Prostate Cancer

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Dedicated out-patient follow-up of patients with prostate cancer: a four-year review

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Introduction: A combined uro-oncological clinic for patients with prostate cancer enables disease progression to be monitored and specialist care to be provided efficiently. This study, undertaken in a district general hospital, reviews the diagnostic and therapeutic activity undertaken for patients with prostate cancer and examines patterns of clinical and PSA progression with respect to age, stage and initial treatment.

Patients and methods: Patients with carcinoma of the prostate who attended a dedicated uro-oncological clinic run by a consultant urologist and oncologist between 1991 and 1995 were evacuated. They included the majority of such patients within the district under urological follow-up. Demographic, clinical and therapeutic activity were recorded prospectively throughout this period on a standard proforma.

Results: A total of 256 patients (mean age 73 years) were followed for a mean period of 20·0 months. Among 76 managed by watchful waiting, 21 (28%) progressed after a median of 10 months; 141 patients were initially treated by endocrine manipulation and 39 (28%) progressed after a median of 15 months. Thirty-one were treated by radical radiotherapy, and of these six (19%) progressed after a median time of 22 months. Following clinical progression, the mean duration of follow-up was 8·5 months, representing 2·7 visits.

Conclusion: Following treatment for prostate cancer, the need for further intervention most frequently arose during the second or third year and patients became increasingly likely to need further treatment with longer survival. Within the first year, progression was mostly due to hormone refractory disease. These findings have important implications for the follow-up of patients with prostate cancer.

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Anxiety in prostate cancer screening

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Introduction: Prostate cancer screening has been criticized for causing anxiety in an asymptomatic population. This study aimed to ascertain the extent of anxiety felt by individuals approached for inclusion in an early detection programme for prostate cancer.

Subjects and methods: A community-based study was performed by this department, where men between the ages of 55 and 70 years of age were invited to attend for a prostate health check. Men were seen in the GP's practice, where a rectal examination and PSA test were performed. A total of 4060 men were invited, with 2078 choosing to attend. Following this study, a questionnaire was sent randomly to 278 patients, with 47 attenders replying (75%) and 46 non-attenders (21%). The questionnaire was compiled following a literature search of any previous screening studies.

Results: The results showed that anxiety did not appear to be a major factor in men who chose to attend with 66% (31) stating no anxiety felt. Amongst the non-attenders 51% (23) did not consider anxiety as a factor for non-attendance. The reasons for anxiety, consistent in both groups, included: the screening process, the examination and the possibility of cancer. Interestingly the attenders were more concerned with the screening process and the possibility of cancer whereas the non-attenders found the examination most worrying. The study identifies possible reasons for these differences.

Conclusions: Recommendations following the study include better communication links, improved practical aspects and patient information, all aimed at reducing the anxiety felt by individuals. We conclude that anxiety should not be considered as major an obstacle to screening, as previously thought.

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The use and abuse of prostate specific antigen

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Introduction: The PSA test, in combination with DRE, may be used to detect prostate cancer. Increasingly, PSA tests are being performed by GPs and non-urological specialists.

Methods: All PSA requests within the South Tees District were audited over a 3-month period. A questionnaire was sent to the doctor who requested each test, asking for data regarding the patient and the reasons for requesting the test.

Results: A total of 899 PSA tests (age range of patients 23–98 years) were performed: 49% were requested by GPs, 33% by urologists and 18% by other hospital specialties and 93% of GPs and 73% of hospital specialists returned the questionnaire. The reasons for requesting a PSA test varied amongst the three groups: GPs tested patients with 'prostatic' symptoms, hospital specialties favoured 'screening', the majority of urologists requests were for known or suspected prostate cancer; 54% of GPs and 48% of non-urologists performed a DRE. The effects of the PSA result on patient management were variable.

Conclusion: GPs participated in the study with great enthusiasm. They expressed some uncertainty in the interpretation of PSA values in a number of clinical situations. The importance of modestly raised PSA values in young men was often not appreciated and too many elderly men were being 'screened'. Many doctors performed a PSA test instead of DRE. As a result of this study, local guidelines have been published in an effort to rationalize the use of PSA.

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Prostatic intra-epithelial neoplasia (PIN), on needle biopsy: a problem for the urologist

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Introduction: High-grade prostatic intra-epithelial neoplasia (PIN) is reported to be often associated with prostatic carcinoma and is considered by some to be a pre-malignant condition. In spite of this association, the management of this condition remains controversial. The aim of our study was to assess the presentation and behaviour of high-grade PIN and from our findings formulate a protocol for managing these patients.

Patients and methods: A total of 2078 men (aged 55–70 years) participated in this study on the basis of an abnormal DRE or a PSA > 4 ng/mL and underwent TRUS and a biopsy. Men in whom high-grade PIN was found were followed up for a year with a PSA check every 3 months and needle biopsy repeated after 6 and 12 months.

Results: Fifty-two men were found to have PIN, the overall detection rate being 2·5%. The cancer detection rate in this group was 3·4%; 17 (32·6%) men had an abnormal PSA > 4 ng/mL, 23 (44·2%) had an abnormal DRE and 12 (23%) were biopsied, as they had a PSA rise of more than 1 ng/mL/year. The mean PSA of the PIN patients was 4·7 ng/mL which matched the benign group and was significantly lower than the patients with cancer, 8·36 ng/mL ($P < 0.001$). In terms of PSA density and PSA velocity (PSA change over 1 year) there was a significant difference between PIN and patients with cancer ($P < 0.001$). Thirty-eight men were evaluated further with repeat biopsies and cancer was detected in five (13·1%).

Conclusion: This study shows that the presence of high-grade PIN on needle biopsy does not necessarily indicate an underlying carcinoma. However, these men will require a long-term follow-up. We feel that following diagnosis, these men should have at least one follow-up systematic biopsy to rule out any cancer missed because of sampling error. PSA density, and in particular PSA velocity, should be used for further follow-up to identify individuals requiring further biopsies.

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Neural network analysis of prognostic markers in prostate cancer

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Introduction: Prostate cancer is unpredictable in its clinical course and biological behaviour, and current investigative methods are unable to predict disease progression. Artificial neural networks based on conventional clinical data have been shown recently to be useful in decision-making for patients with prostate cancer. The aim of this study was to investigate the ability of neural networks in predicting disease outcome in patients with different stages of prostate cancer, using a combination of conventional clinical and experimental laboratory criteria.
Methods: Data from 38 patients with confirmed prostate cancer was considered in this analysis. The data included nine prognostic factors: age, tumour stage, Gleason score, bone-scan findings, serum PSA, tumour ploidy, p53 nuclear protein accumulation and bcl-2 protein overexpression by immunohistochemistry, and the treatment administered (input neurons). Output neurons consisted of three possibilities: 1) immediate failure of treatment, 2) sustained response, and 3) disease progression. The network was trained on 19 randomly selected patients. The resulting trained network was then tested on the remaining 19 different test exemplars.
Results: Of the 19 test exemplars, 17 patients were classified correctly, with a sensitivity of 92·9% and specificity of 80%.
Conclusion: Despite the few patients used to date in this study, artificial neural network analysis has shown a promising ability to predict outcome in various stages of prostate cancer. This warrants further investigation into the possible use and optimization of neural networks in the management of patients suffering from this common but unpredictable malignancy.

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Two new tumour suppressor genes on chromosome 8p in prostate cancer

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Introduction: Allelic loss on chromosome 8p is recognized to be common in prostate cancer, but there is little consensus as to the loci of putative tumour suppressor genes. In addition, incidental prostate cancers have not been studied in any detail on 8p. The aim of this study was to examine a series of prostate cancers, using a number of incidental tumours, at multiple loci on 8p.
Materials and methods: Samples from 72 microdissected frozen ($n = 43$) and paraffin-embedded ($n = 29$) prostate cancers, including 26 incidental tumours, were examined for allelic loss using 16 microsatellite markers on chromosome 8p.
Results: Allelic loss was observed in 46 (64%) of tumours overall. Three specific regions of maximal loss were identified at: LPL (8p22), D8S259 to D8S505 and D8S255 to ANK1 (both at 8p11·1–21·1). Seventeen of 58 (29%) informative tumours had loss at LPL, 20/51 (39%) between D8S259 and D8S505 and 20/66 (30%) at D8S255 or ANK1. Overall, incidental cancers had allelic loss with approximately equal frequency to advanced tumours, but tumours with losses at D8S255 or ANK1 were more likely to be of advanced stage and high grade (9/45 M0 *vs* 11/23 M1 $2P = 0·025$ Fisher's exact test), suggesting that loss in this region is related to tumour progression.
Conclusion: These data show that allelic loss is common even in incidental prostate cancers and suggest that there are three putative tumour-suppressor genes for prostate cancer on chromosome 8p: at 8p22, between D8S259 and D8S505, and between D8S255 and ANK1. Furthermore, there is evidence that gene/s in the latter region may have some prognostic importance.

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Correlation of lymphocytic infiltration with HLA class I expression: evidence of immune regulation in prostate cancer

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Introduction: Recent work in advanced prostate cancer has demonstrated HLA class I down-regulation in 85% of primary tissue ($n = 47$) and all lymph node metastases ($n = 5$). Others have found an association between lymphocytic infiltrate and survival in localized, non-metastatic prostate cancer, suggesting a role for immune regulation of prostate cancer. Current proposals to extend gene/immunotherapy trials in animal models of prostate cancer to patients depends on the presence of a cellular immune response. This investigation has explored the relationship of lymphocytic infiltrate to HLA expression in metastatic and non-metastatic cancer.
Materials and methods: HLA class I expression was assessed by immunohistochemistry in both prospectively collected frozen sections and formalin-fixed archival (1980–86) prostate cancer. Lymphocytic infiltrate was assessed semi-quantitatively in haematoxylin and eosin-stained sections and by immunohistochemistry.
Results: Normal HLA class I expression was associated with a significantly greater infiltrate than cases with complete loss of class I expression. Seven percent of cases with normal HLA expression compared to 40% of those with complete class I loss had no evidence of lymphocytic infiltration. Preliminary results staining for lymphocytic differentiation markers confirm the presence of both cytotoxic and helper T cells within prostate cancer.
Conclusion: The significant correlation between HLA class I expression and lymphocytic infiltration would support a role for the cellular immune response in prostate cancer. It is likely that tumours with loss of HLA class I expression and an absence of lymphocytic infiltrate will respond poorly to gene/immunotherapy regimens reliant on a functioning cellular immune response.

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Quantitative assessment of prognostic factors in prostate cancer patients at initial diagnosis: the design of a prognostic index score

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Introduction: Many clinical trials in prostate cancer have produced conflicting results that leave many clinicians wondering what the best treatment modality for any given stage of the disease should be. A major reason for the confusion is the lack of incorporation of prognostic factors into the design of most of these studies.
Methods: Using multivariate analysis, we designed a hypothetical prostate cancer prognostic factors score at the time of initial diagnosis as shown in Table 1, where 1 is a most favourable status and 4 the least favourable status.

Prognostic factors/scores →	1	2	3	4
Age at diagnosis (years)	> 75	65–74	55–64	< 54
Stage at presentation (DRE ±TRUS)	T0–T1	T2	T3	T4
Performance status (Karnofsky/ECOG)	10/0	8–9/1	6–7/2	0–5/3
Histology (Gleason Score)	2	3–4	5–7	8–10
Prostate Specific Antigen (Normal 0–4 µg/L	< 20	21–60	61–100	> 101
Extent of disease on bone scan	0	1	2	3/4
Pretreatment serum testosterone (Normal 10–37 nmol/L	> 17·8	12·6–17·7	7·5–12·5	< 7·5
Prolactin (Normal 90–400 mIU/L)	< 100	100–250	250–400	> 400

A prostate cancer prognostic index (PCPI) Score (Table 2) was derived by adding the appropriate scores for each prognostic factor listed in Table 1.

Results: A review of two ongoing clinical trials (n = 68) in our unit as well as patients attending our prostate cancer clinics (n = 207) for up to 13 years, revealed that the implications of the PCPI score were probably best represented as shown in Table 2. Treatment consisted of radical prostatectomy (n = 13) and hormonal manipulation (n = 262).

PCPI Score	1-year survival, %	5-year survival, %	Effect of treatment
7–13	95	75	'Watchful waiting' – OK
14–20	80	35	Very good
21–26	50	25	Good
27–32	< 25	< 5	Ineffective

Conclusion: The quantification of prognostic factors in a disease of diverse biological behaviour such as prostate cancer is useful in identifying factors influencing survival and more importantly in the interpretation of clinical trials comparing different treatment modalities.

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The clinical results of radical prostatectomy

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Objective: To determine the clinical outcome of radical prostatectomy. Patients and methods: Ninety-eight patients were followed up for a maximum of 4 years after radical retropubic prostatectomy performed by two urologists using a nerve-sparing technique.
Results: *Quality issues*: There were no deaths but 16 peri-operative complications (four bleeding, three persistent urine leaks, six catheter problems, two deep vein thromboses, one lymphocoel, one pneumonia). There were nine anastomotic strictures, all but one responded to dilatation or bladder neck incision. Of 77 patients followed for at least 6 months, 43 men were completely dry, 24 had minor stress incontinence and 17 had significant leakage requiring more than 1 pad per day. Ten of these required an artificial urinary sphincter (AUS). Poor continence was associated with a previous TURP: of the 13 patients who had a previous TURP, four required an AUS. The overall rate of impotence was 57%, but was lower in patients under age 60 and in those who were fully potent pre-operatively. *Disease control*: 29 patients had a recordable PSA post-operatively and 13 patients developed progressive disease within 2 years. Forty-nine patients were found to have microscopic capsular penetration, 20 had recordable post-operative PSAs and nine developed progressive disease. Excision was histologically incomplete in 27 cases; 12 had recordable post-operative PSAs and five progressed. Poor results occurred with patients presenting with a PSA > 20 ng/mL or a high-grade tumour.
Conclusions: Nerve-sparing radical retropubic prostatectomy is a difficult operation with a steep learning curve during which there is significant morbidity. Long-term continence, potency and disease control may improve after a larger operative experience and with better patient selection.

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Can incontinence following radical prostatectomy be prevented?

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Introduction: Incontinence is a major problem following radical prostatectomy. To determine which factors may predispose to incontinence, two groups, one continent and one incontinent, were compared retrospectively, following radical prostatectomy.
Patients and methods: Group 1 consisted of 61 patients with incontinence following radical retropubic prostatectomy (RRP), and was

compared to a group of 100 continent patients who had undergone the same surgery (Group 2). The groups were analysed according to age, stage and grade of tumour, margin positivity, urological procedures before and after prostatectomy, radiation, and peri-operative blood loss.
Results: There were statistically significant differences between the groups in their mean ages: 66·5 years (Group 1) and 63·4 (Group 2) P < 0·05. Analysed by decade, 85·7% of patients under 50 years of age were continent, compared to only 38·9% over 70 (P < 0·05). Mean blood loss during surgery was 1548 mL (Group 1) and 1229 mL (Group 2) (P < 0·05). The number of patients irradiated following RRP differed significantly between the groups (P < 0·0483) and post-operative radiation was the most potent predictor of incontinence. There were more anastomotic strictures in Group 1 (19/61 vs 2/100). Although more incontinent patients had undergone pre-operative irradiation, transurethral resection and bladder neck incisions, the difference was not significant. High stage, Gleason score, positive margins or nerve sparing did *not* predict incontinence.
Conclusions: Age and post-operative irradiation were clearly associated with a higher incidence of incontinence, as was operative blood loss and anastomotic contracture. These factors will allow better informed consent to be given and hopefully prevent this problem.

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Is radical prostatectomy indicated in incidental prostatic cancer?

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Introduction: Radical prostatectomy is increasingly offered as a treatment for incidental prostatic cancer. A dilemma exists in offering such major surgery as the number of patients that ultimately die of prostatic cancer is unknown. A retrospective study was undertaken to establish the cause of death in these patients and to evaluate our present operative selection criteria.
Patients and methods: Patients with incidental prostatic cancer were identified from the unit database that contains over 10 years of data on all patients with prostate cancer. Their clinical condition, histopathology at presentation and ultimate outcome were recorded. These data were reviewed by the senior author (blinded to the outcome). Patients < 72 years of age with T0-2 disease and no major past medical history were 'offered' radical prostatectomy and compared with actual outcome.
Results: A total of 230 patients were identified: 123 were alive, 107 dead, 29 from prostatic cancer (38 cause unknown). When age-stratified, the most deaths from prostatic cancer (11) occurred for the presentation age-range 65–69 years, median survival 77 months (25·5–131), contrasting with 15 non-cancer deaths in the age range 76–80 years, survival 45 months (18·8–146·7). Of 103 files available for review, 27 of 103 patients were 'offered' radical prostatectomy. Of these, eight were alive with no symptoms or evidence of progression, 13 had symptoms or progression (six requiring treatment), six died (five from prostatic cancer).
Conclusion: The mortality figures for prostatic cancer suggest there is a case for radical prostatectomy in selected cases. We feel our present selection criteria adequately identifies appropriate patients.

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Conventional radiation therapy for the treatment of prostate cancer: analysis of long-term results

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Introduction: Radiation therapy and radical prostatectomy are the only potentially curative treatments for localized prostatic carcinoma which represents the second most common cause of death from malig-

nancy in men. A retrospective study was performed to assess the long-term outcome of external beam radiation therapy in clinically confined prostate cancer. End-points were survival time, local control and development of metastases.

Patients and methods: The study included 250 men with T1-4NxM0 prostate cancer treated by external beam radiation therapy between 1985 and 1994. The median follow-up was 42 months. Failure was defined as a PSA level > 1 ng/mL at ≥ 2 years after radiation, local recurrence or distant metastasis. Multivariate analysis was used to assess outcome.

Results: The 5-year survival for the T1/2 (Gleason 2–5) group was 64%, for Gleason 6–7 was 61% and for Gleason 8–10 as 45%. The 5-year disease-free rates for the same groups were 54%, 47% and 27%, respectively. For the T3/4 group, the 5-year survival and disease-free rates were considerably lower. Compared with historical controls, the T1 (Gleason 2–5) group showed no positive benefit from radiotherapy. Patterns of disease presentation over the 10 years are changing. Younger patients are presenting with early disease. In locally advanced T3-4NxM0 androgen deprivation following radiation resulted in improved local control and survival.

Conclusion: Stage and grade were important in determining the rate of relapse. Overall the results of radical radiation therapy were not encouraging. The introduction of PSA testing has changed the outlook.

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Hormone therapy in advanced prostate cancer – report of the Medical Research Council 'immediate' versus 'deferred' treatment study

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Patients and methods: In a multi-centre study, 938 men with asymptomatic advanced prostate cancer (CaP) were randomized to immediate hormonal treatment (IMM) or to deferred treatment (DEF). Recruitment finished in 1993. Data to March 1995 are included in this abstract; a further year of follow-up will be available for the presentation.

Results: Treatment: 341 of 465 DEF patients have undergone treatment, 50% of M1 patients within 1 year and 50% of M0 patients in 2 years. Forty-nine patients died from causes other than CaP without treatment but 24 died from CaP before they could be treated.

Progression: the development of metastases in M0 patients and metastatic pain occurred more rapidly in the DEF group. Sixty-two IMM, and 136 DEF patients underwent a TUR during follow-up. Ureteric obstruction occurred in 32 IMM and 52 DEF. Other serious complications (e.g. spinal cord compression – nine in IMM, 23 in DEF), were twice as common in DEF patients.

Deaths: Overall, of 623 deaths (303 in IMM, 320 in DEF) 68% were due to CaP. In patients with M0 disease, 73/254 IMM and 99/244 DEF have died from CaP, ($\chi = 7.69$).

Conclusion: If hormonal treatment of advanced CaP is deferred, 10% of patients will avoid treatment before dying from other causes. Treatment will be delayed on average for 1 year in those with metastatic disease and 2 years in non-metastatic disease. However, progression with development of symptoms (bone pain, recurrent outflow obstruction) will occur more rapidly if treatment is deferred, and the chances of developing serious complications, such as spinal cord compression, is doubled. Prostate cancer deaths occur more rapidly in deferred patients with M0 disease, although the survival data are immature and further follow-up is needed.

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Prostatic growth stimulation and binding by human bone marrow: mechanisms of metastatic spread in prostate cancer

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Introduction: Bone metastases from prostate cancer are a major clinical problem. This study examines the mechanism of skeletal metastatic spread using an in vitro model which co-cultures human prostate epithelial cells (PEC) in human bone marrow stroma (BMS).

Materials and methods: Prostatic epithelial cells were isolated from men undergoing prostatectomy for benign hyperplasia (BPH, n = 13) and prostate cancer (CaP, n = 10). Prostatic fibroblasts (PF) were also isolated from the same patients. Cultures of BMS, PF and bone marrow extra-cellular matrix (ECM) were seeded by 5000 prostatic epithelial cells/culture well. Growth and cell-binding characteristics were assessed objectively using microscopic counts of colony size and number and by binding assays. Subjective evaluation used scanning electron and time-lapse video microscopy.

Results: Malignant epithelial growth was significantly greater in BMS than control for colony number and size (BMS colony area $2.1 mm^2$: control 0.3; $P < 0.005$). Epithelia from benign prostates behaved similarly but no effect was observed for CaP or BPH cells in culture, with ECM strongly suggesting a requirement for cell–cell interaction. Binding assays showed preferential prostatic epithelial binding to BMS. Dynamic microscopy revealed the marrow colonization process as both active and invasive, involving close cellular contact.

Conclusion: Human bone marrow preferentially binds prostatic epithelial cells stimulating clonal expansion. The process of cellular growth and invasion is dynamic and requires intimate cell–cell contact.

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Antegrade stenting in ureteric obstruction due to carcinoma of prostate. Is it worthwhile?

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Introduction: Bilateral ureteric obstruction and uraemia occurs in 3% of patients with locally advanced prostate cancer. Left untreated, death by uraemia results. Advances in interventional radiology allows successful relief of obstruction by nephrostomy and antegrade stent insertion, with no morbidity and mortality. The aim of the study was to investigate the survival, life quality and cost-effectiveness of antegrade stent insertion in advanced prostate cancer.

Patients and methods: Between 1991 and 1995, 22 patients were admitted to Southampton General Hospital with ureteric obstruction due to prostate cancer. All underwent nephrostomy and stent insertion. Life quality, survival and cost per procedure were analysed. Patients were grouped according to their previous treatment status.

Results: Fifteen patients had received previous hormone treatment, and the rest were untreated and newly diagnosed. There was no difference in the histological differentiation and bone-scan status between the groups; 17 patients had stent insertion and in five stent insertion was technically difficult. Median survival was 17.8 months in patients who had no previous hormone treatment and 11 months in patients who had previous hormonal manipulation. Life quality was equal in both groups, with most having independent, pain-free ambulant life at home.

Conclusion: Relief of ureteric obstruction should be considered in well-maintained patients with prostate cancer irrespective of their treatment status. Good quality pain-free life could be achieved in most. The procedure is cost-effective and stents can be easily changed by the antegrade route. Cystoscopic stent change is rarely successful.