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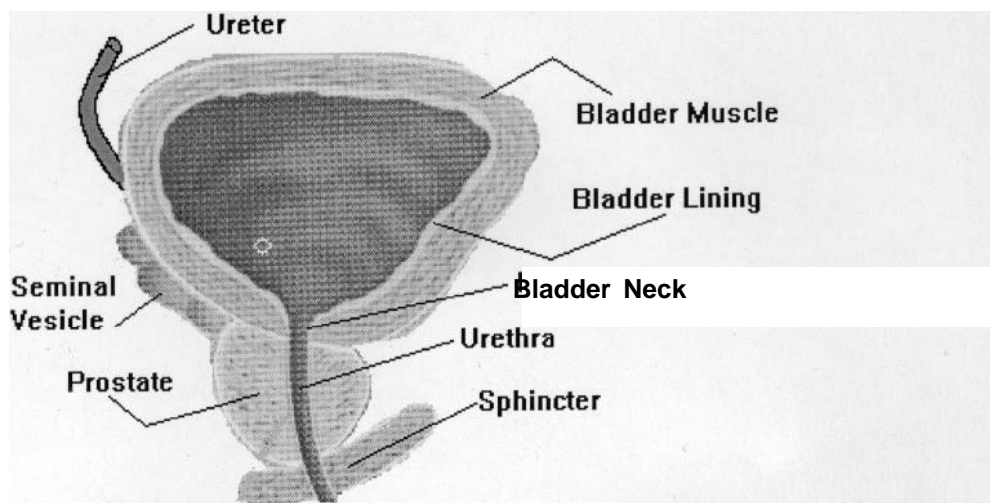
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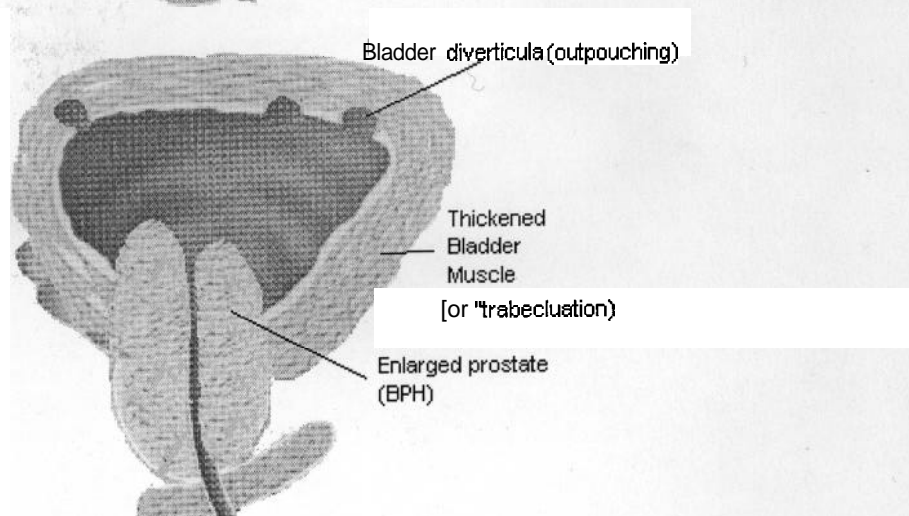
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ALTERNATIVE TREATMENTS FOR BPH



Normal Prostate



Enlarged Prostate

Benign Prostatic Hyperplasia (BPH) is the term used to describe the non-malignant growth of the prostate gland that is responsible for blocking the flow of urine out of the urinary bladder.

In some men, the growth of prostate is outward giving the gland increased overall size. This growth causes blockage by sheer increase in prostate size with impingement on the urinary channel or urethra. In others, the outward growth is minimal but the blockage is caused by increased muscle tone around the urinary channel or urethra. Many men develop both types of obstruction, gland growth and increased muscle tone.

NON-SURGICAL or MEDICAL TREATMENTS FOR BPH

Medical treatment for prostate disease has gone in multiple directions over the period of the last few years. The two major thrusts are in reducing prostate size and secondly, to relax the muscles that

surround the prostate to allow flow through urinary channel.

Hormone or Androgen Suppression

The drug, Proscar or finasteride, suppresses the action of the hormone testosterone in the prostate cells without affecting the level of testosterone in the blood stream. This allows men to have normal libido, but at the same time the prostate responds as if there is very little testosterone present. Current studies suggest that 50-70 percent of properly selected patients are experiencing reduction in prostate volume with reduction of their symptoms over a four to twelve month period.

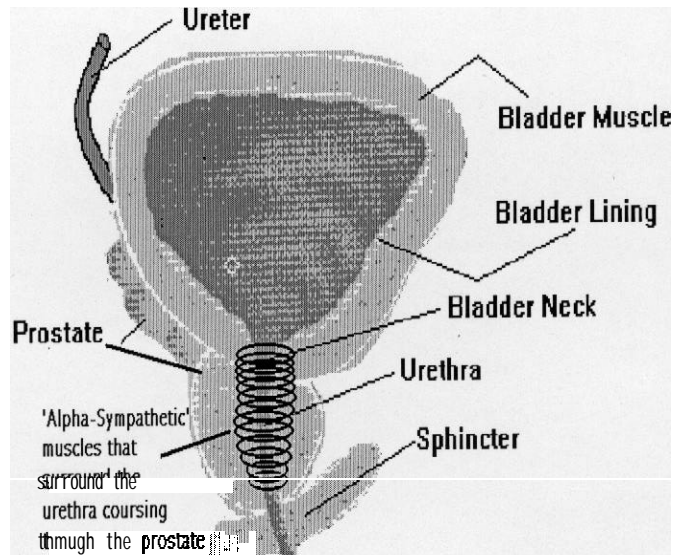
Proscar is taken once a day, indefinitely, and more recent studies have shown that the improvement in urinary symptoms persists as long as the drug is taken. Another interesting advantage of Proscar is the apparent significant reduction in episodes of complete urinary blockage that might require a trip to the emergency room for placement of a catheter into the bladder. In addition, the use of Proscar reduced the need for surgical treatment of prostate enlargement by more than 50%.

Proscar has been shown to be incredibly safe with very few minor side effects. The only commonly seen side effect is a 3% (3 out of 100 men) incidence of loss of sexual potency. Proscar works best in men who's prostate glands are larger than normal size. It has less effect on men who's prostate size is small and the urinary blockage is on the basis of increased muscle tone.

The prostate specific antigen (PSA) test normally reduces about 50% after Proscar has been taken for 4-6 months. Proscar does not really mask prostate cancer but a new baseline PSA may need to be established. Proscar has recently been released as a treatment for male pattern baldness. Studies that are currently active are investigating the possibility that Proscar may reduce the incidence of prostate cancer. The cost is approximately \$45 a month.

Medication that relaxes the muscles that surround the prostate channel

The anatomy of the bladder and prostate is such that a special muscle surrounds the urinary channel in its course from the bladder into the prostate. These muscles are controlled by special nerves called "alpha sympathetics". In many men, increased tone of this muscle occurs with aging and can be a cause of significant blockage of urinary flow without significant prostate growth. This muscle that runs around the prostate channel can be relaxed by taking specific medications known as "alpha blockers". These drugs, Hytrin, Cardura or Flomax (terazosin, doxazosin or tamsulosin), also are used to lower blood pressure in some patients with hypertension. The smooth muscles around the neck of the bladder and prostate are relaxed by these medications, and many men have both subjective and objective improvement of their urinary flow. These improvements usually occur within the first few weeks of taking these medications. These medications seem to work best in patients with smaller prostates, but work in larger glands as well.



The medicine will not stop the growth of the prostate, and theoretically, as the prostate grows over the years, these medicines may become ineffective in a small percentage of users. A percentage of men will have difficulties because of the lowering of their blood pressure to a point where dizziness and even fainting can occur. Some men report chronic fatigue or non-specific malaise. The side effects are also usually apparent soon after starting these medications. These medications cost about \$45 a month and must be taken indefinitely. Patients with high blood pressure might be able to use these medications in combination with other blood pressure treatment.

HERBAL THERAPY (PHYTOTHERAPY)

Herbal therapy is the use of naturally occurring plants or plant extracts for the treatment of various diseases. The American Food and Drug Administration (FDA) views these as food additives and makes little or no effort to control the use or content of herbal therapy. No American studies have been done to establish the safety or usefulness of any herbal treatment for prostate enlargement or symptoms. In the last few years a number of European studies have been done that suggest that herbal therapy can help relieve prostate symptoms. These studies do not give any answers as to why herbal therapy works and none have the safety investigations so necessary for American drug studies. Another problem is the different amount of herbal extract in each product. This means that the amount of herb in each preparation may be different. Many of the preparations come with multiple herbs so that it may be impossible to determine which herb is helping reduce prostate symptoms. Nevertheless many men in the United States have used herbal therapy purchased through drug and health food stores with some success. These drugs do not require prescriptions and are rarely covered by insurance.

The most popular of these extracts is saw palmetto. Saw palmetto is sold under a variety of names and often with a variety of other herbs or extracts. Saw palmetto was originally thought to be similar to finasteride (Proscar). We now believe this not to be true as saw palmetto doesn't lower the prostate specific antigen and prostate volume like finasteride does. Some researchers feel that saw palmetto may reduce prostate inflammation. As of now we do not know why saw palmetto works. It does seem to be safe, without significant side effects.

Warner Lamber, a major US drug manufacturer, has come out with Quanterra Prostate, which has 160 milligrams of Saw Palmetto. They recommend one table twice a day.

Other less well known extracts include Pygeum Africanum, beta-sitosterol, pollen extract, pumpkin

seeds, South African star grass and stinging nettles, meparitin, and radix urticae. These extracts all appear to be safe and well tolerated. Their effectiveness has not been established with any American studies.

Note: All herbal medications come with the disclaimer that:

These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any disease.

SURGICAL or PROCEDURES TREATMENTS FOR BPH

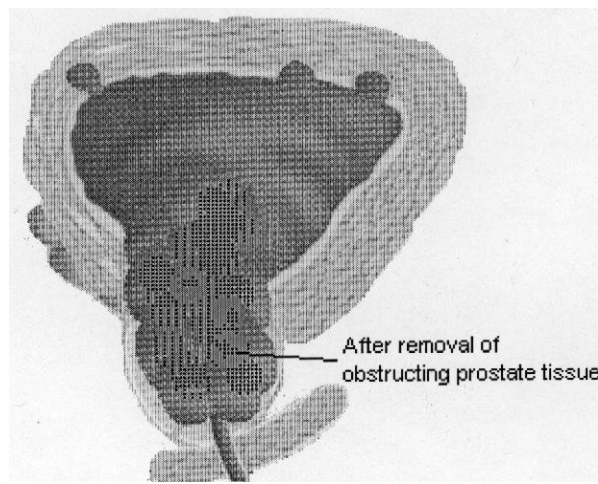
Transurethral RESECTION of the Prostate (TURP)

Transurethral resection of the prostate (TURP) has been the primary choice of treatment for the past 50 years for BPH that is causing obstruction of the bladder outlet

Approximately 400,000 transurethral resections of the prostate are performed annually in the United States. TURP is a safe procedure with four out of five patients experiencing resolution of their voiding symptoms with improvement of all of their urinary flow measurements. Essentially, TURP is the removal of the obstructing portions of the prostate with a telescopic electric knife. The TURP requires an anesthetic and takes about 30-60 minutes to perform. A tube or catheter is inserted into the bladder and is left in place for 24 to 48 hours. The hospitalization lasts from 1-3 days and requires two weeks of severe activity restrictions and another two weeks of modest restrictions. No treatment to date has bettered the long term effectiveness of TURP in alleviating obstruction caused by benign prostatic hyperplasia.

But because TURP is a surgical procedure with some risks, and because of the costs and time off work, other methods of therapy are being looked at intensively by the medical community. These include medical treatments and alternative surgical treatments which are less complicated than transurethral resection of the prostate.

The picture below is a representation of the prostate gland after TURP (transurethral resection of prostate), open prostatectomy, transurethral laser removal of prostate, and transurethral vaporization of prostate.



Transurethral INCISION of the Prostate (TUIP)

A **transurethral** incision of the prostate (TUIP) is the alternative to TURP that comes closest to matching its results in both terms of symptom relief and improvement in flow rates. The basic goal of the procedure is to remove just a minimum amount of prostate tissue to allow adequate **flow** through the prostate. This is done by making a simple cut or incision along the entire length of the prostate. Because of the circular muscle fibers running around the prostate, the TUIP allows the bladder neck to spring open and allows free urinary flow. TUIP is particularly beneficial for smaller prostates and does have a lower incidence of ejaculation disturbances. The success rates for TUIP are about the same as transurethral resection of the prostate, but only in those patients that are carefully selected (smaller prostate). Hospital stays and recovery are much shorter.

Open Prostatectomy

Open prostatectomy refers to a major surgical procedure for removal of the obstructing portion of the prostate. Open prostatectomy entails an incision on the lower abdomen. The prostate **can be approached** either through the bladder (suprapubic) or directly through the capsule of the prostate (retropubic). In either case, the blocking or obstructing portion of the prostate is shelled out from the prostate capsule in one piece. The end result is similar to the TURP in which the obstructing portion of the prostate is removed, leaving the prostate capsule behind. The reason to do an 'open' prostatectomy is the size of the prostate. The telescopic approaches (TURP, TUIP, laser, hyperthermia and balloons) are ineffective or impossible with prostate glands that are in the upper **5-10%** of size (usually greater than 75 - 100 grams). Open prostatectomy requires an anesthetic (general or spinal) and usually 3-5 days of hospitalization. Some prostates are large enough that open prostatectomy is the only treatment option. **Open** prostatectomy, also called 'simple' or 'subtotal' prostatectomy' should not be **confused** with 'radical' prostatectomy, an operation done for prostate cancer in which the entire prostate including capsule is removed.

Balloon Dilation

For the past few years, balloon dilation has been used clinically as an alternative to prostatectomy. It is very similar to the **angioplasties** done for coronary artery disease. Basically, a balloon is placed into the prostatic channel, either by **finger** guidance or telescopic guidance, and the balloon is then inflated to stretch the prostate channel. This has the apparent end result of tearing the prostate gland, creating an opening in the urinary channel. No prostate tissue is removed and the procedure does not work well for very large prostates. It appears that most of the patients **after** balloon dilation have recurrence of their symptoms relatively soon and require repeat treatments within two years. Balloons are **receiving** less acceptance as time goes by and the treatment will most likely be abandoned **within** the next year or **two**.

Transurethral laser removal of prostate

The laser is a high energy source, which has been used in medicine since the early seventies.

Essentially, the procedure consists of passing a laser into the prostatic channel under telescopic guidance. The laser is then used to destroy or heat up the obstructing portions of the prostate. Compared to transurethral resection, the advantages of the laser-assisted procedure are: no significant bleeding, shorter hospitalization, reduced operating time, an apparent decreased incidence of postoperative scarring and decreased incidence of lack of ejaculation. The laser-assisted prostatectomy is not optimum in the treatment of the very large prostate yet because of the necessity for multiple treatments. Another concern is that no prostate tissue is removed so we cannot be certain that cancer does not exist. Given the excellent diagnostic techniques available today with PSA and Ultrasound, the lack of tissue does not seem to be very important. There is also a fair amount of swelling of the prostate channel initially (3-10 days) which requires temporary catheterization (tube through penis into the bladder). A couple of weeks of frequency and irritation of urination occurs while the prostatic channel is healing. The biggest advantages: usually done as an outpatient procedure and there is usually little

bleeding!

Transurethral vaporization of the prostate

'Vaporization' of the prostate is the newest treatment option for prostate enlargement. The vaporizer uses a high energy electric source similar to the electrical source used for transurethral resection or incision of the prostate mentioned above. The difference is the amount of electrical current used (all are safe) and the type of contact made with the instrument. For transurethral resection the electric current is passed through a small wire and this allows cutting of the prostate tissue to remove it, but if the current is turned to a higher setting and a blunt roller ball is used (about the size of a BB) the tissue actually melts or vaporizes.

Essentially, the procedure consists of passing an electrode into the prostatic channel under telescopic guidance. The electrode is then used to vaporize the obstructing portions of the prostate. Compared to transurethral resection, the advantages of the vaporization procedure are: no significant bleeding and shorter hospitalization. The vaporization prostatectomy is not optimum in the treatment of the very large prostate yet because of the necessity for multiple treatments. Another concern is that no prostate tissue is removed so we cannot be certain that cancer does not exist. Transurethral resection for biopsy purposes initially followed by vaporization may solve this dilemma. The biggest advantages: usually done as an outpatient procedure and usually very little bleeding! This technology is very new and long-term results and side effects are yet to be known, although in theory it is very promising.

Prostatic Stents

Stents are wire devices shaped like small springs or coils. Stents are placed within the prostate channel and are used to keep the channel open.

Stents require about thirty minutes to place in the prostate, and the major problems revolve around the irritation and debris that form on the stent. Stents were approved for use in the United States in April, 1997, so that long term experience is still lacking. Stents may offer a temporizing or permanent solution to those patients too sick to undergo other surgical procedures.

Transurethral Microwave Therapy of the Prostate (TUMT)

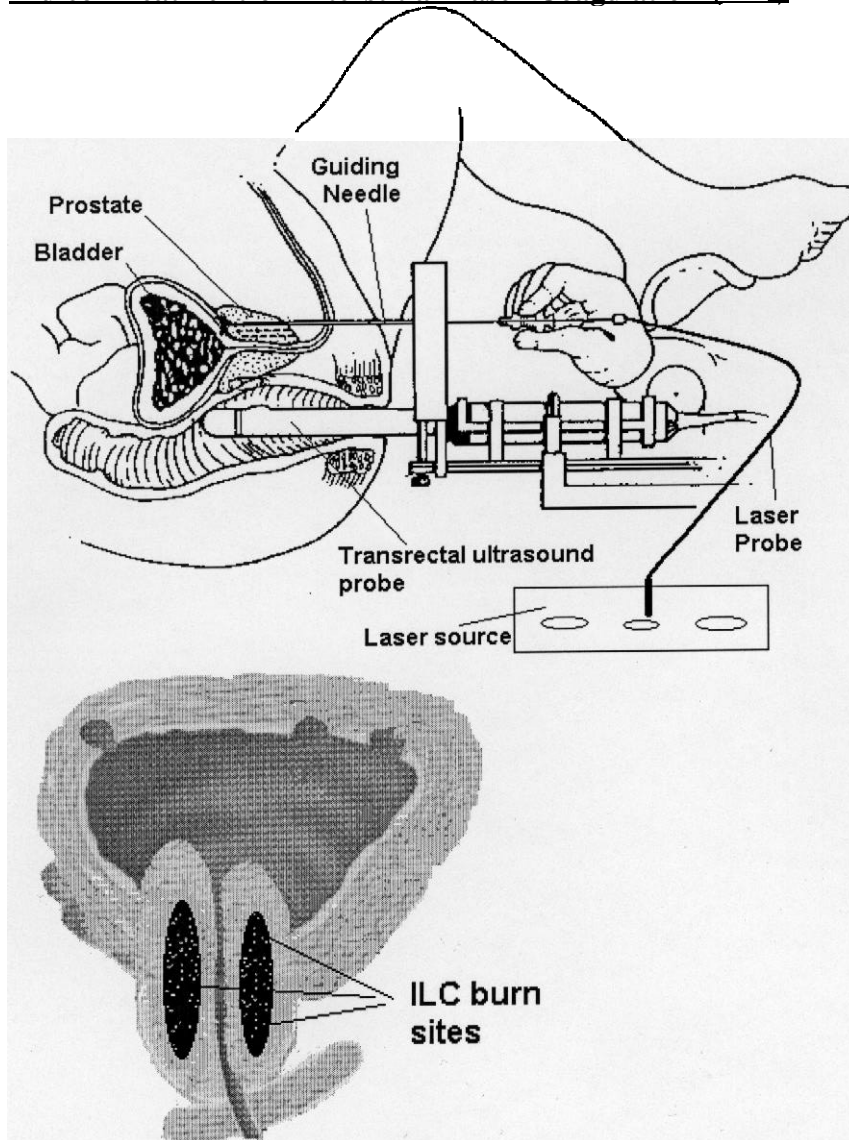
In concept, hyperthermia is similar to the transurethral laser procedure. TUMT is done as an outpatient with local anesthesia and mild sedation. The procedure involves the use of a special catheter which houses a microwave source at its tip. This catheter is placed through the penis so that the microwave source is placed into the prostatic channel. The prostate is heated up to temperatures above 105^o Fahrenheit. This causes destruction to the prostate tissue and shrinkage of the gland and also may act to relax the channel through the prostate by affecting prostatic nerves. Again, no prostate tissue is removed for pathologic diagnosis. Some of the newer techniques revolve around a catheter that cools the lining of the prostate while the prostate tissue deep inside is heated, and this allows for very good recovery times. Some testing of hyperthermia has been done in the USA with reasonably good results with about 50% of patients **benefitting**. Patients with very large prostates or enlargement of the middle lobe of the prostate are not felt to be good candidates for TUMT. Because the prostate is likely to swell initially most patients are discharged with a catheter in the bladder for a few days to allow drainage until the prostatic swelling subsides. Sexual functioning is not usually affected by TUMT. The FDA approved the use of microwave hyperthermia in September, 1995. Experience in the United States is still limited, however.

TransUrethral Needle Ablation of the Prostate (TUNA)

Transurethral needle ablation of the prostate is also similar to laser ablation of the prostate. TUNA is done as an outpatient with local anesthesia and mild sedation. With TUNA a telescope is placed into the

prostatic channel. Through the telescope special needles are placed deep into the prostate tissue. High frequency radiowaves are emitted from the end of the needles which are similar to radio antennae. The prostate is heated up to very high temperatures. This causes destruction to the prostate tissue. The heated prostate tissue is destroyed and initially swells but then shrinks. Most men require a catheter for a period of time after the TUNA procedure until the swelling resides. As with the laser procedure, no prostate is removed for pathologic diagnosis. The FDA has recently approved the use of the TUNA procedure in the United States. Experience in the United States is still limited.

Indigo Treatment or Interstitial Laser Coagulation (ILC)



ILC or Indigo laser treatment of the prostate is another type of laser treatment of prostate enlargement. ILC is done as an outpatient with local anesthesia and mild sedation. With ILC treatments a telescope is placed through the penis into the prostatic channel, Through the telescope special needles are placed deep into the prostate tissue. Indigo laser beams are emitted from the end of the needles which are similar to radio antennae. The prostate is heated up to very high temperatures. This causes destruction to the prostate tissue. The heated prostate tissue is destroyed and initially swells but then shrinks. Most men require a catheter for a period of time (usually three to eight days) after the Indigo procedure until the swelling resides. As with other laser procedures, no prostate is removed for pathologic diagnosis. The FDA has recently approved the use of the ILC procedure in the United States. Experience in the United States is still limited.

High Intensity Focused Ultrasound (HIFU)

A special ultrasound probe is placed into the rectum near the prostate. Ultrasound waves are focused similar to a magnifying glass so that the point of focus reaches temperatures close to the boiling point of water (212° Fahrenheit or 100° centigrade). The prostate is heated up to very high temperatures. This causes destruction to the prostate tissue. The heated prostate tissue is destroyed and initially swells but then shrinks. Most men require a catheter for a period of time after the HIFU procedure until the swelling subsides. As with the laser procedure, no prostate tissue is removed for pathologic diagnosis. This procedure is so new that few reports are available to judge its effectiveness. **The FDA has not yet approved the use of the HIFU or similar devices in the United States.**

Summary

Not every man needs treatment for early BPH. It is normal for a man's urinary flow to reduce as he ages. Mandatory reasons to proceed with some form of treatment include recurring infections, repeated bleeding episodes, bladder or kidney damage and the presence of cancer. When any of the above problems occur, or one's lifestyle is changed by the presence of prostate obstruction, consideration to treat the prostate enlargement should be given.

As time goes on, additional medications and surgical procedures will be developed to treat prostatic enlargement. Today, however, each patient must be taken individually as to what therapy gives him the best chance for successful treatment.