Acta Oncologica Vol. 30 No. 2 1991

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SCREENING FOR CARCINOMA OF THE PROSTATE IN A RANDOMLY SELECTED POPULATION USING DUPLICATE DIGITAL RECTAL EXAMINATION

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Abstract

Of 9 026 males, aged 50–69 years, 1 494 were randomly selected and invited to participate in a screening programme for carcinoma of the prostate. Of these 1 163 (78%) accepted. Rectal examination was performed independently by a general practitioner (GP) and by a urologist at the GP's surgery. Carcinoma of the prostate was suspected by one or both physicians in 45 cases, and subsequently confirmed by cytological investigation in 13 cases. Ten patients underwent radical prostatectomy, one received radiation treatment, one case was too advanced for curative treatment, and one was scheduled for subsequent reassessment. Screening, as a means of early diagnosis of carcinoma of the prostate by either a urologist or a GP, using digital rectal examination, thus appears to be a cost-effective procedure, though the question still remains whether this will lead to prolongation of survival or not.

Key words: Prostate cancer, screening, digital rectal examination.

Cancer of the prostate is an increasing problem in many countries. The Scandinavian countries have a relatively high incidence and it is highest in Sweden, where carcinoma of the prostate accounts for 23% of all newly detected cancers among men (1). It is thus the chief form of cancer in Sweden and the most common cause of death from neoplasm in men (2). At present it is only the early detection by screening in combination with effective treatment that might provide a means of reducing the mortality of prostatic cancer. In order to show that screening reduces mortality from prostatic cancer, however, it is essential to carry out a controlled study comparing a screened and treated risk population with an unscreened. This requires random selection of a high-risk population and a long follow-up period.

The only established non-invasive method of diagnosing prostate cancer today is digital rectal examination. This is the simplest method, and any doctor can perform it. It has been accused, however, of being subjective and difficult to record accurately, and no study has been carried out as to whether the examination should be performed by a urologist or a general practitioner (GP). Our study was designed to evaluate an organization model, and to study the cost, acceptance, and psychological consequences of a screening program in a randomly selected population.

Material and Methods

A total of 1 494 men were randomly selected from a population of 9 026 men aged between 50 and 69 years, from the City of Norrköping, Sweden. This represented the total male population in this age group within the chosen geographical unit.

An invitation was sent to the men selected. The examinations were performed at Primary Health Care Centres with the men standing and supported on their fore arms with the knees flexed and pronated. A senior urologist and a GP performed the examination independently and all findings were recorded.

A firm nodular consistency was the main criterion of malignancy. Prostates with consistency only slightly diverging from the normal, such as slight induration, were

Presented at the Conference on Early Prostatic Cancer. The WHO Collaborating Centre for Urological Tumours, Karolinska Hospital, Stockholm, March 21–23, 1990.

Accepted for publication 2 October 1990.

classified as benign, and were not examined further. If one or both of the examiners suspected malignancy, the examined person was informed immediately, and fine-needle aspiration biopsy, 3 aspirates from each lobe (total 6), performed one week later by an experienced cytologist. The man was told the cytological diagnosis after yet another week.

Each man was asked about discomfort in connection with the digital rectal examination and filled in a questionnaire concerning any mental stress experienced during the weeks before and after the biopsy, the stress involved in the procedure and the information given.

The time required for the examination, travelling time and cost, and loss of income were recorded. The costs were calculated from the internal accounts of the health district administration and an estimate of travelling expenses.

Results

Of the 1 494 mean contacted, 1 163 (77.8%) came for examination. The highest acceptance rate was found in the age group 60–64 years (Table 1). In 45 cases (3.9%) malignancy was suspected and fine-needle aspiration biopsy was carried out in all but one who declined. Carcinoma was confirmed in 13 of these 44 cases (29.5%).

The prevalence of cancer increased with increasing age, the highest figure being 2.9% in the oldest group. The overall prevalence of carcinoma was 1.1% (Table 1). Using the TNM classification (3) one patient belonged to clinical category T1, 11 to T2, and 1 to T3. As regards the grade of malignancy, 7 patients were classified as G1 and 6 as G2. One patient had distant metastases (Table 2). Two patients showed cellular atypia only, and in none of them did repeated aspiration biopsy 3 months later reveal

Table 1

Results of duplicate screening (GP and urologist) for carcinoma of the prostate

Age (years)	Random. select. n	Accept. rate %	Slight indur. %	Nodular consist. n	%	Aspiration biopsy n	%	Confirmed cancer n	%
50–54	357	73.5	10.6	4	1.5	4	1.5	0	0
55–59	360	76.3	16.7	6	2.2	6	2.2	2	0.7
60–64	393	81.4	14.4	15	4.7	14	4.4	2	0.6
65–69	384	79.6	23.5	20	6.5	20	6.5	9	2.9
Total	1 494	77.8	16.5	45	3.9	44	3.8	13	1.1

Table 2

Results of the pretreatment investigations (13 cases), operative lymph node staging (11 cases), histological classification of the specimen (10 cases), and treatment (13 cases). Tumour classification according to WHO 1987 (3)

Patient age (years)	Pretreatment classification (3)			Postoperative classification				
	T palp	N	M	Grade of malignancy	N	pT	Gleason score (6)	Treatment
66	2	0	0	2	0	3	VII	RP/PRT
56	2	0	0	2	0	–	–	RT
68	2	0	0	2	0	2	V	RP
67	2	0	0	2	0	3	VIII	RP/PRT
66	2	0	0	1	0	3	V	RP/PRT
62	2	0	0	1	0	2	VI	RP
62	2	0	0	2	0	3	VII	RP/PRT
66	2	0	0	1	–	–	–	No treat
68	1	0	0	1	0	2	VI	RP
68	3	0	1	2	–	–	–	Endocrine
59	2	0	0	1	1	3	VII	RP/PRT
67	2	0	0	1	0	3	VII	RP/PRT
67	2	0	0	1	0	3	VII	RP/PRT

T palp = Primary tumor palpable by digital rectal examination,
pT = Histological classification of the specimen,
RP = Radical prostatectomy,
RT = Radiation therapy,
PRT = Postoperative radiation therapy.

evidence of carcinoma. The palpation of slight induration, judged to be benign, was noted in 16.5% of all the examined men (Table 1).

In 24 cases, carcinoma of the prostate was suspected by both clinicians, in 10 cases by the GP alone, and in 10 cases the urologist alone. Of the 13 diagnosed carcinomas 8 were suspected by both clinicians, 1 carcinoma by the GP alone and 4 by the urologist alone. The overall positive predictive value was (13/44) 0.30; 0.27 for the GP and 0.35 for the urologist. The sensitivity and specificity of the method cannot be calculated since the true prevalence of the disease is unknown.

The 13 patients found to have carcinoma were offered further investigation and appropriate treatment. Ten patients were treated with radical prostatectomy and 1 by radiotherapy. One patient with advanced disease was given endocrine treatment and another had concurrent disease and was not treated (Table 2). Ten men were examined per hour. The direct cost including salaries, material, and rent was estimated to be USD 23,333, or USD 20 per examination (USD 1 = SEK 6). The additional cost of aspiration biopsy was USD 5,714, or USD 130 per examination. The total direct cost for the screening program, including fine-needle aspiration biopsy and travelling expenses, was USD 36,555, or USD 2,812 per detected cancer (USD 3,323 per case treated by a potentially curative method).

The indirect cost is represented by the participating men's loss of working and leisure time. For the 43% of men examined during working time the expenses were calculated from the average earnings including social costs.

For those examined outside working hours and for retired men, the indirect cost was calculated from figures obtained from the British Ministry of Transport (4). This cost amounted to USD 10,349, or USD 9 per man examined, including fine-needle biopsy. The total cost for the screening program was USD 46,905, or USD 4,264 for each cancer that could be treated by a potentially curative method.

As regards the first examination the younger men complained more of distress than the older ones, but most persons experienced no distress at all (Table 3). Of the 44 men who were recalled due to suspicion of malignancy, 58% were anxious during the week of waiting, 9% had nightmares and 40% were more nervous than normal. While waiting for the cytologist's report 71% felt anxiety and most were more nervous than normal.

Table 3

Judgement by the men selected regarding distress in connection with screening by digital rectal examination

Age (years)	Major distress %	Minor distress %	No distress %
50–54	3.9	14.7	81.4
55–59	4.7	18.0	77.3
60–64	3.8	13.3	82.0
65–69	0.7	8.4	91.0
Total	3.2	13.4	83.4

Discussion

The early diagnosis of prostatic carcinoma is a prerequisite for cure. Unfortunately, symptoms appear late and self-examination is not possible. Screening programs have been suggested, but have so far not been studied in controlled trials. The present investigation was based on random selection of men aged 50–69 years. Prolonged survival of men over 70 years treated by potentially curative methods can hardly be expected.

The present study shows that nearly 80% of all men invited agreed to participate. We find this acceptance rate high, and similar to that in mammographic screening for breast cancer in Sweden (5).

This investigation shows that a program for early detection of prostatic carcinoma can be organized as an integral part of the routine health service. We are convinced that with further training the GP's positive predictive value will rise to the level attained by the urologist.

If larger populations are to be examined, there will be major demands on the responsible sector of the health system. Also staffing and resources of the urology, oncology and cytology departments will be affected.

Our study indicates how a screening procedure can be designed. So far, however, there is no evidence from randomised studies that early detection of prostatic carcinoma and the application of potentially curative treatment prolong survival.

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