dietary Fat Restriction) Reduces Prostate Cancer Proliferation Rates in Men Presurgery.*

Demark-Wahnefried W, Polascik TJ, et al:

*Cancer Epidemiol Biomarkers Prev;* 17 (December): 3577-3587

Three tablespoons of flaxseed powder per day should be recommended before a radical prostatectomy.

**Background:** Flaxseed (linseed) is a popular alternative remedy to reduce cholesterol and hot flashes and to improve overall health. However, its impact on prostate cancer has been controversial, because over a decade ago, some laboratory studies and researchers suggested it may be harmful and encouraged tumor growth despite some positive benefits in men with and without benign prostatic hyperplasia (BPH).

**Objective:** To determine the impact of flaxseed powder and/or a low-fat diet on prostate tissue and other parameters before and after radical prostatectomy.

**Design/Methods:** 161 prostate cancer patients at least 21 days before surgery were randomized to 1 of 4 groups: control (regular) diet, flaxseed (30 grams/day), low-fat diet (<20% total energy), or flaxseed and low-fat diet. Postsurgical specimens were analyzed for Ki-67 (a proliferative biomarker) and apoptosis before (biopsy) and after surgery. The mean time on protocol was 30 days.

**Results:** Proliferation rates were significantly ($P$ <0.002) reduced among men in the flaxseed groups compared to low-fat alone or control. Men on a low-fat diet experienced a significant ($P$ =0.05) reduction in total cholesterol. No other differences were observed between groups.

**Conclusions:** Flaxseed is safe and may provide molecular changes that may ultimately discourage prostate cancer growth.

**Reviewer's Comments:** Few randomized trials in prostate cancer have made me happier than this one! I got so tired of hearing from the radical lifestyle crowd that flaxseed was dangerous for the prostate because some fly by night "experts" or animal or test tube study suggested harm. Flaxseed has a history of being completely heart healthy by reducing cholesterol and perhaps weight and it is a wonderful source of fiber and lignans, which have been shown to reduce hot flashes. However, its best feature is that any patient can afford it because it is so dirt cheap. Gee, I wonder why you do not see any flaxseed powder commercials on TV or pushed by the fly be night "experts" that love to push expensive dietary supplements?! Also, keep in mind that this is one of the largest and well-conducted randomized trials before prostate cancer surgery, so it seems that surgeons have a new recommendation to add to their preop instructions.

**Additional Keywords:** Prostate Tissue

**print tag:** () Refer to original journal article.

# Calcium Supplements May Work Just as Well in Men as in Women

*Randomized Controlled Trial of Calcium Supplementation in Healthy, Nonosteoporotic, Older Men.*

Reid IR, Ames R, et al:

*Arch Intern Med;* 168 (November 10): 2276-2282

Calcium supplements are mostly safe and effective for men who really and truly need them.

**Background:** Calcium supplementation for older women, with and without osteoporosis, and for those taking bisphosphonates has established research. Less known is the clinical impact of calcium supplementation for older men.

**Objective:** To determine the impact of calcium supplementation on bone mineral density (BMD) in older healthy men.

**Design:** Randomized, double-blind placebo-controlled trial.

**Participants/Methods:** A total of 323 healthy men aged 40 years (mean, 57 years) were randomized to 600 mg/day or 1200 mg/day of calcium citrate supplements and were to men receiving placebo over a 2-year period. Men had normal vitamin D blood levels (38 ng/mL), had a low body mass index (26), and <7% were smokers.

**Results:** BMD increased at all anatomic sites measured in the 1200-mg/day group compared to placebo, by a range of 1.0% to 1.5% in lumbar spine, total hip, and overall BMD. The group receiving 600 mg/day of calcium experienced similar results to those of placebo. Age and calcium intake from dietary sources did not influence the results. Dose-related and significant reductions in parathyroid hormone (25%; $P$ <0.001), total alkaline phosphatase (8%; $P$ =0.01), and procollagen type 1 N-terminal propeptide ($P$ <0.001) occurred only in the high-dose calcium group. No difference in constipation, cramps, kidney stones, or tooth loss occurred between groups. A slightly higher rate (3 more cases) of coronary revascularization procedures occurred in the 1200-mg/day calcium group, which was significant ($P$ =0.05), but a significantly lower rate of falls also occurred in this group ($P$ =0.05).

**Conclusions:** Calcium supplementation at 1200 mg/day in healthy, older non-osteoporotic men has similar effects and safety to those observed in postmenopausal women, but 600 mg/day of calcium is ineffective in men.

**Reviewer's Comments:** Are we making a mistake by telling older men that good preventive health recommendations involve behaviors different from those of women? I believe we are, and I believe this is a mistake in many cases. For example, a generation of women has been raised on the importance of calcium and vitamin D supplementation for enhanced bone health and a variety of other benefits. However, it seems that calcium supplementation in men, especially those with osteopenia or osteoporosis, may be just as important for a variety of benefits from maintaining BMD, reducing calcium oxalate stones, reducing colon polyps, and perhaps even reducing prostate-specific antigen level. More data are needed, however, on the long-term impact of calcium supplementation on cardiac health.

**print tag:** () Refer to original journal article.

# Positive Lymph Node Density Predicts Survival After Cystectomy

*Cancer-Specific Survival After Radical Cystectomy and Standardized Extended Lymphadenectomy for Node-Positive Bladder Cancer: Prediction by Lymph Node Positivity and Density.*

Wiesner C, Salzer A, et al:

*BJU Int;* February 11 (epub ahead of print):

Positive lymph node density is an independent predictor of survival in patients undergoing radical cystectomy with curative intent.

**Objective:** To determine potential variables related to lymphadenectomy that may predict survival in patients undergoing cystectomy.

**Participants:** 152 patients were retrospectively analyzed who had undergone a radical cystectomy and extended lymph node dissection to the level of the inferior mesenteric artery (IMA) from 2001 to 2006.

**Methods:** Variables related to the number, location, and density of positive lymph nodes was analyzed for association with survival. Careful mapping of the location of resected lymph node packets was routinely undertaken.

**Results:** 46 patients (30%) had positive lymph nodes, with median of 33 nodes removed. The median number of positive nodes was 3, and the majority of these were found below the level of the aortic bifurcation. Of variables examined related to location, number, and density of nodes removed and positive for cancer, only positive lymph node density was an independent predictor of cancer-specific survival.

**Conclusions:** Positive lymph node density was an independent predictor of cancer-specific survival after radical cystectomy. There were only a small number of positive nodes found above the level of the aortic bifurcation.

**Reviewer's Comments:** It is well established that patients who undergo a radical cystectomy for advanced urothelial carcinoma should undergo a bilateral regional lymphadenectomy. It is also well known that the extent of this dissection exceeds the bounds typically used for patients with prostate cancer. Growing evidence within the last several years has reinforced the importance of a properly done lymphadenectomy, with the demonstration across several studies that parameters such as the number of lymph nodes removed and the lymph node density are associated with better patient outcomes. What remains unknown is just how much of a dissection should be done. Virtually all agree that nodes around the external and internal iliac vessels and obturator fossa laterally to the genitofemoral nerve should be removed. The question has been, how much more should be done? Some advocate also taking the nodes along the common iliac vessels; some will also take the presacral nodes; and others, such as these authors, take nodes up to the IMA. This study concludes that lymph node density is the best lymph node-based parameter to predict outcome since it's the only lymph node-based variable that was an independent predictor of cancer-specific survival. They also conclude that since there were few positive nodes between the bifurcation of the aorta and the IMA that perhaps this area could be omitted. The reader should be cautioned, however, that 3 patients had positive nodes solely in this area that would have been missed. That may not seem like a lot, unless you happen to be those 3 patients.

**Additional Keywords:** Lymph Node Density

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# Male Factor Infertility Associated With Testicular Cancer Risk

*Increased Risk of Testicular Germ Cell Cancer Among Infertile Men.*

Walsh TJ, Croughan MS, et al:

*Arch Intern Med;* 169 (February 23): 351-356

Male factor infertility is associated with a 3-fold increased risk of developing testicular cancer.

**Objective:** To explore the association between testicular cancer risk and infertility in a U.S.-based cohort of men.

**Participants:** 51,461 couples who were evaluated for infertility at 15 centers from 1967 to 1998 in California were recruited; 22,562 men could be linked to data in the California Cancer Registry.

**Methods:** The incidence of testicular cancer was compared to that in the general population using an age-matched sample that was taken from the Surveillance, Epidemiology and End Results (SEER) program.

**Results:** There were 34 histologically confirmed cases of testicular cancer among the men evaluated for infertility. Overall, the risk of testicular cancer was 30% higher in these men than in the age-matched general population (not statistically significant) However, in men who specifically had male factor infertility, on multivariate analysis, there was an almost 3-fold (statistically significant) increased risk of subsequently developing testicular cancer over the general population.

**Conclusions:** Men with male factor infertility have a 3-fold increased risk of developing testicular cancer.

**Reviewer's Comments:** For some time now, it has been recognized that there is a gradual increase in the incidence of testicular cancer in industrialized countries, particularly in Scandinavia as well as the United States. There has also been an increase in the number of couples seeking evaluations for infertility. Several authors have examined whether these trends are related in some way. Studies out of Scandinavia, especially Denmark, have suggested that indeed, infertility leads to an increased risk of testicular cancer. This study is the first to ask the same question at the population level in the United States. The results are intriguing, indicating that male factor infertility specifically is associated with a 3-fold increased risk for subsequently developing testicular cancer. Even though the absolute risk is still very small, only 0.3% in the male factor infertility men compared to 0.1% for non-male factor infertility men, it still represents a profound association. This now raises a host of interesting biologic questions about what may underlie this association. Could it be that the same thing that has been driving up the rates of infertility and testicular cancer is also the link between the two? The trend seems to imply an environmental exposure of some sort, but what exactly that could be remains unknown. Overall, this is a very interesting study that will hopefully stimulate further research.

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# Non-Contrast CT Scan -- A Functional Study?

*Renal Parenchyma Thickness: A Rapid Estimation of Renal Function on Computed Tomography.*

Kaplon DM, Lasser MS, et al:

*Int Braz J Urol;* 35 (January-February): 3-8

Measuring the renal thickness on CT scan and comparing to the contralateral side can give a predictive measure of differential renal function.

**Objective:** To evaluate the relationship between renal parenchymal thickness (RPT) on CT scan and renal function on nuclear renography in chronically obstructed kidneys.

**Design:** Retrospective chart review.

**Participants:** 28 patients with chronic unilateral obstruction who had undergone CT scan and Mag-3 lasix renography within 6 months of each other. Patients with bilateral hydronephrosis, solitary kidneys, or medical renal disease were excluded.

**Methods:** RPT was measured perpendicular to the renal axis at the renal hilum and 1 cm above and below the renal hilum, and the average was determined. The ratio of the obstructed-to-non-obstructed RPT was calculated and compared to the renal scan.

**Results:** The RPT ratio correlated closely with split renal function on renography. A linear equation was computed as Renal Function = 0.48 + 0.80 * RPT ratio. A thickness ratio of 0.68 correlated with a renal function of 20%.

**Conclusions:** RPT is an accurate and readily available predictor of percent function.

**Reviewer's Comments:** The authors included patients who had undergone imaging with CT scan and nuclear renography within 6 months of each other. It is feasible that renal function may have worsened during this duration (in the face of ongoing obstruction) or may have improved (with interval alleviation of obstruction). Indeed, no information is given as to whether patients underwent diversion during the study. It would be of benefit to evaluate a renal scan before and after stenting as this may impact the derived formula to predict renal function based on RPT. It would be helpful to determine the relationship between RPT and nuclear renography in non-obstructed kidneys. If 3 measurements are good, would 5 measurements be better? Especially if the patient suffered from areas of focal segmental renal atrophy? If patients with medical renal disease were excluded from this study, do the authors suggest that this technique be avoided in such patients? Only 3 patients in this study group had renal function <20%. Indeed, further study is warranted.

**Additional Keywords:** CT

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# Obesity Does Has No Impact on Success Rates With Ureteroscopic Stone Tx

*Impact of Obesity on Ureteroscopic Laser Lithotripsy of Urinary Tract Calculi.*

Natalin R, Xavier K, et al:

*Int Braz J Urol;* 35 (January-February): 36-42

Stone-free rates for ureteroscopic stone extraction in the obese and overweight population approaches 94%.

**Background:** Previous studies have reported that the risk of failure of extracorporeal shockwave lithotripsy failure (ESWL) is 2 times higher in obese patients. The focal point of the lithotripter (12 to 14 cm) may limit the maximum skin-to-stone distance where effective stone fragmentation is obtained. Percutaneous nephrolithotomy may be challenging due to the increased distance traversed to obtain calyceal access, and prolonged surgery in a prone position may be of added risk in the obese patient. As such, alternative endoscopic approaches to stone disease in the obese patient are needed.

**Objective:** To compare outcomes with ureteroscopic stone management in obese, overweight, and non-obese patients.

**Design:** Retrospective chart review.

**Participants/Methods:** 107 patients underwent semirigid or flexible ureteroscopy using contemporary instrumentation and techniques. Patients were categorized as non-obese (body mass index [BMI] <25), overweight (BMI 25 to 30), or obese (BMI >30). Stone-free rate was defined by plain radiography as <2-mm residual fragments.

**Results:** More normal-weight patients were women (74%), while more obese patients were men (62%). Average stone size treated was 8 to 9 mm. The stone-free rate for patients with distal ureteral stones was 100%. The stone-free rate for patients with renal and proximal ureteral stones was 94% in patients who were overweight or obese. The operative time was comparable at 70 to 90 minutes across groups.

**Conclusions:** Ureteroscopy is safe and effective in the obese patient with a stone <2 cm in size.

**Reviewer's Comments:** The authors use a fairly liberal definition of stone-free rate: 2-mm fragments on KUB. One would anticipate that the sensitivity of KUB in the obese patient would be lower than that in a non-obese patient, and as such, the primary outcome may be overestimated in this group of patients. It is important to note that this study addressed patients primarily suited for ESWL, with mean stone sizes <1 cm. Future studies should focus on the decision between ureteroscopy and percutaneous nephrolithotomy in the morbidly obese.

**Additional Keywords:** Ureteroscopy

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# Fewer UTIs When Screening Antenatal Hydronephrosis for Reflux

*Vesicoureteral Reflux and Urinary Tract Infection in Children With a History of Prenatal Hydronephrosis-Should Voiding Cystourethrography Be Performed in Cases of Postnatally Persistent Grade II Hydronephrosis?*

Estrada CR, Peters CA, et al:

*J Urol;* 181 (February): 801-807

Fewer urinary tract infections are seen after screening for vesicoureteral reflux in the setting of antenatal hydronephrosis, but at the expense of antibiotic suppression and many negative cystograms.

**Objective:** To determine the risk of febrile urinary tract infection (UTI) in the absence of screening for vesicoureteral reflux (VUR) in children with a history of antenatal hydronephrosis (AH), which is persistent Society for Fetal Urology (SFU) grade 2 hydronephrosis (H) postnatally.

**Participants/Methods:** A longitudinal single-institution database review was performed from 1998 to 2008 identifying all patients with grade 2 H after history of AH. The group was segregated into those with initial screening voiding cystourethrogram (VCUG) and those who were not screened.

**Results:** 1514 patients met criteria for having persistent postnatal grade 2 H. Of these, 76% underwent screening VCUG, with VUR found in 28%. UTI developed in 1.3% of patients screened but found not to have VUR. Of screened patients with VUR (all on antibiotic suppression), 1.6% developed UTI. Projecting this same distribution, of 363 patients who were not screened with VCUG, 101 would be estimated to have reflux, and 5 to have a UTI. In actuality in the non-screened group, 16 patients (4.4%) developed a febrile UTI. VCUG performed in these patients revealed VUR in 12.

**Conclusions:** Patients with AH and persistent postnatal SFU grade 2 H identified to have VUR and treated with antibiotic suppression have a significantly reduced risk of febrile UTI. Patients with this history should be screened with VCUG early in life.

**Reviewer's Comments:** This study represents a large collection of children with AH persistent as grade 2 postnatally. The authors show an increased incidence of febrile UTI in the unscreened group. The argument for screening, however, is really a matter of perspective. The authors could theoretically have prevented 12 UTIs by performing 363 more VCUGs and placing 101 more children on antibiotic suppression. There is no measure of the effect of these UTIs with regard to renal scarring or function. This seems like a tremendous drain on resources and a large family burden for such little gain. This article may fuel enthusiasm for the top-down approach, with the initial assessment being a renal scan to identify those at risk for scarring. This would then direct who would benefit most from screening VCUG and antibiotic suppression.

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# Circumcision in the Setting of PUV Lowers Risk for UTI

*What Is the Effect of Circumcision on Risk of Urinary Tract Infection in Boys With Posterior Urethral Valves?*

Mukherjee S, Joshi A, et al:

*J Pediatr Surg;* 44 (February): 417-421

Circumcision is associated with a lower incidence of urinary tract infection in boys with posterior urethral valves.

**Background:** Circumcision has been shown to reduce the incidence of urinary tract infections (UTIs) in infant boys. It is not the routine of the authors to circumcise boys with posterior urethral valves (PUVs), but some do undergo the procedure for cultural or cosmetic reasons.

**Objective:** To review the authors' experience with children with PUV with or without circumcision.

**Design/Participants:** Retrospective review of boys with PUVs.

**Methods:** Parameters considered were age, diagnostic and treatment method, timing of treatment or urinary diversion, circumcision, and UTI.

**Results:** 78 boys were identified, with a mean age of 6.7 years. A total of 89 culture-positive UTIs were noted in 45 patients within this group; 27 then underwent circumcision, with 8 subsequent UTIs. The incidence of circumcision was reduced from 0.5 UTIs annually in uncircumcised boys to 0.09 in circumcised boys ($P$ <0.01), which represents an approximate 90% decrease in risk of UTI. The number-needed-to-treat calculation translates to each circumcision preventing at least 1 UTI. Median age at valve ablation was 18 days, and median age at circumcision was 5 months. Half the UTIs occurred before age 5 months.

**Conclusions:** Circumcision is associated with a lower incidence of UTIs in boys with PUV when compared to those who are uncircumcised.

**Reviewer's Comments:** This study is interesting in that it looks at a specific population at risk for UTI and assesses the effect of circumcision on that risk. The study is a retrospective cohort study and is limited as such. The boys were circumcised at variable ages, and the likelihood of UTI decreases with age, so comparing UTI before and after circumcision is problematic. There may have been a drop-off even without circumcision. Also, a high incidence of reflux is seen with PUV, and no mention of antibiotic prophylaxis was made. This is another potential confounder. The clinical question is certainly a good one but may be better answered in a randomized controlled fashion. In the U.S., this will likely not occur since nearly all of these children are circumcised at the time of valve ablation.

**Additional Keywords:** Urinary Tract Infection

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# Urethral Ligation Can Be Beneficial for Outlet-Related Incontinence Control

*Bulbar Urethral Ligation for Managing Persistent Urinary Incontinence in Young Men With Myelomeningocele.*

Meeks JJ, Hagerty JA, Chaviano AH:

*BJU Int;* February 24 (epub ahead of print):

In men with myelomeningocele, urethral ligation provides a viable option for management of sphincteric dysfunction, assuming that bladder storage and drainage are optimized by extraurethral means.

**Objective:** To assess a single institution's experience with bulbar urethral ligation for treating refractory urinary incontinence due to sphincteric dysfunction in young men with neuropathic bladder related to myelomeningocele. All patients had had prior interventions for sphincteric dysfunction that had failed.

**Design/Methods:** Retrospective review of men who had undergone prior combined medical and surgical therapy for sphincteric dysfunction that had failed and who had significant perineal excoriation as well as other local issues related to urinary incontinence that necessitated further therapy for management of their incontinence.

**Results:** The authors identified 4 men aged 18 through 20 years with significant local perineal excoriation who had failed progressive therapy and presented for ligation. Therapy included an augmentation cystoplasty in all men with associated functioning catheterizable stomas of different types. Additionally, 3 had undergone prior fascial sling procedures and/or urethral bulking. All men had persistent incontinence, which was a significant problem for them. All 4 underwent bulbar urethral ligation via the perineal approach at least 1 year post-augmentation. Ligation was performed via circumferential dissection and formal division of the urethra, with the proximal end of the urethra being oversewn with 3.0 polyglactin in 3 running layers. Results were satisfactory in all patients, with attainment of continence with this mechanism. Mean follow-up was 49 months. No perineal wound complications developed, and no breakdowns resulting in fistula formation were noted.

**Conclusions:** Ligation of the urethra may present an effective alternative for management of sphincteric dysfunction in young men who have had failed prior interventions. This includes those who have undergone prior outlet procedures. Results are contingent upon adequate urinary storage capabilities as produced by augmentation with catheterizable stoma.

**Reviewer's Comments:** Urethral ligation is a reasonable option for young men with sphincteric dysfunction related to myelomeningocele given that bladder storage parameters are optimized.

**Additional Keywords:** Bulbar Urethral Ligation

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# Obturator Pain Can Be Debilitating Component of Post TVT-O Approach

*Persistent Groin Pain Following a Trans-Obturator Sling Procedure for Stress Urinary Incontinence: A Diagnostic and Therapeutic Challenge.*

Hazewinkel MH, Hinoul P, Roovers J-P:

*Int Urogynecol J Pelvic Floor Dysfunct;* 20 (March): 363-365

Inguinal and medial thigh pain following the tension-free vaginal tape-obturator procedure should be recognized and treated initially medically but with only a short effort at control prior to surgical removal if pain is significant.

**Objective:** To assess and review a case of groin pain after placement of a midurethral tape via the tension-free vaginal tape-obturator (TVT-O) approach.

**Design:** Case report assessing nerve complications with tape.

**Results:** The authors review 2 cases of significant groin and inguinal discomfort after placement of a TVT-O procedure. Despite extensive investigation, the cause of the pain was not identified. Both patients experienced inguinal and medial thigh pain consistent with obturator distribution pain. Despite intensive medical therapy, surgical removal was necessitated. Pain was partially improved after tape resection, which was performed via the vaginal approach with an "attempt" to remove as much tape as possible on the side involved with the pain. However, sensory loss and partial persistence pain persisted in both patients >12 months post-procedure. The authors specifically note that no leg incisions were made to remove any aspect of the tape that may have been actually in the obturator foramen or distally in the leg.

**Conclusions:** Obturator pain can be initiated and insighted by TVT-O slings. Based on their experience, the authors conclude that early removal is necessary if this occurs and fails after a short period of medical therapy.

**Reviewer's Comments:** Inguinal and groin pain remains a significant problem in the management of patients undergoing mesh implantation surgeries. The overall incidence of this complication is uncertain but clearly is problematic, especially in those individuals who experience it. Most large-scale studies reveal an incidence of much less than 1%, but this should be a component of the informed consent regarding the implantation of these particular devices. This pain clearly can occur not only with sling-type procedures, but also with prolapse repairs, and anterior and posterior compartment prolapse repairs are at risk for this. Herein, these results represent a reasonable diagnostic algorithm for management of these cases.

**Additional Keywords:** Persistent Groin Pain

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# Testosterone Replacement in Women With Low Libido

*Testosterone for Low Libido in Postmenopausal Women Not Taking Estrogen.*

Davis SR, Moreau M, et al:

*N Engl J Med;* 359 (November 6): 2005-2017

Testosterone therapy provides some benefit, although modest, in the treatment of hypoactive sexual disorder in postmenopausal women who are currently not users of estrogen or estrogen plus progesterone.

**Background:** The literature suggests that the prevalence of sexual problems in women ranges from 9% to 43%, and among these women, hypoactive sexual disorder is commonly reported. This is characterized by a decrease or an absence of interest in sexual activity, causing distress. Data pertaining to use of testosterone replacement in women not receiving estrogen or estrogen plus progestin are lacking.

**Objective:** To determine the efficacy of a testosterone patch without estrogen for treatment of hypoactive sexual desire disorder in women.

**Design:** Double-blind, randomized, placebo-controlled phase III trial.

**Participants/Methods:** This was a multicenter study using 65 centers across the northern hemisphere. Women were aged <70 years and had been postmenopausal for at least 12 months. Women had hypoactive sexual disorder based on questionnaire data. Groups received a testosterone patch with 150 or 300 g/day of testosterone or a placebo. Efficacy measurements comprised a weekly sexual activity log, a profile of female sexual function score, and a personal distress score.

**Results:** At baseline, approximately 50% of all sexual episodes were satisfying, and the increase in 4-week frequency of such episodes significantly increased in the group receiving testosterone 300 g/day compared to the group receiving placebo, with an increase of 2.1 episodes versus 0.7 episodes. The increase in these sexual episodes was not significant between the 150-g/day group and the placebo group. Both groups receiving active drug had significant increases in scores for sexual desire and decreases in scores for personal distress compared to the placebo group. Treatment did not differ significantly between women who had undergone natural menopause versus those who had undergone a surgically induced menopause.

**Conclusions:** This study shows that testosterone therapy provides some benefit, although modest, in the treatment of hypoactive sexual disorder in postmenopausal women who are currently not users of estrogen or estrogen plus progesterone. There were significant improvements in the mean frequency of satisfying sexual episodes, although numerically modest. Except for a higher incidence of hair growth reported in women assigned to testosterone, the incidence of androgenic adverse events was similar to that of prior studies

**. Reviewer's Comments:** Use of a patch delivering 300 g/day of testosterone significantly improves sexual function and decreases distress in postmenopausal women who do not receive estrogen replacement. These findings indicate that exogenous estrogen or estrogen-progesterone combinations are not required for testosterone to be effective in the treatment of hypoactive sexual desire disorder.

**Additional Keywords:** Low Libido

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# Penile Extenders Show No Significant Improvement in Peyronie's Disease

*Use of Penile Extender Device in the Treatment of Penile Curvature as a Result of Peyronie's Disease. Results of a Phase II Prospective Study.*

Gontero P, Di Marco M, et al:

*J Sex Med;* 6 (February): 558-566

Penile extenders do not produce significant improvement in length nor reverse the curvature of Peyronie's disease.

**Background:** Peyronie's disease (PD) is a common deformity of the penis. Some have claimed that penile extenders, a nonsurgical device using mechanical traction, can produce significant improvement in length and can reverse the curvature of PD.

**Objective:** To test whether a penile extender produces significant improvement in penile curvature as a result of PD, using a prospective method.

**Participants/Methods:** For eligibility, patients had to have a curve not exceeding 50-degree plaques detectable through palpation or ultrasound, PD over 12 months, and no pain. Baseline investigations included use of the International Index of Erectile Function. Degree of curvature was measured from pictures taken by the physician and, in some cases, self-photographs when patients were unwilling to do this. Curvature measurements were made based on these photographs, and penile length measurements were obtained using the method of Wessells. The device used was a supposedly common brand of penile extender called the Andropenis. Patients had to wear the device for up to 9 hours per day with a minimum of 5 hours for eligibility in this study.

**Results/Conclusions:** Of 40 patients referred for curvature, 19 met inclusion criteria, yet only 15 were enrolled. Patients reported a median time of daily use of 5.5 hours (3.0 to 6.0 hours). The penile curvature decreased from a baseline value of 31 degrees to 27 degrees after 6 months of treatment. This was not a significant change. After 6 months of treatment with the extender, a significant and overall mean gain of 1.3 cm for flaccid length and 0.83 cm for stretched length was observed. These were significant. Plaque size did not show any changes during the study.

**Reviewer's Comments:** This is obviously a negative study. In this series, the mean curvature decreasing by 4 degrees is modest and, by any means, is not significant in the measures of this study. The authors are to be congratulated for publishing such a negative study. This modest, insignificant or borderline change in effect is similar to borderline significant improvements of curve with intralesional injection therapy. The authors state that their patients using the device for only 5 hours per day may account for a lower degree of curvature reduction. They assumed that patients with stable disease and moderate curvature not exceeding 50 degrees would be ideal because there was no specific treatment available for men in this category. The curvature was calculated using photographs, a methodology known to underestimate bending.

**Additional Keywords:** Penile Extender Device

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