The Practitioner®

Optimising the management of early prostate cancer

Aning J. Optimising the management of early prostate cancer.
Practitioner April 2020;264(1836):11-15

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Practitioner
Medical Publishing Ltd

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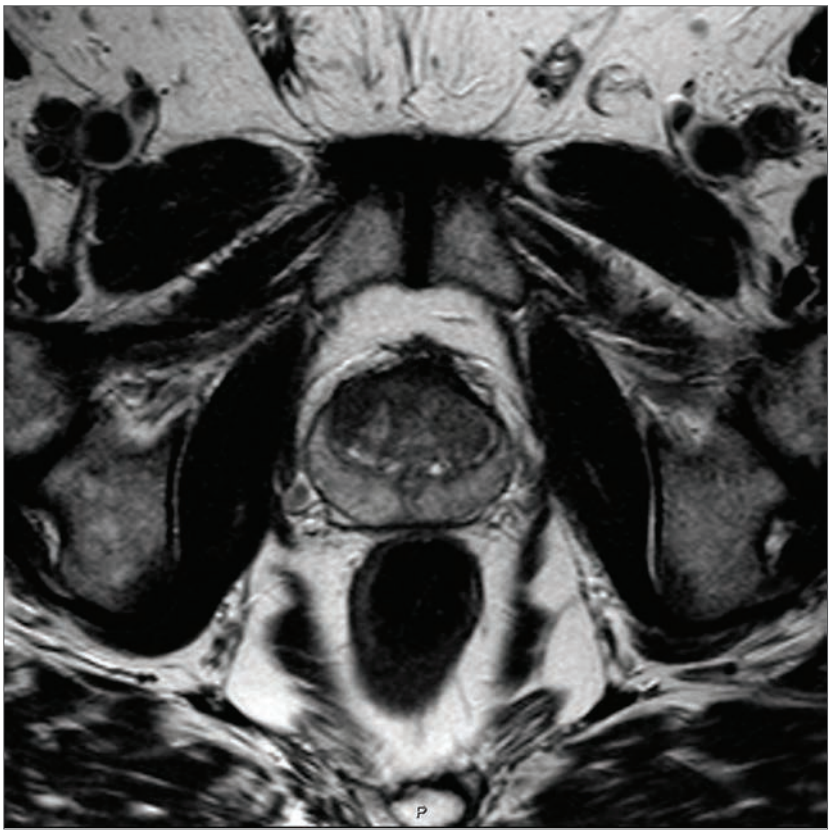

Axial MRI prostate demonstrating right peripheral zone prostate cancer

Which men are at increased risk?

How should patients be assessed?

What are the treatment options?

IN 2017, 48,600 MEN WERE DIAGNOSED WITH PROSTATE CANCER IN THE UK AND IT REMAINS THE MOST common male cancer. Men born after 1960 now have a 1 in 6 estimated lifetime risk of being diagnosed with prostate cancer.[1]

Despite improvements in diagnostic pathways and increased patient awareness, the number of men diagnosed at a late stage, when the disease is potentially less treatable, remains relatively static at around 4 in 10.[1] GP referral is the route by which the highest proportion of prostate cancer cases are diagnosed at an early stage.[1]

The prostate cancer management landscape continues to evolve, the evidence from several recently published studies has driven changes in practice which have been incorporated in the recently updated NICE guidelines for the diagnosis and management of prostate cancer.[2]

PRESENTATION

Most men with early prostate cancer attending their GP's surgery will have no signs or symptoms of the disease. Recent media coverage of celebrities speaking out about their prostate cancer diagnosis has encouraged many more men to seek medical advice if they have concerns or just to get 'checked out'.[3] Asymptomatic men may present because of awareness campaigns, experiences of family members and friends or after encouragement by a partner.

Common symptoms that lead men to present to their GP which should stimulate a discussion about prostate cancer risk are: problems with urination; blood in the urine or semen; erectile dysfunction (ED); pain in the hips, back, or bones; weakness or numbness in the lower limbs or loss of bladder control.

It is imperative that the man's reasons for attending are explored as well as his fears and understanding of prostate cancer risk. This is important even if your suspicion is that any lower urinary tract symptoms (LUTS) described are due to benign enlargement of the prostate. Many men do not know where the prostate is located or what its function is, and a brief explanation is often appreciated.

RISK FACTORS

The aetiology of prostate cancer is poorly understood but it is accepted that genetic and environmental factors are likely to contribute.

Factors known to be associated with an increased risk of the disease are: age, ethnicity, family history, gene mutations and obesity.

The risk of prostate cancer increases with age, most men are diagnosed over the age of 50 years.[4]

Prostate cancer is more common in Black African men. These men have a lifetime risk of 1 in 4 of developing the disease.[5] »

The risk of prostate cancer is increased if a first-degree relative has been affected particularly if aged < 55 years at diagnosis. Prostate cancer risk is 2.1-2.4 times higher in men whose father has/had the disease and 2.9-3.3 times higher in men whose brother has/had the disease.[6]

Approximately 5-10% of all prostate cancers are likely to be associated with hereditary gene mutations.[7] For example, men with BRCA2 mutations have been shown to be more likely to develop clinically significant prostate cancer and have poor survival outcomes.[8] If these men are screened using the PSA test more serious prostate cancers are detected in this population than in those who are non-carriers.[9]

Men who are overweight are at increased risk of being diagnosed with advanced prostate cancer.[10] The risk of advanced prostate cancer increases by 9% for every 5-unit increment in body mass index (BMI).[11]

EXAMINATION AND INVESTIGATION

An assessment of LUTS, relevant risk factors and past medical history are essential. Current guidelines recommend performing a digital rectal examination (DRE) to examine the prostate.[2] A DRE will give an impression of prostate size. If the prostate feels malignant on DRE this should trigger a fast track referral to secondary care, via a suspected cancer pathway referral,[12] even if the PSA is normal. An abdominal examination is useful to exclude a palpable bladder, a sign of urinary retention, or other abdominal pathology and should be routinely performed.

If bothersome LUTS are described a midstream urine sample should be collected and dipstick analysis performed to exclude urinary tract infection (UTI). If a UTI is suspected a specimen should be sent for microscopy and culture.

NICE recommends that men over 50 years old who request a PSA should be fully informed about the test beforehand. It is important to explain to patients that the PSA test is not specific for prostate cancer, and that raised levels may be caused by other factors such as inflammation or benign enlargement.

The test should also be offered to men with LUTS or an abnormal DRE.[2] An elevated PSA may be associated with significant prostate cancer, and the test is used to stratify referral for further investigations. Men with PSA values above the age-specific reference range should be referred to urology urgently, via a suspected cancer pathway referral.[12]

Despite its limitations the PSA is still the best and most established method available for identifying men who might be at risk of having a significant prostate cancer at an early stage when treatment options and survival outcomes may be better.

Men should be reassured that not all individuals with an abnormal PSA will undergo invasive prostate biopsies. Where low risk or suspected clinically insignificant prostate cancer is identified active surveillance (disease monitoring) is the nationally accepted primary management option. Box 1, below, lists frequently asked questions about PSA testing.

CONFIRMING DIAGNOSIS

All men referred to urology with suspected prostate cancer will be reviewed either face to face or remotely by a member of the multidisciplinary team (MDT).

Men who would be eligible for curative treatment will routinely be offered a multiparametric magnetic resonance imaging (MP-MRI) scan of their prostate.[2] This technique is able to identify abnormal areas in the prostate, consistent with significant prostate cancer which merit further investigation, better than untargeted prostate biopsies alone.[17]

If MP-MRI is performed first and abnormal lesions are identified, targeted biopsies of these lesions improve the detection of clinically significant prostate cancer.[18] This NICE recommended pathway enables approximately 28% of men to avoid a biopsy when compared with the previous strategy of performing untargeted systematic biopsies alone.[18]

Men investigated using this pathway who are at low risk of having a significant prostate cancer will be counselled and discharged back to primary care for follow-up with triggers for re-referral. Generally men will be advised to get their PSA measured at 6 months and then every year with a trigger based on either PSA density (a PSA value which leads to the PSA density rising above 0.15 ng/ml/ml) or velocity (a PSA rise which is greater than 0.75 ng/year).[2] The PSA density is calculated by dividing the serum PSA level (ng/ml) by the volume of the prostate (ml). The prostate volume is normally measured from the MRI scan or transrectal ultrasound scan image. Both these parameters are indicative of significant prostate cancer.

PSA and MRI abnormalities alone are not enough to confirm a diagnosis of prostate cancer. A tissue diagnosis

Box 1

Frequently asked questions about PSA testing

What is the current position on prostate cancer screening in the UK?
There is no formal PSA screening programme in the UK. Evidence from the largest screening study to date which included more than 182,000 European men, aged 55-69 years, with 16 years of follow-up showed that PSA screening reduced the risk of prostate cancer metastases and mortality. The numbers needed to be invited to screening and to be diagnosed to prevent 1 death were 570 and 18 respectively.[13]

Do younger men benefit from PSA testing?
Data suggest that younger men potentially have the most to gain from early detection of prostate cancer. If a high-risk cancer is detected intervention will improve overall survival.[14]

If the PSA blood test is abnormal is there any value in repeating the PSA test?
Repeating the PSA test prior to referral to secondary care is valid especially if history and examination findings are consistent with infection or if the patient describes a factor that may have caused this such as a history of ejaculation within 48 hours of performing the test. A repeat PSA in a not insignificant proportion of men may return to within normal limits sometimes this will be unexplained.[15]

What is the value of a single PSA screening test?
Current evidence shows that a single PSA screening intervention in a UK population when compared with standard practice without screening does not lead to a significant difference in prostate cancer mortality at a median follow-up of 10 years.[16] Based on this a pragmatic approach should be that if a PSA is performed in primary care and found to be normal the PSA should be repeated at regular intervals.

is usually mandated for curative treatment options to be considered. Prostate biopsy is generally carried out under local anaesthetic using ultrasound guidance via the transrectal or transperineal route.

After a prostate cancer diagnosis is made, the International Society of Urological Pathology (ISUP) prostate cancer grading system[19] is used to risk stratify the disease (see box 2, below).

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

All new prostate cancer cases are discussed at an MDT meeting with at least core members (radiologists, oncologists, surgeons and cancer nurse specialists) present. Investigation results are reviewed and checked and decisions made regarding recommended treatment options.

Men will have the opportunity to discuss all their treatment options with their specialist team including the potential side effects as well as benefits before making a decision. Predict Prostate is an online individualised prognostic modelling tool endorsed by NICE for men newly diagnosed with non-metastatic prostate cancer to help them decide between conservative and radical treatment management strategies (see Useful information box, p15).

Cancer nurse specialists play a pivotal role, acting as a point of contact for patients and supporting their holistic needs.

LOCALISED PROSTATE CANCER TREATMENT

Active surveillance

Active surveillance is recommended for low-risk prostate cancer. NICE defines low-risk prostate cancer as: PSA < 10 ng/ml, Gleason score ≤ 6 and stage T1 to T2a. It is important to recognise that active surveillance is often considered for a broader group of patients than the defined low-risk criteria. In clinical practice, patients' comorbidities are taken into account in addition to their preferences and active surveillance can be offered to men with low volume intermediate-risk prostate cancer (PSA < 20 ng/ml, Gleason score 7 and stage T2) or men who choose not to have immediate radical treatment because of the potential side effects.

Patients have regular tests, scans and consultations to ensure that their prostate cancer has not spread. If evidence of disease progression is demonstrated either radiation or surgery can be offered.

The aim of active surveillance is to enable men to avoid, or delay, the potential side effects from prostate cancer treatments such as incontinence, ED and bowel problems.

Recently reported UK data from a randomised controlled trial showed that 50% of men on active surveillance (before the addition of MRI to the diagnostic pathway) did not require treatment within ten years of diagnosis.[20] Other long-term prospective series have demonstrated the safety of this approach within a 15-year timeframe.[21] Recommended protocols are described in current NICE guidance.[2]

Radiotherapy

External beam radiation is more effective when given in combination with androgen deprivation therapy (ADT). Patients will be started on ADT before radiation treatment and continue this for a period after treatment. External beam radiation usually involves 4-6 weeks of outpatient treatment on a daily basis during the week.[22]

In brachytherapy 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 should be discussed by the specialist. In high dose rate brachytherapy, temporary hollow needles are inserted into the prostate through which radiation is passed. The source of radiation is then removed. The side effects of radiation include urinary symptoms, bowel symptoms, ED, fatigue and those associated with ADT. Loss of libido, ED, hot flushes, changes in body composition including weight gain and gynaecomastia are commonly recognised side effects of ADT.

Surgery

Radical prostatectomy aims to cure prostate cancer by removing the prostate gland in its entirety. This is now most commonly carried out using a robot-assisted approach in the UK[23] although conventional laparoscopic and open surgery are still sometimes performed.

The surgeon will discuss the surgical approach and outcomes with the patient. It has been shown that the experience of the surgeon, rather than the surgical modality, is the most important factor in oncological outcomes.

Men undergoing minimally invasive surgery are more likely to have a shorter hospital stay and be less likely to require a blood transfusion after surgery.

Surgeon reported outcomes after radical prostatectomy are published on line and patients can access this information.[24] The side effects of surgery include incontinence and ED.

Watchful waiting

In watchful waiting treatment is not started unless symptoms caused by prostate cancer develop. Close monitoring is not carried out. Some patients with localised prostate cancer may have significant comorbidity, which is more likely to affect their life expectancy. Others may not wish to undergo treatment.

Other treatment approaches

High intensity focused ultrasound and cryotherapy aim to eradicate prostate cancer by heating or freezing the prostate respectively. Currently »

Box 2

The ISUP prostate cancer grading system[19]

Grade group	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

key points

SELECTED BY

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In 2017, 48,600 men were diagnosed with prostate cancer in the UK and it remains the most common male cancer. Men born after 1960 now have a 1 in 6 estimated lifetime risk of being diagnosed with prostate cancer. Common symptoms that lead men to present to their GP which should stimulate a discussion about prostate cancer risk are: problems with urination; blood in the urine or semen; erectile dysfunction; pain in the hips, back, or bones; weakness or numbness in the lower limbs or loss of bladder control.

Factors known to be associated with an increased risk are: age; ethnicity; family history with a first-degree relative affected; genetics such as BRCA2 mutations; and obesity. Most men with prostate cancer are diagnosed over the age of 50 years. Black African men have a lifetime risk of 1 in 4 of developing the disease. Prostate cancer risk is 2.1-2.4 times higher in men whose father has/had the disease and 2.9-3.3 times higher in men whose brother has/had the disease. The risk of advanced prostate cancer increases by 9% for every 5-unit increment in BMI.

NICE recommends that men over 50 years old who request a PSA should be fully counselled about the test beforehand. The test should also be offered to men with LUTS or an abnormal DRE. A prostate that feels malignant on DRE should trigger a fast-track referral to secondary care even if the PSA is normal. Men with PSA values above the age-specific reference range should also be referred to urology urgently, via a suspected cancer pathway referral. Men referred to urology with suspected prostate cancer who would be eligible for curative treatment will routinely be offered a multiparametric magnetic resonance imaging (MP-MRI) scan of their prostate. This technique is able to identify abnormal areas in the prostate, consistent with significant prostate cancer which merit further investigation, better than untargeted prostate biopsies alone. PSA and MRI abnormalities alone are not enough to confirm a diagnosis of prostate cancer. A tissue diagnosis is usually mandated for curative treatment options to be considered.

Localised prostate cancer treatment options include: active surveillance, radiotherapy by external beam radiation which is more effective when given in combination with androgen deprivation therapy, brachytherapy, and radical prostatectomy which is now most commonly carried out using a robot-assisted approach in the UK.

The primary aims of follow-up are to identify and treat side effects of therapy and to monitor response to treatment. PSA is used to monitor patients after active treatment. Following 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 an urgent referral. After radiotherapy, successful treatment should result in the PSA being very low. A rise of 2 ng/ml or more above the lowest value after treatment should trigger an urgent referral.

there are no long-term follow-up data for these treatments and thus they are not recommended by NICE outside clinical trials.[2]

FOLLOW-UP

The primary aims of follow-up after treatment of localised prostate cancer are to identify and treat side effects of therapy and to monitor individuals' response to treatment. It should also address men's holistic needs whether physical, emotional or psychological. The care of patients beyond the diagnosis and treatment phases of cancer is termed survivorship and is increasingly important as the number of men living with, and beyond, a prostate cancer diagnosis continues to rise exponentially.[25] The role GPs can play in prostate cancer survivorship programmes has been described in a previous article in this journal.[26]

PSA is used to monitor patients after active treatment. The aim of follow-up is to identify recurrent disease at a stage where further treatment might be effective. Although conventional follow-up was predominantly hospital based updated NICE guidance now recommends that after 6 months' follow-up, a remote follow-up strategy for men with a stable PSA should be considered.[2] In contemporary practice patients should be 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 and a clear management plan should be detailed by the discharging team.

Following 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 an urgent referral for specialist review.[27]

The rationale behind assessment and investigation in secondary care at this point is to establish whether or not any prostate cancer recurrence is confined to the pelvis. If there is no evidence of disease outside the pelvis then men may be offered more treatment with the intention of curing their disease. Such treatments are termed salvage treatments. After surgery (a radical prostatectomy) the most common salvage treatment is radiotherapy. Patients who have biochemical recurrence with no evidence of visible disease detected on imaging are counselled very carefully before making their treatment decision. All additional treatment carries a risk of side effects and the chance it may ultimately not cure their disease. Some men will have a greater probability of dying from other comorbidities or old age than their prostate cancer even if it has recurred. For these reasons many men may opt initially for close observation with PSA monitoring alone in secondary care.

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 or more above the lowest PSA value after treatment. A rise above this level should trigger an urgent referral for specialist review so that salvage treatments may be considered if appropriate. Surgery in the form of a salvage radical prostatectomy is the most common treatment offered after failed radiotherapy.[28]

CONCLUSION

During a patient's prostate cancer journey he may see numerous members of the secondary care team and receive a huge amount of information to process. For most men and their families their GP remains a trusted person who knows them well and as such can provide a valuable source of clear information, guidance and reassurance throughout the pathway.

GPs play a pivotal role once patients have made their treatment decision and are in long-term follow-up. GPs have expertise in managing patients with coexisting chronic medical conditions and supporting patients to lead as healthy and active a life for as long as possible. Prostate cancer survivors value a holistic approach and it is important for GPs to be aware of individuals' oncological, functional and psychological needs and where to signpost patients for additional support locally if required.

The American Cancer Society has issued guidelines for primary care physicians responsible for managing men with prostate cancer in the community. These provide a comprehensive summary of the evidence base for managing the wide variety of long-term effects survivors may present with.[29]

Competing interests: None

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Useful information

Public Health England
Prostate cancer risk management programme (PCRMP): benefits and risks of PSA testing.
www.gov.uk/government/publications/prostate-cancer-risk-management-programme-psa-test-benefits-and-risks

Predict Prostate
A decision aid tool for patients to help them choose their treatment strategy
www.prostate.predict.nhs.uk

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