

National Guidance on Gynaecological Cancer Management: An Audit of Gynaecological Cancer Services and Management in the South East of England

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Summary

Objective: To evaluate the appropriateness of the structure and the process of care for gynaecological cancer against national guidelines.

Setting & Sample: Incident cases of ovarian and cervical cancer managed between 1 January, 1999 and 31 December, 2000 in the South East of England.

Methods: Completion of an audit form, by a researcher, using the clinical record. Qualitative interviews with gynaecologists at each hospital.

Main Outcome Measures: Whether hospitals meet the requirements for being a 'centre' or a 'unit' for gynaecological cancer and whether gynaecologists manage ovarian or cervical cancer according to the guidelines.

Results: Stage was recorded in the notes of 53% (262/492) of women with ovarian cancer but information to assist in determining stage was recorded in 86%. Of women who had a stage recorded by the consultant, who should have had a laparotomy and be referred for chemotherapy, 81% (169/209) were managed according to the guidelines, ignoring whether there was removal of disease to nodules of less than 1 cm. Stage was recorded in the notes of 60% (188/315) of women with cervical cancer, although information relevant to staging the patient was recorded in 66%. Overall 76% (142/188) of women with stage recorded in the notes were managed according to the guidelines but 40% (127/315) of women audited were not assessable.

Only one site met the criteria for being a cancer centre. Of the remaining sites, most striking was the inability to assemble a team of professionals, including a radiologist, a pathologist and an oncology nurse to discuss individual patient care.

Conclusions: Retrospective note audits will be hampered by missing data in the clinical record until systems are developed to improve the quality of notes. This research suggests that guidelines based on FIGO staging for the management of ovarian and cervical cancer are not followed and that this may be associated with incomplete cancer management teams.

Key words: Ovarian cancer; Cervical cancer; Endometrial cancer; Audit; Prospective study; Guidelines.

Introduction

The United Kingdom gynaecological cancer survival rates have been improving gradually but lag behind the best in Europe [1]. Previous audits of ovarian cancer management have concluded that care needs to be centralised and performed by gynaecological oncologists in preference to gynaecologists [2] or general surgeons [3]. Others state that care should be delivered in close cooperation with radiotherapy and chemotherapy specialists in multi-disciplinary teams [4, 5]. A previous audit in the South East of England showed that inappropriate management of women with gynaecological cancer was associated with poorer survival [6-8].

In August 1999, "Improving Outcomes in Gynaecological Cancers" 9 was published in the UK, which recommended the management of gynaecological cancers in cancer centres by gynaecological oncologists working

closely within a multidisciplinary team including radiotherapy and chemotherapy specialists. The initial assessment of women with gynaecological cancer and the management of the earliest stages of cervical cancer should take place in cancer units, under the responsibility of a lead clinician working within a multidisciplinary team. The document defined the methods of diagnosis, the criteria for referral from units to centres as well as the operative and oncological management, using a series of systematic reviews of the literature to provide the best evidence.

This paper reports an audit of the extent to which hospitals are able to follow this national guidance, not only with regard to the presence of the required facilities but also as to whether the recommended management is followed. It uses structured hospital visits and an audit of gynaecological cancer management to assess adherence to national guidance.

Methods

Gynaecologists who manage cases of ovarian and cervical cancer in the South East of England were asked to participate in an audit which involved completing a data collection form for each incident case of primary cancer. The date of diagnosis was

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defined as the date on which a procedure was performed which resulted in histological confirmation of the cancer. Incident cases in this audit were those for which the date of diagnosis was between 1 January, 1999 and 31 December, 2000. Cases were ascertained by a variety of methods. First gynaecologists were asked to list cases of invasive gynaecological cancer. If they could not do so, pathologists were asked to supply a list, based on a search of their computer systems. The forms were completed either by the gynaecologist using the case notes or by one author (MS) from the medical case notes, during regular visits conducted between June 1999 and February 2001.

Data Collected for Diagnosis, Staging and Management of Ovarian Cancer

The audit requested data about diagnostic and staging investigations including the results of ultrasound scanning, computed tomography, serum CA125 levels and chest X-ray. The operative findings were recorded, describing the sites of the tumour in the pelvis (ovary, uterus, other organ sites and lymph nodes) and in the abdomen (bowel, omentum, liver, diaphragmatic surface and para-aortic lymph nodes). The type of surgery undertaken was noted including whether a bilateral salpingo-oophorectomy, hysterectomy and omentectomy were performed as well as the sites of additional tumour resection such as the peritoneum or bowel. The diameter of the largest lesion of residual disease, after completion of the procedure, was requested. Histological data were collected about the type of tumour and grade. Results of biopsies of metastases to the lymph nodes and omentum were recorded as was the peritoneal fluid cytology. Finally, the International Federation of Gynecology and Obstetrics (FIGO) stage was requested.

Assessment of Guideline Requirements for Ovarian Cancer

The recommendations [9] pertinent to the gynaecological management of ovarian cancer state first that specialised gynaecological oncologists should carry out surgery for gynaecological cancer at Cancer Centres. Second, women who present as emergencies should, whenever possible be stabilised and transferred to a Cancer Centre. Third, women should be assessed using trans-

vaginal ultrasound and serum CA125. Fourth, the aim of surgery should be to remove as much cancer tissue as possible at the time of initial surgery and to stage the disease accurately. When removal of tissue to nodules of less than 1 cm in diameter is not possible a second attempt may be appropriate after referral for chemotherapy. Finally referral for chemotherapy is appropriate for all women, except those with Stage I ovarian cancer, in whom there are no indicators of poor prognosis.

The short duration of specialist training programmes at the time of the audit meant that it was inappropriate to assess whether specialist oncologists carried out surgery. The concept of a Cancer Centre and the referral or transfer of cases was also too new to be assessable.

From these guidelines, a number of standards were set. All women should undergo ultrasound and serum CA125 estimation. All women should undergo chest X-ray and staging laparotomy. Staging should include aspiration of peritoneal fluid (or lavage if there is none), biopsy of enlarged lymph nodes and infracolic omentectomy [10]. If women are over 30, removal of tissue should include total abdominal hysterectomy and bilateral oophorectomy. (The age of 30 was used as an arbitrary cut-off to indicate decreased likelihood of wanting to preserve fertility). Finally residual disease ought to be recorded. The proportion of women for whom these standards were met was reported.

Data Collected for Diagnosis, Staging and Management of Cervical Cancer

The audit gathered data about the method of cervical biopsy and the histology result. The pelvic findings during examination under anaesthesia were recorded as well as the outcome of cystoscopy and rectal examination. The nature of the operative procedure was recorded including method of removal of the cervix (trachelectomy or simple, extended or radical hysterectomy) and the method of biopsy of pelvic and para-aortic lymph nodes. The results of operative histology were requested as was the FIGO stage.

Assessment of Guideline Requirements for Cervical Cancer

The recommendations [9] for cervical cancer state that all women with adenocarcinoma of the cervix or squamous cell

Table 1. — *Proportions of units providing elements of gynaecological cancer unit services.*

Recommendation	Proportion meeting requirement
THE CANCER UNIT TEAM	
Was reported to include a lead gynaecologist	100% (18/18)
Was reported to include a lead pathologist	56% (10/18)
Was reported to include a lead radiologist	28% (5/18)
Was reported to include a lead nurse	67% (12/18)
SERVICES PROVIDED BY THE CANCER UNIT	
Dedicated rapid assessment service for women with a pelvic mass	28% (5/18)
Dedicated colposcopy service	100% (18/18)
Fortnightly meetings to discuss individual patient care	39% (7/18)
CARE FOCUSED ON LEAD GYNAECOLOGIST/GYNAECOLOGICAL ONCOLOGISTS	
General practitioner letters and within hospital referrals sent to lead clinician/gynaecological oncologists	61% (11/18)
THE CANCER CENTER TEAM	
Two gynaecological oncologists, one acting as lead	17% (3/18)
Radiotherapy specialist	22% (4/18)
Chemotherapy specialist	22% (4/18)
At least weekly meetings to discuss the management of individual patients	17% (3/18)

Stage Ib or higher disease should be referred to a specialist centre for management. For those with Stage Ia disease, a cone biopsy may be all the treatment that is appropriate unless the biopsy suggests poor prognostic factors. The recommendations for treatment state that while radiotherapy and surgery are equally effective in terms of survival, surgery should be offered whenever possible since it is less likely to impair sexual enjoyment, bowel or bladder function. However where radical surgery (radical hysterectomy and pelvic lymphadenectomy) is unlikely to remove the entire tumour, radiotherapy and chemotherapy should be offered.

As with ovarian cancer, recommendations about referral were not assessable. The guidelines make recommendations about management in terms of the stage of disease, so the proportions of cases for whom the appropriate staging investigations [11] were performed is reported, allowing ultrasound, intravenous pyelogram (IVP) or computed tomography (CT) to assess for blocked ureters (Stage IIb). For Stages IIb-IV, the proportion of women undergoing primary oncological management is reported. For adenosquamous Stage I and for squamous cell Stages Ib-IIa, the proportion of women undergoing primary radical hysterectomy and pelvic lymphadenectomy is reported. For women with squamous cell Stage Ia2, the proportion of women undergoing simple hysterectomy is reported and for Stage Ia1, the proportion of women undergoing simple hysterectomy or cone biopsy is reported.

Interviews assessing the Structure of Hospital Care

During 1999, site visits to each hospital were conducted by one author (MS) at which the gynaecologists were asked to describe their service in a semi-structured qualitative interview which collected information about the elements that should be in place according to the national guidelines [9]. Questions were asked about outpatient diagnosis, treatment and follow-up clinics for gynaecological cancer patients. In addition the team of staff who assisted in the management of gynaecological cancer was listed as well as whether they met regularly to discuss the care of individual patients.

Cancer unit status was determined by applying four criteria [9]. First: was there a cancer unit team consisting of a lead gynaecologist, a pathologist, a radiologist and a nurse? Second: were there meetings of the lead gynaecologist with the remain-

der of the team, at least once a fortnight, either together or individually, to discuss the management of individual patients? Third: was the assessment of women with possible cancer focussed on the lead clinician through departmental policy? Fourth: was there a rapid assessment service for women referred with potential gynaecological cancer?

A hospital was considered for cancer centre status only if it met the criteria for a cancer unit. In addition, the cancer centre team had to include two gynaecological oncologists, with one acting as lead, a radiotherapy specialist and a chemotherapy specialist. A gynaecological oncologist was defined as a person who has subspecialty accreditation or who was accredited to supervise a training programme. A clinical nurse specialist had to have qualifications in oncology nursing. For the other members of the team, a pragmatic definition of "special interest" was adopted: "regular attendance at the gynaecological oncology team meetings". The cancer centre team had to meet at least weekly to discuss individual patient care.

The quantitative data were entered into EPI-DATA version 2.0 and descriptive statistics generated using Stata 7.0. A handwritten record of the interview with the consultants was compiled into a standard report. Records were analysed for statements indicating whether the aforementioned criteria were met.

Results

All the hospitals in the counties of Greater London (south of the Thames), Kent, Sussex and selected hospitals from western Surrey were invited to take part. Eighteen of the 22 (81%) hospitals invited, volunteered to participate. At these hospitals, 77 gynaecologists managed cases of gynaecological cancer. At 14/18 (77%) sites, pathology data were the main means of identifying cases. At the remainder, registers maintained by the gynaecology department were used to identify cases. At 16/18 (89%) sites, the investigator collected almost all the data; at the remaining sites, the gynaecologists were responsible for completing the audit forms. All of the 18 hospitals participated in the qualitative interviews and at all sites at least the lead the gynaecologists involved in cancer management were interviewed.

Table 2. — *Assessment of compliance with the national guidelines for ovarian cancer.*

Assessment of recommendation	Practice	Missing Data
OVARIAN CANCER	(N = 492, unless otherwise stated)	
PRE TREATMENT		
Proportion with an ultrasound and a serum CA125 performed.	76% (371)	9% (46)
STAGING		
Chest X-ray	57% (282)	21% (105)
Ascites present or lavage done	70% (346)	26% (129)
Cytopathology reported if ascites or lavage	80% (277/346)	20% (69/346)
Biopsy of enlarged lymph nodes	18% (10/56)	45% (222)
Infracolic omentectomy	57% (278)	21% (101)
Stage recorded	53% (262)	47% (230)
MANAGEMENT		
TAH, BSO, if over 30 (110 women excluded)	57% (217/382)	16% (63/382)
Residual disease recorded	52% (255)	48% (237)
Referral for chemotherapy if Stage II-IV according to gynaecologist	80% (141/176)	14% (24/176)

The Structure of Care

One hospital met the requirements to be a cancer centre and a cancer unit. In principle, all the remaining sites should fulfil the criteria to become cancer units but none succeeded. The most striking failure was of assembling a regularly meeting team of personnel cooperatively to manage individual cases. Most often the teams failed to include radiologists (72%, 13/18); although there was also a lack of pathologists (44%, 8/18). Less frequently missing was the involvement of an oncology nurse (33%, 6/18). Few sites provided a rapid assessment service for women with pelvic masses although all reported that women would be seen within two weeks of referral.

The Process of Care for Ovarian Cancer

Stage was recorded in the notes of 53% (262/492) of patients but information to assist in determining stage was recorded in 86% (423/492). The presence of residual disease was recorded in only 52% (255/492) of women and in these cases, the size of the residual nodules was less than 1 cm in 16% (42/255).

Using the consultant's recorded stage, 55% (17/31) of women with Stage IV disease underwent laparotomy and referral for chemotherapy. Of women with Stage III disease 84% (113/134) underwent laparotomy and referral for chemotherapy. One hundred percent (11/11) of women with Stage II disease underwent laparotomy and were referred for chemotherapy. Eighty-five percent of women (28/33) with Stage Ic disease or Stage I disease and poor grade underwent laparotomy and referral for chemotherapy. Of women with a stage recorded by the consultant, who should have had a laparotomy and been referred for chemotherapy, 81% (169/209) were managed appropriately, ignoring whether there was removal of disease to nodules of less than 1 cm.

The Process of Care for Cervical Cancer

Stage was recorded in the notes of 60% (188/315) of women although information sufficient to stage the patient

was recorded in 66% (208/315). Using the consultant's recorded stage, 80% (8/10) of women with Stage IV disease were referred for radiotherapy. Of women with Stage III disease 94% (33/35) were referred for radiotherapy. Seventy-one percent (15/21) of women with Stage Ib cervical cancer were referred for radiotherapy.

Ninety percent (9/10) women with Stage IIa disease were managed appropriately either by referral for radiotherapy or by radical hysterectomy and pelvic lymphadenectomy. Forty-four percent (8/18) of women with Stage I adenocarcinoma were managed appropriately by the same criteria while 74% (53/72) of women with Stage Ib squamous cell carcinoma were managed either by referral for radiotherapy or radical hysterectomy and lymphadenectomy. None of the four women with Stage Ia2 squamous cell cervical cancer were managed by hysterectomy or radiotherapy. Of women with Stage Ia1 cervical cancer 89% (16/18) were managed by cone biopsy or simple hysterectomy. Overall 76% (142/188) of women with a stage recorded in the notes were managed appropriately but 40% were not assessable.

Discussion

The site visit interviews were conducted at a time of transition from pre-guideline working. A number made changes to the services provided after the current study was completed. It follows that the interviews indicate the baseline status. Most striking was the lack of ability to assemble teams of staff to meet regularly to review individual patient care. Missing staff members were radiologists, pathologists and oncology nursing staff. This might be associated with national staff shortages in these areas.

Data were obtained from the medical records by means of a methodical, end-to-end search for all relevant information in the written notes, in the letters, in the results and on hospital computer systems. Despite this, the proportion of missing data varied between 9% and 48% for women with ovarian cancer and between 2% and 20% for women with cervical cancer.

Table 3. — *Assessment of compliance with the national guidelines for cervical cancer.*

Assessment of recommendation	Practice	Missing Data
CERVICAL CANCER		
(N = 315, unless otherwise stated)		
STAGING INVESTIGATIONS		
Chest X-ray	37% (117)	20% (65)
Renal obstruction assessed by ultrasound, CT or IVP	42% (131)	7% (22)
Examination under anaesthesia	64% (201)	2% (7)
Cystoscopy performed if examined under anaesthesia	59% (120/201)	6% (13/201)
Rectal examination performed if examined under anaesthesia	71% (142/201)	13% (26/201)
MANAGEMENT		
Referred for chemotherapy or radiotherapy if Stage IIb-IV	85% (56/66)	40% (127/315)
Radical hysterectomy and pelvic lymphadenectomy or referral for radiotherapy or chemotherapy if squamous cell Stage Ib-IIa or Stage I adenocarcinoma	70% (70/100)	had no stage recorded in the clinical record
Managed by biopsy (large loop excision of the transformation zone) or simple hysterectomy if squamous cell Stage Ia1.	89% (16/18)	

The proportion of missing ultrasound or CT results was considerably lower than the proportion of missing chest X-ray results. This may relate to a higher workload generated by chest X-rays for radiology departments and to difficulties ensuring the reports are filed in the notes. The high proportion of hospitals without radiologists who regularly attend team meetings suggests that perhaps better staffing and better team working could lead to decreases in the missing data.

The recording of ovarian cancer stage (53% of cases) was poorer than the previous audit (64% of cases) in the South-East of England [6] but better than the proportion of 24% reported from the North-West of the country [12]. The failure to record residual disease in 47% of cases is similar to the North-West audit, which showed that the majority of women have no stage and no residual disease recorded [12].

Lack of some of the staging data for ovarian cancer, such as recording of the presence of ascites, whether an omentectomy had been performed or whether lymph nodes were enlarged, might indicate either that relevant negative findings were not reported in the notes or that consultants were using criteria other than FIGO stage to decide their next course of action (referral for chemotherapy). The failure to record residual disease is surprising because it would be reasonable to expect that oncologists would find this information useful to assess the success of chemotherapy. Increasing the proportion of hospitals with regular meetings with oncologists to discuss individual cases may lead to improvements in the reporting of relevant data.

For cervical cancer, stage was recorded in 60% of cases, an increase over the previous South-East figure of 15.6% [7] and similar to the figure of 53% from the South-West [13]. It is not clear why staging information is so often inadequately recorded, when management is determined by the spread of disease, as described by the staging system [11]. Once more it is possible that consultants were using other criteria than stage to determine their next course of action.

A small proportion (5%, 16/315) of the women not undergoing examination under anaesthetic for cervical cancer may be accounted for because this procedure may be inappropriate for those with Stage Ia1 disease. A larger proportion might be accounted for because examination in the outpatient setting (not recorded) was deemed sufficient.

A problem for research of this nature is the poor quality of clinical record keeping. Systems are required which ensure that all data relevant to the management of a patient are recorded in the clinical notes. In cancer management, it is particularly important to record relevant negative results. Retrospective review cannot distinguish failures of record keeping and unrecorded negative results; both appear as missing data. As a consequence a note-based audit could be viewed as a poor guide to the behaviour of clinicians. Alternatively, it may indicate

failure to be systematic, which may reflect difficulties with the work environment, lack of specialist training, failure to build teams of the relevant staff and failure to use audits to improve the quality of care.

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