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Identifying and managing men with early prostate cancer

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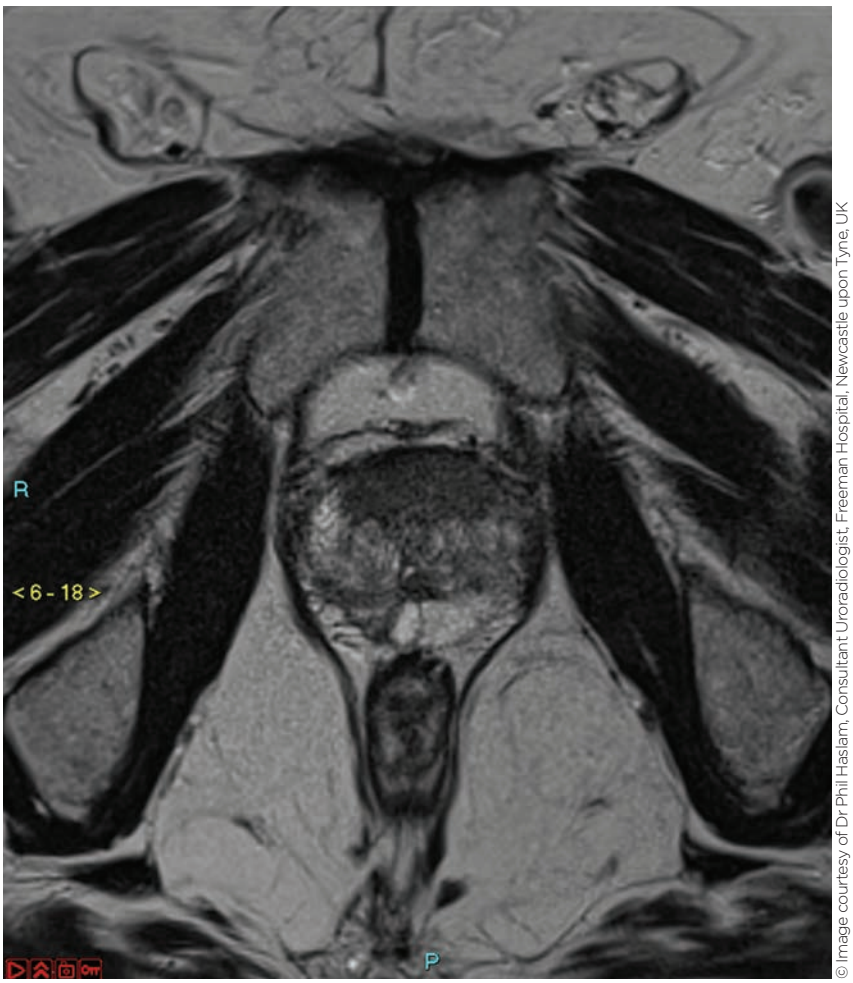

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FIGURE 1
Axial T2 weighted MRI image illustrating an anterior prostate tumour

How should diagnosis be confirmed?

What are the management options?

How should patients be followed up?

PROSTATE CANCER IS THE MOST COMMON CANCER IN MEN IN THE UK. IN 2015, 47,151 MEN WERE NEWLY diagnosed with prostate cancer and currently men have a 1 in 8 lifetime risk of being diagnosed with the disease.[1]

GPs have a vital role to play in identifying men with prostate cancer. GP referral is the route by which the highest proportion of prostate cancer cases are diagnosed at an early stage. Currently in the UK at least 4 in 10 prostate cancer cases are diagnosed at a late stage. When prostate cancer cases are identified as an emergency presentation, more than 70% have advanced disease when treatment options may be more limited.[1]

The diagnosis and management of prostate cancer is evolving towards targeted individualised treatment.

PRESENTATION

As most men age prostate enlargement occurs and many men will experience lower urinary tract symptoms as a consequence which may lead them to consult regarding their risk of prostate cancer. Common symptoms that may trigger a discussion regarding prostate cancer include:

- Urinary frequency
- Weak or interrupted flow or the need to strain to empty the bladder
- Haematuria
- Nocturia
- Haematospermia
- Erectile dysfunction
- Discomfort during urination

Asymptomatic men may request an assessment of their prostate cancer risk because of a family history or in response to awareness campaigns or stories in the media. It is important that these men are not dismissed without exploring their reasons for presenting, eliciting their fears and explaining their options for further investigation.

RISK FACTORS

The underlying cause of prostate cancer is currently poorly understood although genetic and environmental factors are likely to contribute. A number of factors are associated with an increased risk of the disease:

Age: The risk of prostate cancer increases as men get older, most men are diagnosed over the age of 50 years[2] »

Ethnicity: Prostate cancer is more common in black men. These men have a lifetime risk of 1 in 4 of developing the disease[3]

Family history: The risk of prostate cancer is increased if a first-degree relative has been affected particularly if the relative was under 55 at diagnosis.[4] Approximately 5-10% of all prostate cancers are likely to be associated with gene mutations.[5] One example of such a genetic link which is being investigated in British men is BRCA1 and BRCA2 mutations seen in breast cancer patients. Although we are aware that inherited DNA repair gene mutations such as BRCA are more prevalent in men with advanced prostate cancer the clinical implications are not fully understood. Currently genetic testing is not offered outside the confines of clinical trials or selected '100,000 Genomes Project' centres. Men with these mutations have been shown to have poor survival outcomes.[6]

Obesity: Men who are overweight are at increased risk of being diagnosed with more advanced prostate cancer.[7]

PSA TESTING

A raised prostate specific antigen (PSA) level can confer a higher suspicion that a prostate cancer might be present. However, the PSA test is not specific for prostate cancer, raised levels may be caused by non-cancerous factors such as inflammation or benign enlargement. Despite its limitations the PSA is currently the best and most established method available for identifying men who might have prostate cancer at a stage when treatment options and survival outcomes may be better. Situations in which a PSA test should be deferred are listed in table 1, below.

The UK currently operates an 'informed choice approach' in asymptomatic men over 50 years and men at increased risk of prostate cancer. The aim of this approach is to ensure men are adequately counselled about the risks and benefits of undergoing the test prior to making their choice about having a PSA test.

Public Health England guidance to help primary care teams give balanced information about the PSA test is available at the Prostate Cancer Risk Management programme online.[8] Decision aids and information leaflets are available for men wishing to consider undergoing a PSA test.

Prostate cancer screening using the PSA test is currently not supported by the UK National Screening Committee, the European Association of Urology or the United States Preventive Services Task Force.

PSA screening remains controversial because the mortality and quality of life benefits of treatment may be outweighed by the harms from overdetection and overtreatment of clinically insignificant disease. A number of large well conducted studies with long term follow-up have reported results recently which can be helpful when counselling patients. These have been summarised in box 1, below.

It is important to explain to men that a PSA test is just the first step of a journey to investigate their risk of having prostate cancer. Men referred to a urology department with an abnormal PSA according to local criteria will be reviewed by a secondary care team with expertise in interpreting their PSA and prostate cancer management.

It is no longer routine practice that all men with an abnormal PSA will undergo invasive prostate biopsies. Additionally, in men where low risk or suspected clinically insignificant prostate cancer is identified active surveillance is the nationally accepted primary management option.

Table 1

When to defer a PSA blood test

- If a man has not been counselled about the PSA test
- In the presence of an active urinary tract infection
- If ejaculation has taken place in the past 48 hours
- If vigorous exercise has taken place in the past 48 hours
- If a prostate biopsy has been performed in the previous six weeks

Box 1

Recent PSA screening trial outcomes

- The ERSPC trial was a European study that included 162,243 men who were randomised to either PSA screening at one-, two- or four-year intervals or no screening. At 13 years' follow-up a 21% risk reduction in prostate cancer mortality and a 30% risk reduction in metastatic disease was identified with screening. This benefit however came at a cost. The number needed to be investigated was 1,055 in order to diagnose 37 cancers to prevent 1 death.[9]

- The CAP trial was a UK study that included 419,582 men aged 50-69 years. Men were randomised to either a group receiving no invitation to undergo screening or a group receiving a single invitation to undergo screening in a nurse-led community clinic. The study found that there was no difference in mortality between the groups after a median follow-up of ten years. Thus there was no evidence to support a single PSA test used alone to screen for prostate cancer.[10]

- In a UK trial that included 1,000 men aged 40-75 years, men were randomised to either the use of a PSA decision aid or no decision aid. The study found men who used a decision aid were more informed about the PSA test but more likely to have less positive attitudes to the test.[11]

'The PSA test should be repeated prior to referral to secondary care'

REFERRAL

The NICE recommendations for referring men with suspected prostate cancer, via a suspected cancer pathway referral, are shown in box 2, opposite.

GPs should perform a digital rectal examination (DRE) in every case where a man presents with concerns about possible prostate cancer. Recent evidence has highlighted that DRE offers prognostic usefulness when the PSA is > 3 ng/ml.[12]

The PSA test should be repeated prior to referral to secondary care especially if any factors in table 1, left, have not been taken into account. A repeat PSA in a not insignificant proportion of men may show that the level has returned to within normal limits.[13] Once a decision to

undergo a PSA test has been made current evidence supports these men being offered further PSA tests at regular intervals after the initial PSA test.[9,10]

EARLY DETECTION

PSA alone is not enough to diagnose prostate cancer, a tissue diagnosis from a biopsy is mandatory for curative prostate cancer treatment options to be considered. A paradigm shift is currently taking place in the management of patients who are referred with suspected prostate cancer to try to reduce overdiagnosis and overtreatment of clinically insignificant prostate cancer. Although this evolution in practice is not yet reflected in formal guidelines it is now evident in widespread clinical practice and several UK led studies reported recently have driven this change.

Untargeted systematic transrectal ultrasound (TRUS) guided prostate biopsies, which up till recently accounted for more than 90% of prostate biopsies performed in the UK[14] have been shown to miss around half of clinically significant prostate cancers.

Multiparametric magnetic resonance imaging (MP-MRI) performed prior to prostate biopsy has been shown to have the potential to reduce the overdiagnosis of clinically insignificant prostate cancer without missing most clinically significant cases.[15] MP-MRI performed first followed by targeted prostate biopsies if abnormal lesions are identified on the MP-MRI has since been shown to improve detection of clinically significant prostate cancers but enable approximately 28% of men to avoid a prostate biopsy when compared with systematic biopsies alone.[16]

MP-MRI has also demonstrated particular utility in detecting anterior or apical tumours which are poorly sampled by traditional systematic TRUS biopsies, see figure 1, p11. The ability of MP-MRI to identify anterior prostate regions of interest is clinically relevant because it influences biopsy strategy thus enabling such areas to be better targeted. Transperineal prostate biopsies are considered better for targeting anterior prostate lesions and are associated with a lower infection risk when compared with TRUS prostate biopsies. The data indicate that use of MP-MRI prior to biopsy does not appear to be inferior to standard systematic prostate biopsies and may be superior.[16]

Recent reports from the National Prostate Cancer Audit illustrate that approximately 70% of centres in the UK have incorporated MP-MRI prior to prostate biopsy as part of routine practice.[17]

Although the evidence from recent studies highlights the potential benefits of pre-biopsy MP-MRI, for these to be realised in routine clinical practice across the NHS significant work needs to be done to standardise the conduct and reporting of scans to an equivalent quality of those centres included in the studies.[18] Additionally, capacity planning for diagnostic pathways and training of radiologists is necessary, this work is in progress. It has yet to be demonstrated whether pre-biopsy MRI as an intervention will translate into improved overall prostate cancer survival.

Evolution in prostate cancer diagnostic pathways in the future will almost certainly incorporate genomics and new biomarker blood tests to improve stratification of prostate cancer patients and guide treatment options.

MANAGEMENT

After a prostate cancer diagnosis is made, the secondary care uro-oncology multidisciplinary team (MDT) has several priorities:

- **To risk stratify the disease**

— The pathologist allocates a grade to indicate the likely risk of the disease identified based on the morphological appearance. The recently adopted ISUP prostate cancer grading system, in addition to the traditional Gleason grade, is shown in table 2, below. The aim of the transition to this classification system is to simplify and improve risk stratification.

— Imaging is also performed to ascertain the extent of local and distant spread. If no evidence of spread outside the prostate gland is demonstrated the prostate cancer is defined as localised disease.

- **To support the man diagnosed with prostate cancer**

Cancer nurse specialists play a vital role in supporting men through their cancer journey acting as a point of contact and supporting their holistic needs.

- **To guide men through their treatment options**

All new prostate cancer cases are discussed at an MDT meeting with at least core members present (radiologists, oncologists, surgeons and cancer nurse specialists). The MDT makes decisions regarding recommended treatment options for individual patients.

Men will be given the opportunity to discuss all their treatment options with their specialist team and this discussion »

Box 2

NICE referral criteria for men with suspected prostate cancer (NG12)

- Refer men using a suspected cancer pathway referral (for an appointment within 2 weeks) for prostate cancer if their prostate feels malignant on digital rectal examination (DRE)

- Consider a prostate specific antigen (PSA) test and DRE to assess for prostate cancer in men with:
— Any lower urinary tract symptoms, such as nocturia, urinary frequency, hesitancy, urgency or retention or
— Erectile dysfunction or
— Visible haematuria

- Refer men using a suspected cancer pathway referral (for an appointment within 2 weeks) for prostate cancer if their PSA levels are above the age-specific reference range

www.nice.org.uk/guidance/ng12

Table 2

Prostate cancer classification[19]

ISUP grade*	Gleason score	Morphological appearance
1	≤ 6	● Only individual discrete well formed glands
2	3 + 4 = 7	● Predominantly well formed glands with a lesser component of poorly formed/fused/cribriform glands
3	4 + 3 = 7	● Predominantly poorly formed/fused/cribriform glands with a lesser component of well formed glands
4	8	● Only poorly formed/fused/cribriform glands or ● Predominantly well formed glands with a lesser component lacking glands or ● Predominantly lacking glands with a lesser component of well formed glands
5	9-10	● Lacks gland formation (or with necrosis) with or without poorly formed/fused/cribriform glands

*ISUP = International Society of Urological Pathology

key points

SELECTED BY

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Prostate cancer is the most common cancer in men in the UK. Men have a 1 in 8 lifetime risk of being diagnosed with the disease. GP referral is the route by which the highest proportion of prostate cancer cases are diagnosed at an early stage. In the UK, at least 4 in 10 prostate cancer cases are diagnosed at a late stage. When prostate cancer cases are identified as an emergency presentation, more than 70% have advanced disease when treatment options may be more limited. Factors associated with an increased risk of the disease include age > 50 years, black ethnicity, a first-degree relative with prostate cancer, and obesity.

Patients may present with erectile dysfunction or lower urinary tract symptoms (LUTS) such as frequency, hesitancy, nocturia, or haematuria. However, LUTS may be due to benign prostate enlargement. Asymptomatic men may request an assessment of their prostate cancer risk because of a family history or in response to awareness campaigns. Asymptomatic men should be counselled about the risks and benefits of undergoing a PSA test prior to making a decision.

Repeated PSA screening at one-, two- or four-year intervals has been shown to reduce prostate cancer mortality and metastatic disease whereas a single PSA screening intervention did not reduce mortality. PSA testing should not be carried out in the presence of an active urinary tract infection, if ejaculation or vigorous exercise has taken place in the past 48 hours, or if a prostate biopsy has been performed in the previous six weeks. Digital rectal examination should be performed in all men presenting with concerns about possible prostate cancer. The PSA test should be repeated prior to referral to secondary care.

Untargeted systematic transrectal ultrasound (TRUS) guided prostate biopsies, which until recently accounted for more than 90% of prostate biopsies performed in the UK have been shown to miss around half of clinically significant prostate cancers. Multiparametric magnetic resonance imaging (MP-MRI) followed by targeted prostate biopsies if abnormal lesions are identified has been shown both to improve detection of clinically significant prostate cancers and enable approximately 28% of men to avoid a prostate biopsy.

PSA is an excellent test for monitoring prostate cancer patients after active treatment to identify recurrent disease at a stage where further treatment might be effective. After radical prostatectomy, successful treatment should result in a PSA which is either undetectable or < 0.1 ng/ml. A PSA rise to > 0.2 ng/ml is considered indicative of recurrent disease and should trigger a referral for specialist review. After radiotherapy, successful treatment should result in the PSA being very low. The definition of biochemical evidence of disease recurrence after treatment is a rise of ≥ 2 ng/ml above the lowest post-treatment PSA value. A rise above this level should trigger a referral for specialist review.

will include the side effect profile of the treatments in addition to the potential benefits before making their treatment decision.

Treatment options for localised prostate cancer

Active surveillance

Patients undergoing active surveillance will have ongoing tests, scans and consultations with their specialist at regular intervals to ensure that their prostate cancer has not spread.

If evidence of disease progression is demonstrated while on active surveillance treatment in the form of radiotherapy or surgery can be offered.

'External beam radiation has been shown to be more effective when given in combination with androgen deprivation therapy'

The aim of active surveillance is to enable men to avoid or delay the potential side effects from prostate cancer treatments safely which may include incontinence, erectile dysfunction and bowel problems.

Active surveillance is recommended for low-risk prostate cancer in men who are candidates for active treatment. Currently low-risk prostate cancer is defined as PSA < 10 ng/ml and Gleason score < 7 (ISUP grade 1) and cT1-2a.[25] In the UK National Prostate Cancer Audit Report for 2015-2016 only 8% of men with prostate cancer received potentially unnecessary treatment for low-risk disease indicating that clinicians are practising in accordance with national guidelines.[17]

Recent UK evidence suggests that 50% of men on active surveillance do not require treatment within ten years of their diagnosis.[20]

Radiotherapy

External beam radiation has been shown to be more effective when given in combination with androgen deprivation therapy (ADT). Patients choosing this treatment option will be started on ADT before radiotherapy and will continue this for a period after completing their radiotherapy course. External beam radiation usually involves 4-6 weeks of daily outpatient treatment.[21]

Brachytherapy is an alternative way to deliver radiation but from inside the prostate. Very small radioactive seeds are inserted into the prostate gland under anaesthetic. The seeds release radiation into the prostate slowly over a 6-12 month period. ADT is not routinely given in combination with brachytherapy, the nuances of this and whether additional external beam radiation is required would be discussed by the specialist at a consultation. The side effects of radiation include urinary symptoms, bowel symptoms, erectile dysfunction, fatigue and those associated with ADT. Loss of libido, erectile dysfunction, hot flushes, changes in body composition including weight gain and gynaecomastia are commonly recognised side effects of ADT.

Radical prostatectomy

Radical prostatectomy is now most commonly performed using a robot-assisted minimally invasive keyhole approach in the UK although conventional laparoscopic or open surgery is still carried out.[17] If the patient chooses to undergo surgery the surgeon should discuss their surgical approach and outcomes with them.

It has been shown that the experience of the surgeon rather than the surgical modality is the most important factor in oncological outcomes. There is no significant difference in oncological outcomes between the surgical techniques. Men undergoing minimally invasive surgery are more likely to have a shorter postoperative stay in hospital and less likely to receive a blood transfusion after surgery. Surgeon reported outcomes after radical prostatectomy are now published on line and patients can access this information.[22] The side effects of surgery include incontinence and erectile dysfunction.

Watchful waiting

Some men diagnosed with localised prostate cancer may suffer from

'It has been shown that the experience of the surgeon rather than the surgical modality is the most important factor in oncological outcomes'

significant comorbidity, which is more likely to impact on their life expectancy, and may not wish to undergo treatment after a prostate cancer diagnosis is made. Watchful waiting describes the conscious decision not to start treatment unless symptoms caused by prostate cancer develop. Close monitoring and follow-up is not performed in this situation.

High intensity focused ultrasound and cryotherapy

High intensity focused ultrasound and cryotherapy aim to eradicate prostate cancer by heating or freezing the prostate gland respectively. There is no long-term follow-up data for these treatments and thus they are not recommended by NICE as treatment options which should be routinely offered to patients outside clinical trials.[14]

FOLLOW-UP

As well as monitoring individuals' response to treatment and identifying and treating side effects, follow-up should also address men's holistic needs which may be physical, emotional or psychological. The care of patients beyond the diagnosis and treatment phases of cancer i.e. survivorship is increasingly important as the number of men living with and beyond a prostate cancer diagnosis continues to rise exponentially.[23] The role GPs can play in prostate cancer survivorship programmes has been described in a previous article in this journal.[24]

PSA is an excellent test for monitoring prostate cancer patients after active treatment to identify recurrent disease at a stage where further treatment might be effective. Although conventional follow-up of this patient group was predominantly hospital based contemporary practice is moving to models which facilitate remote follow-up in the community and patients are being empowered to self-manage their own follow-up where appropriate.

When stable prostate cancer patients who have undergone active treatment are discharged to primary care for follow-up a clear management plan should be detailed by the discharging team.

After radical prostatectomy, successful treatment should result in a PSA which is either undetectable or < 0.1 ng/ml. A PSA rise to > 0.2 ng/ml is considered indicative of biochemical evidence of recurrent disease and should trigger a referral for specialist review.[25] It is vital that primary care teams maintain robust systems to ensure that prostate cancer patients are not lost from follow-up. Ideally a recall system for PSA testing should be in place in the community.

After radiotherapy, successful treatment should result in the PSA being very low. The definition of biochemical evidence of disease recurrence after treatment is a rise of ≥ 2 ng/ml above the lowest PSA value after treatment. A rise above this level should trigger a referral for specialist review.[26]

CONCLUSION

The diagnosis and treatment of localised prostate cancer is evolving rapidly. Men presenting to their GP to discuss their risk of prostate cancer should be counselled so that they can make an informed decision about whether to undergo further prostate investigations.

Currently 85% of men in the UK diagnosed with prostate cancer are predicted to survive for five years or more, this represents an improvement on previous years' figures.

Competing interests: None

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Useful information

Cancer Research UK
www.cancerresearchuk.org

Prostate Cancer UK
https://prostatecanceruk.org

Macmillan Cancer Support
www.macmillan.org.uk

British Association of Urological Surgeons
www.baus.org.uk

The Urology Foundation
www.theurologyfoundation.org

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