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Outcomes following implementation of symptom triggered diagnostic testing for ovarian cancer

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ABSTRACT

Objectives: UK is the first country to implement symptom triggered testing for suspected ovarian cancer (OC) following guidance from National Institute of Clinical Excellence in 2011. We evaluated its impact on cancer outcomes and implications on clinical practice.

Study design: This is a cohort study and we analysed data for all new urgent referrals for suspected OC from two large teaching hospitals using a prospectively collected electronic referral database, supplemented with clinical data from electronic records. We evaluated outcomes prior to (2011) and after (2013) implementation of guidance to evaluate stage shift, referrals workload and surgical procedures generated.

Results: Secondary care received 2185 new referrals from primary care for women with suspected gynaecological cancer in post guideline cohort. Of these, 217 women were referred for suspected OC. 90% of primary care referrals were not compliant with guidance. Following implementation of guidance, more women with OC were diagnosed through urgent referral (rapid access clinics): Almost double, 21 of the total 67 (31.34%) OCs in 2013 (post guidance) in comparison to only 11 of 69 OCs (15.94%) were diagnosed in 2011 (pre guidance) through urgent referrals, $p = 0.03$. The predictive value of detecting cancer through rapid access clinics increased, from 4.5% to 9.6%, $p = 0.04$; however, no stage shift was noted. Over 25% of patients underwent surgeries for non-malignant conditions in the post-guideline cohort. No increase was seen in workload of cancer clinics.

Conclusion: Implementation of Symptom-triggered testing is challenging in clinical practice. Such testing results in more patients with OC accessing expedited care pathways leading to streamlined routes of diagnosis and care. However, current implementation does not lead to stage shift in diagnosis and may not achieve significant mortality benefit.

Introduction

The lifetime risk of developing ovarian cancer is 1 in 54. It is the eighth most common cause of cancer death in women and the most common cause of death in a gynaecological malignancy [1]. Most patients will present at advanced stage, (stage III/IV) and the 5 year survival rate for this group is at best 40%. As with all cancers, ovarian cancer (OC) survival is stage dependent, with 5 year relative survival at 92% for localized disease (stage 1) vs. 27% with distant spread [2]. International cancer bench marking projects consistently report that OC survival in the UK is significantly lower than in other western countries [3]. This difference in survival has been attributed to a delay in diagnosis as well as the surgical effort required to achieve complete cytoreduction at diagnosis.

Symptoms of OC are common, non-specific with variable duration between presentation and diagnosis [4–6]. Diagnostic challenges are considerable given the low incidence of OC and the low positive predictive value of symptoms (only 1 in 400–600 symptomatic women have OC) [7,8]. Data from other cancers shows that patients with cancer presenting as emergencies have worse survival than non-emergency presentations [9]. Rapid access/2 week wait clinics were established by the Department

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of Health in 2000 to expedite cancer diagnosis and management. Patients are referred through these clinics as urgent referrals and are prioritized for further investigation and management with target dates and timelines set for definitive treatment [10].

The American Cancer Society, the Foundation of Women's Cancer and the Society of Gynecologic Oncologists committee issued a joint advisory in 2007 recommending symptom triggered testing for ovarian cancer [11]. In 2011, the National Institute of Clinical Excellence (NICE), the UK body that advises on standards of clinical care also recommended symptom triggered testing and issued guidance on the recognition and initial management of ovarian cancer [12]. NICE recommended that symptoms considered suspicious (Fig. 1) should trigger diagnostic testing in the primary care setting and urgent referral to rapid access clinics based in secondary care within 2 weeks (2 week wait clinics) for abnormal test results. The diagnostic pathway involves sequential testing of serum CA 125 followed by pelvic ultrasound scan (USS) if the serum CA 125 was >35IU/L. No age limits were issued but women over 50 years were considered high risk. Of note, both diagnostic tests were recommended to be performed in the primary care setting. No guidance on what constituted an abnormal ultrasound was issued.

The objectives underpinning this guidance were to diagnose OC at an earlier stage and aims to improve mortality by allowing, primary care physicians access to rapid diagnostic testing (previously only accessible via secondary care) and fast track referrals. A publicity campaign aimed at disseminating information and raise symptom awareness in patients and professionals led by the Department of Health (DH) National Awareness and Early Diagnosis Initiative (NAEDI) preceded the guidance. It was estimated that 10% of deaths from ovarian cancer might be avoided by this initiative.

Currently, the effectiveness or impact of symptom triggered diagnostic testing in routine clinical practice to improve ovarian cancer diagnosis and mortality remains unknown. We investigated outcomes from implementation of symptom triggered diagnostic testing and referrals to secondary care in two large teaching hospitals in UK. We compared the results to the cancer outcomes from rapid access referrals to 2011, prior to release of guidance.

Materials and methods

Women with suspected ovarian cancer because of symptoms or clinically palpated mass referred from primary care to a cancer unit (secondary care) via the 2 week wait (2 WW) system at Sandwell and West Birmingham Hospital NHS Trust (SWBH) and Birmingham Women's Hospital NHS Trust (BWH) from 1st January 2012 to 18th March 2013 were compared to a similar cohort referred in 2011. Combined, both trusts serve a catchment population in excess of 500,000. Doctors in primary care use a standardized 2 week referral form to refer patients to doctors in secondary care for all suspected gynaecological cancers. This form is used to triage patients to postmenopausal bleeding clinic, vulval clinic or

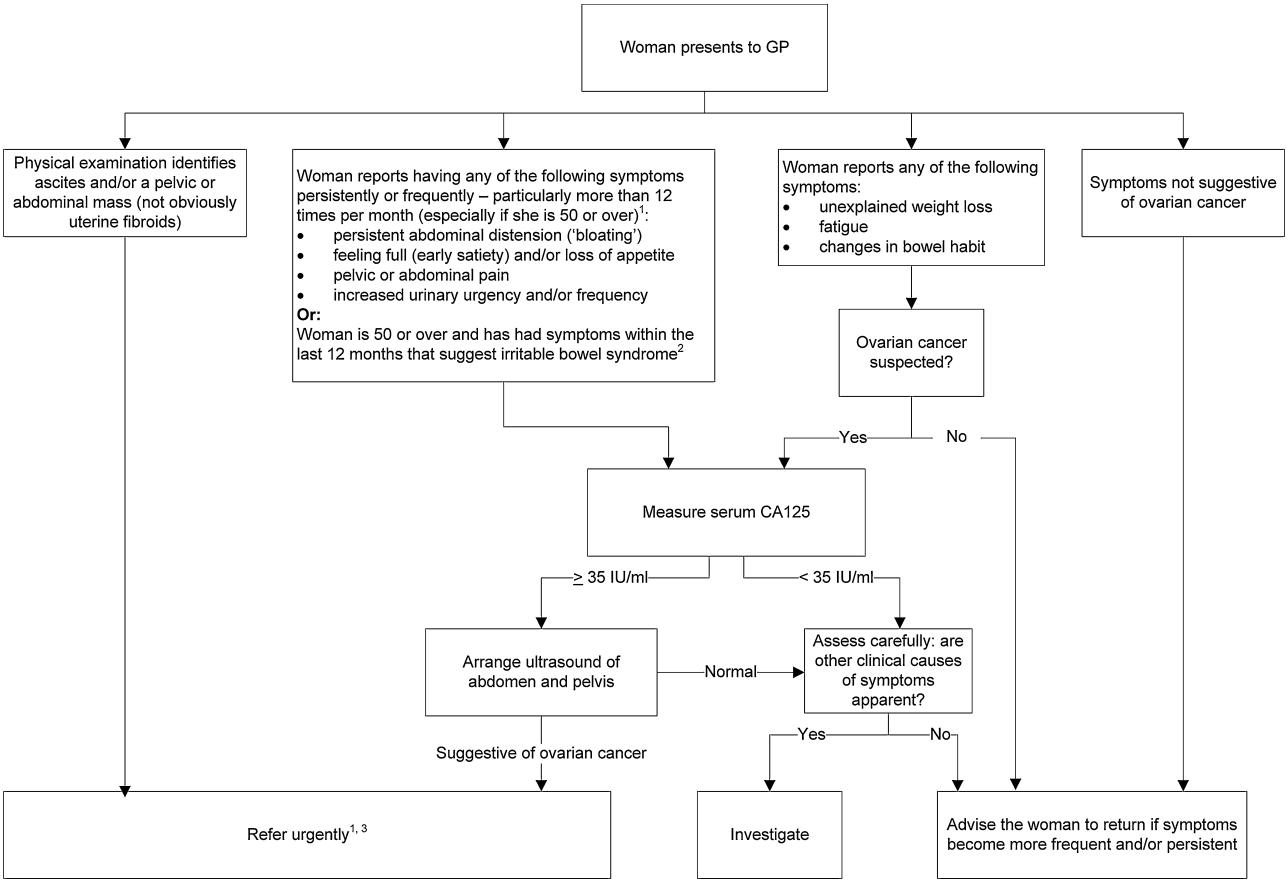

Fig. 1. Detection in primary care.

[1] See also 'Referral guidelines for suspected cancer' (NICE clinical guideline 27; available at www.nice.org.uk/guidance/CG27) for recommendations about the support and information needs of people with suspected cancer.

[2] See 'Irritable bowel syndrome in adults' (NICE clinical guideline 61; available at www.nice.org.uk/guidance/CG61). Irritable bowel syndrome rarely presents for the first time in women of this age

[3] An urgent referral means that the woman is referred to a gynaecological cancer service within the national target in England and Wales for referral for suspected cancer, which is currently 2 weeks.