

# Screening program for prostate cancer at a university hospital in eastern Saudi Arabia

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## ABSTRACT

**Objectives:** Implementation of a pilot screening program for prostate cancer among Saudi patients that would serve as a nucleus for a Kingdom-wide screening program.

**Methods:** A prospective study on 1,213 Saudi males between 50-80 years of age who attended the Outpatient Department at King Fahd Hospital of King Faisal University, Al-Khobar, Kingdom of Saudi Arabia during a period of 18 months (April 2001-October 2002). They were included at random from different clinics including the urology clinic. Free and total prostate specific antigen (PSA), and digital rectal examination (DRE) of the prostate were performed in all patients. Patients with abnormal DRE or PSA were scheduled for transrectal

ultrasound (TRUS) and ultrasound guided biopsy of the prostate.

**Results:** Abnormal DRE or PSA were present in 84 out of 1,213 patients. Only 63 patients agreed to have TRUS and ultrasound guided biopsies. Prostate cancer was confirmed in 14 out of 1,192 patients who completed the study (1.17%).

**Conclusion:** The incidence of prostate cancer among Saudi men in this hospital based study is low. A population based screening for prostate cancer may reveal the incidence of this disease.

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**P**rostate cancer is a major health problem in the western world. Estimates of the year 2000 indicate a worldwide prostate cancer incidence of 542,900 new cases, 204,313 of them have died.<sup>1</sup> Prostate cancer is the leading cancer diagnosis and the second most common cause of cancer-related death in males in the United States.<sup>2</sup> The exact morbidity and mortality rates from this cancer on the national scale are not known in the Kingdom of Saudi Arabia (KSA).<sup>3</sup> Most of the national conference presentations showed a low incidence of prostate cancer among the Saudi population.<sup>4-10</sup> Figures of the National Saudi Tumor Registry showed a low incidence of this disease.

Most of screening programs, in the western world, used prostate specific antigen (PSA) and digital rectal examination (DRE) as basic tests in screening<sup>11-18</sup> The cut off value of 4 ng/ml is the

standard value in almost all of those screening programs. The critical ratio of free to total PSA suspicious of prostate cancer in use is 19%.<sup>19</sup> A huge multicenter screening program for prostate cancer is already going on in Europe by the European Randomized Study of Screening for Prostate Cancer (ERSPC), with 8 European countries sharing in this work. Their preliminary results were recently published. The age of inclusion into these studies varies from 45-85 years.<sup>11-18</sup>

**Methods.** This is a hospital based screening program for patients between 50-80 years of age who attended the Outpatient Department at King Fahd Hospital of King Faisal University, Al-Khobar, KSA from April 2001-October 2002. The patients were selected randomly from different

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clinics including the urology clinic. Informed consent was obtained from all patients to enter the study. Complete history taking and general medical examination were performed. Blood samples for free and total PSA were taken prior to DRE. Patients who were recently subjected to DRE or urethral manipulations were deferred for 2 weeks before taking the blood samples. The PSA was determined by the radioimmunoassay (Abott Laboratories). Patients who complained of symptoms of benign prostatic hyperplasia (frequency, urgency and nocturia) were not excluded from the study.

Exclusion criteria included: 1) patients referred from other centers with suspected or diagnosed prostate cancer; 2) patients already diagnosed as having prostate cancer prior to the study; 3) patients with already diagnosed prostatitis; and 4) patients who refused to undertake DRE or transrectal ultrasound (TRUS).

Patients who had DRE suspicious of prostatic cancer, high PSA (above 4 ngm/ml) or both were scheduled to have TRUS and TRUS guided biopsy. The cut off value of 19% for the ratio of free/total PSA was used to differentiate between benign and malignant lesions. Transrectal ultrasound was performed by a single consultant familiar with the technique. The TRUS guided biopsies were taken in the same session under local anesthesia (xylocaine jelly) from suspicious hypo-echoic areas in the prostate or at random when no hypo-echoic lesions were seen (5 biopsies from each lobe). The TRUS probe (B & K us 45637) and the prostatic biopsy gun were used to take the biopsies. Biopsies were studied by one pathologist experienced in prostate cancer. All patients received one dose of a broad-spectrum antibiotic (for example second generation cephalosporin or ciprofloxacin) 3 hours before the procedure, and continued for 3 days if a biopsy was taken. They were instructed to report immediately to the emergency room if complications as fever or anal bleeding were experienced. Gleason's histological classification was used for grading the prostate cancer cases.

**Results.** One thousand two hundred and thirteen patients accepted to enter the program during the study period (56.2%) and 942 patients refused to enter the program in spite of detailed explanation of the concept of screening, and its importance to their health. The mean age of patients who entered the study was 64.6 years (range: 50-80 years). High PSA and abnormal DRE were encountered in 29 patients (total: 84) and 55 patients (total: 84). The PSA and DRE were both abnormal in 21 of those 84 patients. Free/total PSA ratio below 19% was present in 16 out of 29 patients with high total PSA. Prostate specific antigen exceeded

100 ng/dl in 5 patients, and was exceptionally high (>1000 ng/dl) in 2 of them. Twenty-one patients refused to have TRUS or did not show up, and were excluded from the study. The number of patients who remained in the study was reduced to 1,192. Sixty-three patients had TRUS. Abnormal TRUS findings were found in 53 patients. Forty-three had TRUS guided biopsies taken from hypo-echoic lesions. Biopsies were taken at random in the remaining 10 patients where the prostate was normo-echoic. Adenocarcinoma was found in 14 patients. They all had high PSA and low free/total PSA ratio, and represented 1.17% of the total number of patients who completed the study (1,192 patients). Other biopsy findings included benign prostatic hyperplasia in 36 patients, high-grade prostatic intraepithelial neoplasia in 4 and chronic prostatitis in 9. In 8 of the prostatic carcinoma patients, Gleason score was above 7. Two of them had evidence of bone metastasis by bone scan. Six patients had Gleason score less than 4.

**Discussion.** This present study was a prospective randomized study on Saudi males between 50–80 years. The feasibility of performing a screening program for prostate cancer in KSA was evaluated. Patient acceptance to the idea of screening was remarkably astonishing. The acceptance of Saudi elderly men of 56% to enroll in the screening program was comparable to similar studies in France (60%),<sup>13</sup> and more favorable than in other studies from Belgium (29%)<sup>11</sup> and Spain (23%).<sup>15</sup> The method used in these studies to make contact with the volunteers was through mail rather than personal contact as adopted in the present screening program. Our patients were already seeking medical advice in the hospital and were probably easier to convince to enroll in a health-oriented screening program than healthy volunteers.

It is argued that screening for prostate cancer is not a cost effective approach for the decrease of mortality from this disease.<sup>19,20</sup> Experts from several fields including urology and epidemiology were asked to provide a consensus statement on prostate cancer screening for the International Cancer Union (UICC) in 1994. The expert group unanimously agreed that there is insufficient evidence to justify prostate cancer screening, as no significant reduction in mortality was detected.<sup>21</sup> A similar conclusion was reached by the World Health Organization (WHO) Panel on prostate cancer screening.<sup>22</sup> The United States Preventive Task Force recommendations are consistent with the WHO and UICC Policy, as they concluded that the evidence is insufficient to determine whether the benefits outweigh the harm for a screened population.<sup>23</sup> Nevertheless, controversy prevails as

the American Cancer Society continues to recommend annual screening with PSA and DRE for men aged over 50 years.<sup>24,25</sup>

The biopsy rate in the present study of 5.12%, which was hospital based and conducted by urologists, was slightly higher than in other studies that were community based and conducted by general practitioners.<sup>11-18</sup> According to the National Saudi Tumor Registry, prostate cancer ranked 9th and 10th, and constituted 2.9% among male cancers in the 1994–1996 and 1997–1998 reports. In spite of the small number of Saudi males included in this screening program, the very low incidence of detected prostate cancer (1.17%) may support the general belief that prostate cancer is not a common disease among the Saudi population. This requires further verification by performing a population based study for prostate cancer in Saudi Arabia.

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