Is there still a role for digital rectal examination in the prostate cancer diagnostic pathway in the COVID-19 and post COVID-19 era?

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ABSTRACT
Digital rectal examination (DRE) is routinely performed as part of a urology clinical assessment in patients with a clinical suspicion of prostate cancer. An abnormal DRE or a raised prostate specific antigen (PSA) level are part of the criteria for primary care referral to secondary care due to a suspicion of prostate cancer. The current Coronavirus-19 (COVID-19) pandemic has resulted in the rapid adoption of virtual consultations in the form of telephone or video consultations making clinical examination difficult. In the case of prostate cancer diagnostic pathways, often clinicians now rely on PSA measurements and MRI, where radiological services are available, without the requirement for a DRE. We discuss the limited role DRE has in the modern prostate cancer diagnostic pathway due to the widespread adoption of MRI particularly in the COVID-19 era.

The value of DRE in prostate cancer diagnosis has been questioned by historic reports. The Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial reported that the role of DRE is limited when PSA is <3 ng/ml [5]. The European Randomised Study of Screening for Prostate Cancer shows that DRE has a positive predictive value (PPV) of between 4% and 33% in detecting prostate cancer in patients with a PSA of <4 ng/ml [6]. A meta-analysis of DRE diagnostic performance for prostate cancer screening suggests a pooled sensitivity of only 53.2% [7]. This questions the role of DRE, a clinical test with a low sensitivity, as an assessment that cannot reliably exclude a diagnosis of prostate cancer.

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The uptake of prostate MRI has also revolutionised prostate cancer diagnostics. Recent efforts to reduce scanning time and the requirement for intravenous contrast while maintaining diagnostic performance have shown great promise and results of validation studies are eagerly awaited. The sensitivity of a prostate MRI outperforms DRE findings performed even by the most experienced clinicians.

NICE recommends that patients with an MRI Likert score of ≤2 and a PSA density of <0.15 ng/ml/ml or PSA velocity of <0.75 ng/year can safely be discharged to primary care for PSA monitoring without the need for prostate biopsy irrespective of DRE findings [1]. We feel where patients are increasingly having MRIs earlier in the two-week-wait pathway to minimise breaches, any additional clinical information that DRE provides does not alter management over the information provided by a MRI of the prostate.

Proponents for DRE would argue that it is cost effective, well tolerated by patients and in the hands of a clinically trained practitioner may increase the sensitivity of a PSA test in isolation. Data from meta-analysis suggest that the addition of a DRE increases the sensitivity of a raised PSA alone to identify prostate cancer from 72% to 90% [7]. However, this is based on a raised PSA threshold of >4 ng/ml in an era where widespread PSA testing was not adopted. We therefore believe the absolute increase in sensitivity that DRE offers is limited [7]. In fact, there could be drawbacks to performing DRE. It is estimated that 15.8% of men feared a DRE and 26.5% felt ashamed and this may add an additional barrier to seek medical care [8]. The specificity of DRE varies considerably between 18% and 99.5% highlighting that investigating patients with an abnormal DRE in isolation would result in a significant number of false positive cases.

Figure 1. NICE guidelines for suspected prostate cancer pathway [1].

Referral under suspected cancer pathway (within 2 weeks) for suspected prostate cancer if:
- Prostate feels malignant on digital rectal examination
- Prostate-specific antigen (PSA) is above the age-specific reference range

Multiparametric MRI
- Offer multiparametric MRI as first line investigation for people with suspected clinically localised prostate cancer.
- Do not routinely offer multiparametric MRI to people with prostate cancer who are not going to be able to have radical treatment.

Likert Score ≤ 2
- Consider omitting prostate biopsy, but only after risks & benefits
- For those with raised PSA
  - Repeat PSA at 3-6 months
  - Offer prostate biopsy if strong suspicion of cancer
  - Discharge to primary care if suspicion is low

Likert Score ≥ 3
- Offer mpMRI influenced prostate biopsy

Likert Score ≤ 2, *PSA & negative biopsy
- Repeat PSA at 3-6 months, AND
  - Offer prostate biopsy if strong suspicion of cancer
  - Discharge to primary care if suspicion is low

Likert Score ≥ 3
- Consider omitting prostate biopsy, but only after risks & benefits
- For those with raised PSA
  - Repeat PSA at 3-6 months
  - Offer prostate biopsy if strong suspicion of cancer
  - Discharge to primary care if suspicion is low

Positive Biopsy
- Stage disease

Negative Biopsy
- Discuss at MDT with view to repeat biopsy

*PSA & negative biopsy
particularly in patients with a PSA <4 ng/ml [6,7]. In patients with a normal age-specific PSA, subsequent investigations for suspected prostate cancer based on a DRE alone are likely to induce unnecessary anxiety, provide a low yield of detection of clinically significant cancer and increase healthcare expenditure [5,6]. Particularly relevant in the COVID-19 era, recent reports have suggested that a faecal-oral route may be a source of transmission for COVID-19. It is estimated that >50% of patients with known COVID-19 infection continue to harbour COVID-19 positive RNA in faecal samples for a mean of 11.2 days even after respiratory samples tested negative [9].

While there is a convincing argument that DRE has a limited role in modern prostate cancer diagnostic pathways due to widespread use of MRI, is the role of DRE truly dead? We believe DRE may provide clinically useful information in addition to PSA where MRI facilities may not be readily available. In the COVID-19 era, MRI services may be limited and patients with an abnormal DRE with a raised PSA may be triaged to urgent prostate biopsy. However, where MRI services are available, the need to perform a DRE routinely should be questioned and consideration should be given to remove this as a requirement from the current two-week-wait suspected prostate cancer pathway especially in patients with a PSA <4 ng/ml.

Disclosure statement

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