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EFFECT OF PRULIFLOXACIN ON RAISED PSA

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ABSTRACT

Objective-to evaluate the role of prulifloxacin on raised PSA **Introduction-** Prostate specific antigen is a glycoprotein that is serine protease. It is secreted primarily by prostate. An increase in prostate specific antigen usually indicates a prostate disease such as BPH, prostati and prostate cancer,or it may a result of manipulation of prostate like the massge of prostate or its biopsy. There may be an increase of PSA in cases of prostate disease, but it is not a necessary finding in all the men suffering from prostate disease.2 Also, an increase in PSA is not always specific to prostate cancer. .Subclinical prostatic inflammation or physiological fluctuation in PSA levels have been observed in 20-40 % cases in various clinical trials. In our study we aim to investigate effect of prulifloxacin therapy in patients with raised PSA. **Methods-** study was conducted on patients with Lower urinary tract symptoms, and elevated PSA(prostate specific antigen) 4-10ng/ml.3 week of tab prulifloxacin 600mg od is given to patients and PSA was repeated after 3 weeks if PSA is still found to be raise then 12 core TRUS(transrectal ultrasound) biopsy was done. **Result-**In 61 patients (82.4%) PSA values decreased, while in 13 patients (17.56%) PSA values increased from the initial values. 4 patients had PSA value above 50ng/ml, whose PSA values dropped significantly, after prulifloxacin administration **Conclusion-** There was a significant decline in the levels of PSA after three weels of purifloxacin treatment. Patients in whom there was a decrease in PSA levels of less than 4ng/mL with more than fifty percent reduction, the biopsy can be delayed. Antibiotics treatment before undergoing prostate biopsy can significantly avoid unnecessary biopsies.

KEYWORDS

prostate specific antigen, biopsy , TRUS, LUTS

INTRODUCTION AND OBJECTIVES:

The late 1980s introduced a widely used test that was performed for detection and follow up of prostatic cancer. The test was the total prostate specific antigen (PSA). PSA is not specific to prostate cancer.Even benign prostrate hyperplasia (BPH) and prostatitis show an increased PSA levels.[1] A change in the levels of PSA due to physiological fluctuation has also been demonstrated.[2] 65-70% of patients who show abnormal prostate specific antigen (PSA) are found not to have prostate cancer when undergoing biopsy. Prostate biopsy is a potentially morbid procedure. Prostatitis is the most common diagnosis made through biopsies. So as to reduce the number of needless biopsies, patients showing lower urinary tract symptoms (LUTS) with normal urinalsis, but with elevated levels of PSA were administered with PRULIFLOXACIN to study its effect on the levels of PSA. PSA levels are commonly reevaluated so as to decide on TRUS biopsy even in asymptomatic patients as it is better to reevaluate than make the patients undergo interventions with risk of complications. Antibiotics are usually the preferred mode to reduce the effect of inflammation before undergoing biopsy, and this is called as normalization of PSA.Some studies do indicate a decease in the levels of PSA on using antibiotics, but there is still a lack of consensus on determining TRUS biopsy. Therefore, we conducted a prospective randomized, controlled study to meet the demand about this issue.

MATERIAL AND METHODS:

The study was conducted between March, 2018 and Dec,2018. 74 patients with LUTS, and elevated PSA (4.62- 104.44 ng/ml), were selected. These patients are generally considered for prostate biopsy. Prulifloxacin was administered to these patients for three weeks. An alpha-blocker was added if the patient had bothersome symptom.After three weeks, PSA was again done and if no decrease in PSA levels was seen below 10 ng/mL, biopsy was done. For patients showing levels of PSA between 4 and 10 ng/mL, Free PSA/Total PSA % was calculated after 3 weeks of prulifloxacin administration. If it was less than 15 percent, prostate biopsy was performed. If the patients had a history of prostate biopsy or prostate surgery (TURP), or any family members had a history of prostate cancer, or the patient had underwent 5-alpha reducatse inhibitor treatmetn, they were excluded. Also, any patient who after urinalysis showed pyuria and bacteriuria indicating acute urinary tract infection , or has an allergy to quinolones is excluded. Any recent history of instrumetation of the urinary tract resulted in exclusion. Patients having psa value>4 ng/ml were given 600 mg oral prulifloxacin once a day for 21 days. All patients were reevaluated using the same parameters, at the end of 3 weeks If PSA value decreased in 3 weeks time and if repeated psa is >10 ng/ml,then prostate biopsy was done and for those patients whose PSA value did not decrease after treatment.

RESULTS

Mean age was found to be 69 years

AGE GROUP	N	%
40-50	1	1.35
50-60	11	14.86
60-70	32	43.2
70-80	24	32.4
80-90	6	8.1

In 61 patients (82.4%) PSA values decreased, while in 13 patients (17.56%) PSA values increased from the initial values. 4 patients had PSA value above 50ng/ml, whose PSA values dropped significantly, after prulifloxacin administration.

Table-2

PSA After 3 weeks of prulifloxacin		
PSA <4 ng/ml	PSA 4-10ng/ml	PSA >10 ng/ml
23 patients	21 patients	30 patients

Out of 74 patients 23 patients PSA was less then 4 ng/ml,while 21 patients have PSA between 4-10 and rest 30 patients has PSA more then 10 ng/ml.All these patients were biopsied subsequently, in which 3 were benign and 1 patient whose PSA dropped from 54ng/ml to 35.8ng/ml showed adeno –carcinoma on HPE. High grade PIN with BPH was detected in 2 cases , whose PSA value had increased even after treatment with prulifloxacin.in those 21 patients whose PSA was in grey zone ratio of FreePSA to Total PSA was calculated and patients with ratio<15% was subjected to biopsy. only 04 patients have ratio significant.

Table -3

Patients in grey zone (PSA 4-10ng/ml) Free PSA/Total PSA	
No of patients Free PSA/Total PSA <15%	No of patient with Free PSA/Total PSA >15%
04	17

1 patient PSA value increased from 18.2ng/ml to 31.3ng/ml with free PSA/Total PSA ratio of 31.4%., while in the second case PSA value increased from 5.7ng/ml to 10.3ng/ml with free PSA/Total PSA ratio of 18.1%.

DISCUSSION:

After 3 weeks of prulifloxacin treatment, approximately 82.4 percent of patients with LUTS and elevated PSA reported a fall in their PSA levels although only 23 patients saw a significant drop resulting into postponed prostate biopsy. This must be done very carefully through close follow-up of those patients whose PSA levels particularly do not fall to normal levels. Depending on age, race, prostate volume, and biological variability, serum PSA levels in healthy people were known to vary. Several reasons can lead to an increase in the levels of PSA like any rectal or urethral procedures, or trauma or even ejaculation. Due to diseases such as benign prostatic hyperplasia and prostatitis, it may also increase.2 Many studies have shown that being treated with antibiotics can decrease PSA values to normal levels before choosing to have a biopsy, and that biopsy can be deferred.Serratta and colleagues noticed that 59 percent of patients had a drop in PSA after a 3-week antibiotic treatment. They reported that PSA levels were unchanged and decreased by 40% and 20.3% of patients diagnosed with PCa, respectively.19Furthermore, in patients with a PSA level below 4 ng / mL, cancer was not detected, and the study suggested that biopsy could be deferred if PSA levels diminished by more than 50% or below 4 ng / ml. Kaygisiz and colleagues showed a similar drop in rates of PSA after antibiotics in patients with and without prostatitis, demonstrated by prostatic secretions.7 In 10.8 percent of patients, they found PCa and all these patients had a PSA value of > 4 ng / mL. The study concluded that in patients with PSA rates > 4 ng / mL following antibiotics, there was still a high risk of PCa, even if they were medically diagnosed with prostatitis. Overall, before deciding on TRUS biopsy, they recommended antibiotic therapy for three weeks. Baltaci and associates reported antibiotics treatment for three weeks in 100 patients with normal levels of DRE and PSA between 4 and 10 ng / ml. An overall reduction in the PSA value of 7.15 percent was detected. The research also recorded PCa following antibiotic treatment in 29.4 percent (5/17) of patients with PSA rates < 4 ng / mL.18 The researchers reported that antibiotic therapy may significantly reduce serum tPSA, although the threat of PCa will not be reduced. To asymptomatic patients with elevated PSA levels, however, they did not recommend antibiotics. In our study only 1 patient with initial PSA value > 50 ng/ml had adenocarcinoma and 2 patients showed high grade PIN. Recently, Heldwein and colleagues21 investigated the effect of a 30-day trial of levofloxacin in asymptomatic patients with a raised PSA. They contrasted the treatment group with a significantly smaller control group without randomization and found that the PSA variability induced by antibiotic treatment has reduced predictive quality with respect to biopsy results and therefore should not be prevented from using antibiotic treatment in this manner. A study by Jon Johnson(2018)showed probability of prostate carcinoma in relation to free PSA/ total PSA ratio.

Table-4

FREE PSA/ TOTAL PSA %	PROBABILITY OF PROSTATE CARCINOMA
<10%	56%
11-15%	28%
16-20%	20%
21-25%	16%
>25%	8%

In our study,after prulifloxacin administration, 4 patients had free PSA/ total PSA ratio of ≤ 15%. Subsequently, prostate biopsy was done. In 1 case chronic prostatitis was detected while 3 had BPH on HPR.

CONCLUSIONS

On a daily basis, a considerable number of patients with a gray-zone PSA show up in the urology departments.Most of the times, they are given antibiotics and the PSA levels are reevaluated in order to avoid needless needle biopsies. But this behavious does not have a consensus.By presenting this prospective study, we aimed to highlight the issue. Significant reductions in PSA rates are found after 3 weeks of treatment with prulifloxacin. Biopsy can be delayed in patients with PSA values below 4 ng / mL, followed by a drop of more than 50%. For a precise conclusion, however, larger studies are needed. Administering antibiotics before deciding biopsy is helpful to avoid unnecessary biopsies. On the basis of their past clinical experience for every individual patient, the urologists should make decisions regarding biopsy so as not to burden the patients with the potential ramifications of antibiotics. Prulifloxacin is found to have good tolerability and acceptability by the patients as none of the patients in the study developed untoward side effect due to drug. Also, it helps in preventing infections.

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