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TRANSRECTAL ULTRASOUND-GUIDED BIOPSY: A PROSPECTIVE STUDY OF PATIENTS TOLERANCE AND COMPLICATIONS

A.A. ELABBADY
Department of Urology, Faculty of Medicine, University of Alexandria, Alexandria, Egypt

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ABSTRACT

This prospective study comprised 113 patients who underwent TRUS-guided biopsy from the prostate or from pelvic recurrence following radical cystectomy. The patients' tolerance was assessed by scoring the severity of discomfort during the procedure and their acceptance was estimated by questionnaires following it. Most of the patients (56.6%) experienced either no discomfort at all or only mild pain during the procedure. Intravenous sedation was needed in 31% of the patients and general anaesthesia was necessary in two patients. Haematuria was the commonest complication (59.6%) followed by rectal bleeding and haemospermia, which occurred in 36.7% and 17.4% of the patients, respectively. A vasovagal attack occurred in one patient. There was one major complication, a prostatic abscess which resulted in a temporary urethro-rectal fistula. We conclude that TRUS-guided core biopsy is safe with frequent minor but very rare major complications. The majority of the patients tolerate the procedure with accepted discomfort but a considerable number of patients need sedation to complete the procedure effectively.

INTRODUCTION

The use of transrectal ultrasound (TRUS) with the possibility of taking multiple transrectal core biopsies of the prostate has become a standard procedure in the diagnosis of prostate cancer. It is more accurate than digitally directed biopsies. TRUS-guided biopsy is considered safe and is commonly performed in an outpatient setting. It has a valuable role in early detection of prostatic cancer and it is an integral part of cancer screening programs. Although frequently performed without anaesthesia, it is generally and uncontroversially accepted that it does cause discomfort or minor or even major complications[1-3].

This prospective study determines the morbidity and patient tolerance of TRUS-guided biopsy from suspected malignant prostate or pelvic recurrence after radical cystectomy.

PATIENTS AND METHODS

Between December 1999 and June 2000, a total number of 113 patients underwent TRUS and transrectal core biopsies from the prostate (n = 109 patients) or from pelvic recurrence after radical cystectomy (n = 4 patients). The patient age ranged from 54 to 81 years with an average of 67.1 years. Referral for prostatic biopsy was made because of either elevated serum prostatic specific antigen (PSA) or abnormal digital rectal examination. Eleven of those patients who had been referred for prostatic biopsy had urine retention with already inserted indwelling catheters. The four patients with pelvic recurrence following cystectomy had positive CT findings and were referred for histological proof. Routine laboratory investigations including prothrombin time, partial thromboplastin time and serum creatinine were performed for each patient. All patients were recommended to take 500 mg

Table 1: Pain and Discomfort Experienced by the Patients During the Procedure (n=113)

Pain Score	No. Of Patients	%	Comments
0 (no discomfort)	5	4.4%	
1 (mild pain)	59	52.2%	
2 (moderate pain)	26	23.0%	14 patients needed I.V. sedation (Diazepam, 10 mg)
3 (severe pain)	21	18.6%	All patients needed I.V. sedation (Diazepam, 10 mg)
4 (intolerable pain)	2	1.8%	General anaesthesia was used

Ciprofloxacin orally the night before the procedure and for two further doses after the biopsy. The patients were also encouraged to empty their bowel in the morning without the use of enema.

TRUS was performed with the patient in the left decubitus position, using a Cheetah 2003 scanner with a 7 – 10 MHz bi-planer attached probe, type 8551 (B&K Medical AS, Glostrup, Denmark). Biopsies were taken during longitudinal scanning, using 18 G tru-cut biopsy needles loaded on a biopty gun. At the conclusion of the procedure, the patients' tolerance was assessed by scoring the severity of discomfort as: 0—no pain or discomfort, 1—slight pain, 2—moderate pain, 3—severe pain, 4—intolerable pain (Table 1). The patients also completed two questionnaires regarding pain and discomfort after the procedure. Complications encountered during the procedure were recorded. The patients were allowed to leave within 30 minutes after having a complete explanation of the possible complications and they were asked to return back within five to seven days to have their pathology reports. At that time, the patients were interviewed again for any undesirable complications.

RESULTS

A total of 116 TRUS-guided core biopsies were carried out on 113 patients. The procedure had to be repeated in three patients (two patients with suspicious prostate cancer and one with pelvic recurrence after radical cystectomy) because of inconclusive histology. In these three patients, the complications and tolerance were assessed at the first procedure only. For each patient, the average number of biopsies taken was 8.7 (range 3-13) and the average duration of the procedure was 14.5 minutes (range 8-19.5).

Most of the patients (56.6%) experienced either no discomfort at all (4.4%) or only mild pain (52.2%) during the procedure (Table 1). Intravenous sedation (10 mg Diazepam) was needed in 35 patients (31%). Although 14 out of the 35 patients reported their pain as moderate, I.V. sedation was needed to complete the procedure safely. Two patients needed general anaesthesia (one patient with suspicious prostate and the other had pelvic recurrence after radical cystectomy) to complete the procedure, one of them had mild anal stenosis due to previous anal surgery. The patients who completed the procedure without I.V. sedation or anesthesia (n=76) answered the questions on the questionnaire regarding pain and discomfort. Thirty-five patients (46.1%) found pain and discomfort as was expected from the pre-procedure explanation while 41 patients (53.9%) found it more than expected. However, only 23 patients out of 76 (30.3 %) expressed their wish to have I.V. sedation if the procedure was to be repeated while 69.7% did not.

The complications occurring after TRUS-guided biopsy in pelvic recurrence were minimal and included passage of some blood with stools in two patients only, both of them had orthotopic urinary diversion. The complications related to TRUS-guided prostatic biopsies are listed in Table 2. Most of the complications were minor and did not necessitate hospitalization. Haematuria was the commonest complication (59.6%) which lasted for one to four days. Rectal bleeding and haemospermia occurred in 36.7% and 17.4%, respectively, and also lasted for few days at maximum. The incidence of dysuria was

Table 2: Complications Following TRUS-Guided Prostatic Biopsy (n=109)

Complication	No.	%
Haematuria	65	59.6%
Blood in stools	40	36.7%
Haemospermia	19	17.4%
Dysuria	13	11.9%
Perineal and/or anal pain	7	6.5%
Pain at defecation	6	5.5%
Fever, chills	6	5.5%
Urine retention	4/98*	4.1%
Prostatic abscess, urethro-rectal fistula	1	0.9%
Vasovagal attack	1	0.9%

* Eleven out of the 109 patients referred for prostatic biopsy had already urine retention at presentation

11.4%, which was severe enough to cause urine retention in four (4.1%) patients out of the 98 patients who did not have retention before the procedure. Less frequent complications included perineal and/or anal pain (6.5%), fever and chills in 5.5% and pain at defecation (5.5%). A vasovagal attack occurred in one patient only. At the end of the procedure, the patient was pale, drowsy, sweaty and irritable. Blood pressure was 90/55 mmHg and the pulse was 74 beat per minute. The patient was kept in flat position and intravenous fluids were given which was sufficient to correct the condition.

The most serious complication was a temporary urethro-rectal fistula, which occurred in a 72-year-old man who had initially presented with mild dysuria and prostatism. Total serum PSA level was 63.2 ng/ml and digital rectal examination revealed a stony hard enlarged prostate with an irregular more bulging right lobe. TRUS revealed a 73 cc heterogeneous prostate with hypoechogenecity prevailing in the right lobe. Multiple biopsies were taken from different sites of the prostate. The next morning, the patient suffered from dysuria which progressed to severe difficulty and complete urine retention within two days. Few hours following retention, turbid urine came out through the anus. At hospitalization, the patient was feverish, toxic with tachycardia (124 bpm) and a blood pressure of 95/65 mm Hg. Digital rectal examination revealed an enlarged tender irregular soft mass at the region of the prostate (prostatic abscess). At that time, serum creatinine was 2.5 mg % and W.B.C. was 20,000/ ml. A urethral catheter was inserted, a blood sample was taken for culture and intravenous fluids, Cefotriaxone and Metronidazole were administered. The blood culture grew anaerobic gram-negative bacilli. The patient improved rapidly and bilateral orchidectomy was done because of bone metastasis present. The urethral catheter was removed four days post orchidectomy and the patient voided spontaneously.

DISCUSSION

Ultrasound-guided transrectal biopsy of the prostate is a current standard procedure which has a key role in early detection of prostate cancer. As the number of men enrolled in screening programs increases, the number of TRUS-guided biopsy also increases. The advantages of TRUS-guided prostatic biopsy over the finger-guided transperineal or transrectal needle biopsy are indisputable. It is an outpatient procedure and it is cost effective. Moreover, it is easy to choose the site of biopsy and to map the whole prostatic zones with great accuracy.

It is well established that extended core biopsies (additional peripheral and transition zone cores) significantly increase the detection rate for prostate cancer compared with the sextant biopsies alone[4-7]. In this study, the number of biopsies taken was based on a high PSA level only (i.e. negative DRE findings) ranging from 10 –13 depending on the prostate size. The average number of biopsies for all patients together was 8.7. This number is higher than the numbers of cores in previous reports taken in a sextant pattern or directed toward palpably or ultrasonographically suspicious areas[1,8,9].

In this study, 47 (41.6%) patients estimated their pains as moderate to severe and intravenous sedation was needed in 35 patients (31%). Two patients needed general anaesthesia. Although the pre-procedure explanation and assurance was very helpful, 41 patients (53.9%) of those who completed the procedure

without I.V. sedation or anaesthesia (n=76) found pain and discomfort more than expected. However, only 23 patients (30.3%) recommended that I.V. sedation should be used during the procedure while 69.7% did not. Collins et al.[10] reported that two thirds of their patients (n=89) experienced mild discomfort during the biopsy, 22% considered it painful and 40% of patients felt embarrassed during the procedure. Only three patients expressed a preference of some form of anaesthesia for the procedure. Clements et al.[11] reported that 70% (n=230) of their patients undergoing TRUS-guided prostate biopsy experienced mild discomfort while 30% considered it painful. Irani et al.[1] reported that 19% of their patients (n=81) would not agree to undergo TRUS-guided biopsy again without some form of anesthesia. Although the degree of patient acceptance varies considerably and is difficult to be quantified, it is apparent that the tolerability in this study is less and the need for sedation is higher compared to previous reports. This may be related to the increased number of cores rather than to the different socio-cultural environment. In their individual experiences, Rodriguez and Terris[3] demonstrated that age, rather than the total number of biopsies or the specific sites of the prostate at which biopsy is done, was the most important factor determining patient tolerability; they found that younger patients had more pain and discomfort. Some recent reports recommend the use of intrarectal lidocaine gel during prostatic biopsy[12] while others performed transrectal ultrasound-guided prostatic nerve blockade which resulted in a more comfortable procedure for the patient[13].

Bleeding is the most common complication after transrectal ultrasound-guided needle biopsy with haematuria most prevalent followed by rectal bleeding and haemospermia[3,10,14]. It is usually of an acceptable degree and lasts from few hours to few days. In this study, the incidence of haematuria was 59.6%, haematochesia was 36.7% while haemospermia occurred in 17.4% of the patients. These complications were comparable to those reported in the previous studies. In our practice, we encourage patients to discontinue aspirin use at least 1 week before biopsy. However, some authors recently suggested that the use of this medication should not be considered an absolute contraindication to prostate biopsy[3].

Various regimens of prophylactic antibiotics ranging from none to oral and parenteral antibiotics have been involved in different series. Several studies have shown a decreased rate of infections when antibiotic prophylaxis was used[8,15,16]. Thompson et al.[17] cultured blood and needle tips from patients who underwent biopsies and discovered that patients were most commonly exposed to anaerobes, especially bacteroids, followed by aerobes, especially Enterococcus. They also revealed that bacteraemia that can develop after transrectal needle biopsy may remain undetected, as it is usually asymptomatic and self-limited. In this study, the true incidence of bacteraemia or urinary tract infection (UTI) can not be assessed as blood and urine cultures were not routinely performed after the procedure. However, fever, chills and dysuria, which might reflect bacteraemia or UTI, were infrequent and easily controlled. Davison and Malamet[18] did not use routine antibiotics in most of their cases and they reported post-biopsy pyrexia in 27% of 113 patients, while four patients developed Escherichia Coli septicaemia, one fatal. At least another 2 deaths from anaerobic sepsis in the post biopsy period have been reported[2,19]. In this study, the only severely morbid infectious complication, which occurred in one patient only, was prostatic abscess, septicaemia and consequently an urethro-rectal fistula. The offending organism was anaerobic gram-negative bacilli. Therefore, it seems that fluoroquinolone alone was not sufficient in this patient. Some authors recommend the use of fluoroquinolone for aerobic coverage in addition to metronidazole for anaerobic coverage[3].

Collins et al.[10] reported 7% voiding difficulty in the post-procedure period and other studies reported urine retention in less than 0.2%[15,20]. In this study, dysuria occurred in 11.9% and urine retention in 4.1% out of the 98 patients who presented for prostatic biopsy without pre-procedure retention. These relatively high incidences may be related to the higher numbers of biopsies, which result in increased intra-prostatic haemorrhage and congestion.

In the literature, the incidence of vasovagal episodes at the time of TRUS – guided biopsy is minimal. Although most patients do not have this complication, Rodriguez and Terris[3] reported vasovagal episodes in 5.3% of their patients (n=128), with the systolic blood pressure lowered to below 90 mm Hg. The only patient requiring hospitalization in their series had a severe vasovagal response that induced seizures. In the present study, only one patient

(0.9%) suffered from a vasovagal attack which was easily corrected with intravenous fluids and did not require hospitalization.

In conclusion, extended (additional peripheral zone and transition zone cores) transrectal ultrasound-guided prostatic needle biopsy is considered safe and can be done as an outpatient office procedure in most of the patients. Major complications are rare while minor complications are frequent but they are self-limited or easily controlled.

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All correpondence to be sent to:

A.A. Elabbady, M.D.; Department of Urology; Faculty of Medicine; University of Alexandria; Alexandria; Egypt