

2018 Ovarian Cancer Guidelines Audit (Ca125): Pilot Audit

Introduction

The Scottish Clinical Biochemistry Network (SCBN) is leading on a piece of national work, “Audit of current practice in primary care for investigation of women presenting with symptoms, which may be due to ovarian cancer, against the Scottish cancer referral guidelines”. This is a joint audit through both the Scottish Clinical Imaging Network (SCIN) and SCBN. This report summarises the pilot audit which has been conducted in NHS GG&C. The audit will now be rolled out to the other NHS boards across Scotland, to obtain a national picture.

The aim of the audit was twofold: firstly to assess the uptake of the Scottish Cancer Referral Guidelines (patients without a prior history of ovarian cancer having a Ca125 test, are also recommended to have an urgent ultrasound scan carried out). The second part was to assess the clinical effectiveness of including ultrasound with Ca125 testing at initial investigation i.e. assessing whether or not this pathway facilitated an earlier diagnosis of ovarian cancer.

Results

Data was received from clinical biochemistry in Greater Glasgow and Clyde, covering CA125 tests for the period between 01/01/15 and 30/06/15 (inclusive). During this six-month period, there were 3,504 CA125 tests performed on 3,329 women. 34 women were excluded from analysis due to invalid CHI numbers, which resulted in 3,469 tests being considered during the audit.

66 women were identified as being newly diagnosed with Ovarian Cancer in the data collection period (01/01/15 and 30/06/15) using data from the Socrates database. 18 (27.3%) of these diagnoses were picked up by laboratory screening +/- ultrasound scanning initiated in primary care.

The first aim of the audit was to assess guideline uptake.

Ca125 tests in GG&C				
Diagnostic Status	Tests	Patients	% of tests	% of patients
Known Ca Diagnosis	140	79	4.00%	2.40%
New Ca Diagnosis	19	18	0.50%	0.60%
No Diagnosis	3310	3197	95.40%	97.10%
Grand Total	3469	3294	100%	100%

Table 1: Shows a breakdown of test and patient numbers which led to eventual cancer diagnosis category. Note table includes small rounding errors.

3215 women with no previous ovarian cancer diagnosis had a Ca125 request within the audit period. 1420 of these women also had an ovarian/pelvic U/S giving an uptake rate of 44%.

Only a small fraction (0.6%) of women who were referred for a Ca125 test went on to be diagnosed with ovarian cancer.

18/66 (27%) women with a new ovarian cancer diagnosis had Ca125 measured in primary care and in only 10/66 (15%) of these, were the guidelines followed and both investigations carried out (Ca125 + U/S).

Effectiveness of Guideline

Average days to new diagnosis			
Method	Patients	Avg Days to Diagnosis	Std. Deviation
Ca 125 only	8	17.6	+/- 13.7
Ca125 + Scan	10	22.6	+/- 14.1

Table 2: Shows the average days from CA125 result to the date of diagnosis of ovarian cancer

The average time from initial testing to cancer diagnosis was 17.6 days for CA125 measurement alone (n=8) and 22.6 for CA125 plus scan (n=10) suggesting that inclusion of U/S scanning at initial investigation was not associated with a quicker diagnosis, although numbers are too small to have statistical significance.

Ca125 Cut-off

Ca125 Detection Rate (3a)			Ca125 False Positives (3b)		
Ca125 Result	Tests	% total	Ca125 Result	Tests	% total
Elevated	15	83.30%	Elevated	278	8.40%
Normal	3	16.70%	Normal	3032	91.60%
			Grand Total	3310	100%

Tables 3a and b: Shows the false-positive and false-negative aspects of CA125 testing, based on an eventual diagnosis of ovarian cancer.¹

¹

A Ca125 result greater than or equal to 35IU/ml is elevated. Of the women who were newly diagnosed with ovarian cancer, 15/18 (83.3%) had an elevated Ca125, however three women with a normal Ca125 would also be diagnosed. Ca125 was elevated in 278 women (8.4%) who did not go on to be diagnosed with ovarian cancer.

Conclusion

The pilot audit shows that uptake of the guideline is low. Less than 50% of women being investigated for symptoms consistent with ovarian cancer have both a Ca125 and urgent ultrasound performed. Only 18/66 women receiving a new diagnosis of ovarian cancer had investigations instigated by their GP, suggesting that a significant percentage of undiagnosed ovarian cancer do not present to primary care. A rollout of the audit across all NHS Scotland boards is required, to see if this pattern is confirmed and to enable statistically significant conclusions to be drawn.