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The accurate staging of ovarian cancer using 3T magnetic resonance imaging – a realistic option

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Objectives The aim of the study was to determine whether staging primary ovarian cancer using 3.0 Tesla (3T) magnetic resonance imaging (MRI) is comparable to surgical staging of the disease.

Design A retrospective study consisting of a search of the pathology database to identify women with ovarian pathology from May 2004 to January 2007.

Setting All women treated for suspected ovarian cancer in our cancer centre region.

Sample All women suspected of ovarian pathology who underwent 3T MRI prior to primary surgical intervention between May 2004 and January 2007.

Methods All women found to have ovarian pathology, both benign and malignant, were then cross checked with the magnetic resonance (MR) database to identify those who had undergone 3T MRI prior to surgery. The resulting group of women underwent comparison of the MR, surgical and histopathological findings for each individual including diagnosis of benign or malignant disease and International Federation of Gynecology and Obstetrics (FIGO) staging where appropriate.

Main outcome measures Comparisons were made between the staging accuracy of 3T MRI and surgical staging compared with histopathological findings and FIGO stage using weighted kappa. Sensitivity, specificity and accuracy were calculated for diagnosing malignant ovarian disease with 3T MRI.

Results A total of 191 women identified as having ovarian pathology underwent imaging with 3T MR and primary surgical intervention. In 19 of these women, the ovarian disease was an incidental finding. The group for which staging methods were compared consisted of 77 women of primary ovarian malignancy (20 of whom had borderline tumours). 3T MRI was able to detect ovarian malignancy with a sensitivity of 92% and a specificity of 76%. The overall accuracy in detecting malignancy with 3T MRI was 84%, with a positive predictive value of 80% and negative predictive value of 90%. Statistical analysis of the two methods of staging using weighted kappa, gave a K value of 0.926 (SE ±0.121) for surgical staging and 0.866 (SE ±0.119) for MR staging. A further analysis of the staging data for ovarian cancers alone, excluding borderline tumours resulted in a K value of 0.931 (SE ±0.136) for histopathological staging versus MR staging and 0.958 (±0.140) for histopathological stage versus surgical staging.

Conclusion Our study has shown that MRI can achieve staging of ovarian cancer comparable with the accuracy seen with surgical staging. No previous studies comparing different modalities have used the higher field strength 3T MRI. In addition, all other studies comparing radiological assessment of ovarian cancer have grouped the stages into I, II, III and IV rather than the more clinically appropriate a, b and c subgroups.

Keywords 3.0T MRI, ovarian cancer, staging.

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Introduction

Ovarian cancer is the fifth most common malignancy affecting women, with nearly 7000 women diagnosed with ovarian cancer each year in the UK. It continues to have a poor prognosis resulting in 4500 deaths from the disease annually, making it the most common cause of gynaecological cancer death. It tends to affect older women, with half of them occurring over the age of 65 years. Data from the International Federation of Gynaecology and Obstetrics (FIGO) quotes 5-year overall survival rate as increasing from 27% in the 1960s to 42% in the 1990s. However, because of its surreptitious nature, 75% of women have the disease extending beyond the pelvis (stages III and IV) at the time of presentation.[1]

Although overall survival rates have improved, the late presentation of the disease means it continues to have a poor

prognosis in the majority of women with only 25% 5-year survival for advanced disease.[2] Improvements in imaging techniques have allowed characterisation of ovarian masses and identification of metastatic disease resulting in better management of women undergoing treatment. This has reduced the incidence of unnecessary surgery in unsuitable women. For example, detection of the presence of bulky disease in the upper abdomen at such sites as the porta hepatis, gastrohepatic ligament, lesser sac, liver and lymphadenopathy above the renal hilum makes the possibility of optimal debulking unlikely (Figure 1). Instead, those women with advanced disease and who are deemed inoperable receive chemotherapy prior to surgery, some avoiding surgery altogether.

The usual modalities for imaging of the female pelvis are ultrasound, Doppler ultrasound, computed tomography (CT) and magnetic resonance imaging (MRI). All these methods have been used extensively and are widely reported in the literature, with CT and MRI have accuracies ranging from 60 to 90% for diagnosis and staging of ovarian malignancy.[3–10] The overall findings indicate that MRI is superior to Doppler ultrasound and CT in determining malignancy, but there appears to be no difference in the accuracy of CT and MRI in staging the disease.[11,12] MRI is cost-effective and reliable when the results of ultrasound evaluation are not clear.[13–15] CT is usually not recommended in the evaluation of adnexal masses because of poor soft tissue discrimination and the hazards of ionising radiation. MRI is often very helpful in characterising adnexal masses as the signal intensity (SI) and morphological appearance of the lesion reflect the underlying pathology. For example, benign endometrial cysts have a high SI (appear 'bright') on T1-weighted images and a low SI (appear 'dark') on T2-weighted images, whereas serous malignancies often contain vegetations that are of low SI on T2-weighted images (Figure 2) and typically enhance following contrast administration.

The current FIGO guidelines recommend exploratory laparotomy as the gold standard for all women suspected of having ovarian cancer. This should provide tissue for histological assessment to confirm the diagnosis, allow maximal debulking of tumour volume and provide information on the extent of spread of the disease for staging. Such use of surgery has meant that traditionally imaging has played a limited role in the initial management of these women. However, laparotomy may not detect all deposits, carries its own risks and may delay further treatment such as chemotherapy. Thus, imaging is required preoperatively to determine sites of disease and hence areas in need of biopsy. In addition, women with advanced disease can be referred to a Cancer Centre and Gynaecological Oncologist, as specialist treatment produces a significant improvement in survival.[16] Observational studies have provided convincing evidence to support this statement, with data suggesting that 3 years after treatment by a specialist gynaecologist, a woman's chance of dying is 25% lower than if treated by a general gynaecologist and 33% lower than if treated by a general surgeon.[17]

The correct staging of ovarian cancer is essential, particularly for those with apparent early stage disease. Numerous studies have shown that understaging of ovarian cancer is common and as many as 30–40% women who were thought to have early disease on initial operative findings were found to have a more advanced stage of the disease on re-investigation at tertiary referral centres.[18,19] As a consequence of these reports, it has been advised that ovarian cancer should be

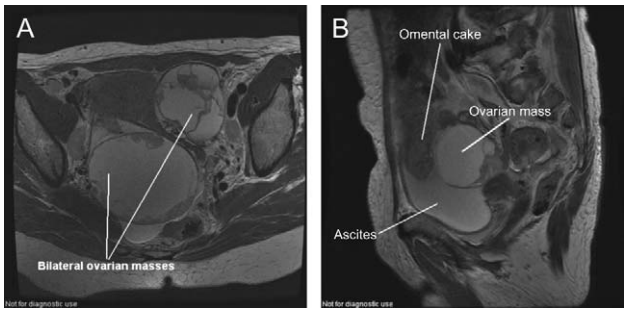

Figure 2. (A) Axial 3T MR image of bilateral serous cystadenocarcinomas showing complex cyst structure in a patient with FIGO stage IIIc disease. (B) Sagittal 3T MR image of a patient with FIGO stage IIIc disease showing ascites, omental cake and ovarian masses.

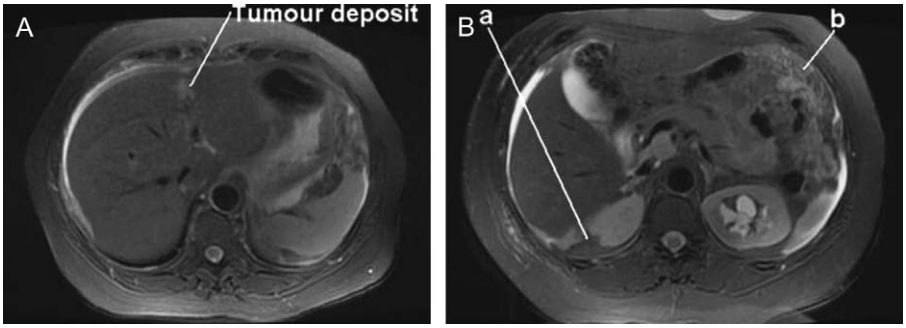

Figure 1. (A) Abdominal image showing small tumour deposit in falciform ligament. (B) Abdominal image showing tumour deposit on the right (a) hemi-diaphragm and (b) omental disease.

diagnosed and staged surgically with laparotomy aiming for complete resection of the tumour or at the very least, optimal debulking with individual tumour deposits measuring no more than 1.2–2.0 cm in size.[20–22] One benefit of primary surgical intervention is that it provides tissue for histological diagnosis.

In those women who are deemed to be inoperable, that is optimal debulking is unlikely to be achieved, then neoadjuvant chemotherapy may be commenced followed by interval debulking surgery. Due to the continued controversy about the use of debulking surgery in the management of advanced ovarian cancer, a current Medical Research Council study, 'CHORUS' is continuing. This is designed in part to determine if chemotherapy or upfront surgery is the better treatment in women with advanced (stage III or IV) ovarian cancer (http://www.ctu.mrc.ac.uk/studies/CHORUS.asp).

In a paper by Spencer published in 2005, CT is quoted as being the mainstay of imaging of women believed to have ovarian cancer based on a combination of its efficacy and availability.[23] It was also felt that MRI should be used as a 'problem solving' investigation for the indeterminate adnexal mass rather than a preoperative staging tool due to its limited availability in most hospitals.

We would like to challenge the idea that MRI cannot be used to stage ovarian cancer, particularly since the introduction of 3.0 Tesla (3T) MRI, which produces better image quality compared with the lower field strength 1.5T magnetic resonance (MR) machines due to the increased signal-to-noise ratio (SNR).

Patients and methods

A search of the histopathology database (LabCentre, Clinicom CliniSys) was performed for the period of May 2004 to January 2007 to identify all women reported as having ovarian pathology, both benign and malignant cases as determined by SNOMED (Systemized Nomenclature of Medicine) coding. This time period coincided with the introduction of the 3.0 Tesla Signa HDX whole body MR scanner (GE Medical Systems, Milwaukee, WI, USA). Overall, 528 women were recorded as having ovarian pathology, some of whom were incidental findings of ovarian tumours, metastases and recurrences of previously diagnosed malignancy. The records of all women diagnosed with ovarian pathology in whom 3T MRI had been performed prior to surgery were then reviewed. Women with a diagnosis of ovarian cancer, but who had chemotherapy rather than primary debulking surgery were excluded, as were women who had alternative imaging prior to surgery such as ultrasound scan, 1.5T MRI or CT imaging.

To avoid bias, the staging was determined from the initial MRI report and the source images were not reviewed for the purpose of this study. When not already stated in the text of the MRI report, the staging was deduced from the MRI findings as described in the text, according to the FIGO classification of ovarian cancer (Table 1). Images were acquired using a Signa HDX 3T MR scanner with an eight-channel pelvic phased array coil (GE Healthcare). A dielectric pad consisting of a 1.6 l of an aqueous solution of 50 g of manganese sodium was used for 3T MRI to prevent any signal inhomogeneity.[24] In cases where the lesion was predominantly cystic, gadodiamide contrast agent (Omniscan; Amersham Health AS, Oslo, Norway) was given intravenously at a dosage of 0.1 mmol/kg body weight to aid visualisation of the internal architecture. All women received 20 mg of hyoscine butylbromide (Buscopan; Boehringer Ingelheim Ltd, Bracknell, UK) unless contraindicated, to reduce peristalsis-induced image blurring. T2-weighted fast spin echo (FSE) images were acquired (repetition time [TR] 2800 ms/echo time [TE] 105 ms) through sagittal, axial and oblique planes in the pelvis. When using contrast T1-weighted spin echo, images were acquired both pre- and postcontrast. Abdominal imaging was acquired using signal averaged fast recovery FSE with a TR of 5000 ms and TE of 82.4 ms. Breath hold axial images were acquired as single shot FSE with TR of 1600 ms and TE of 80.3 ms. The same

Table 1. FIGO Staging of Ovarian Cancer (1986)

Stage I—tumour limited to one or both ovaries
IA—involves one ovary; capsule intact; no tumour on ovarian surface; no malignant cells in ascites or peritoneal washings
IB—involves both ovaries; capsule intact; no tumour on ovarian surface; negative washings
IC—tumour limited to ovaries with any of the following: capsule ruptured, tumour on ovarian surface, positive washings
Stage II—tumour involving one or both ovaries with pelvic extension or implants
IIA—extension or implants onto uterus or fallopian tube; negative washings
IIB—extension or implants onto other pelvic structures; negative washings
IIC—pelvic extension or implants with positive peritoneal washings
Stage III—tumour involving one or both ovaries with microscopic peritoneal implants outside of the pelvis; or limited to the pelvis with extension to the small bowel or omentum
IIIA—microscopic peritoneal metastases beyond pelvis
IIIB—macroscopic peritoneal metastases beyond pelvis less than 2 cm in size
IIIC—peritoneal metastases beyond pelvis >2 cm or lymph node metastases
Stage IV—tumour involving one or both ovaries with distant metastases; if a pleural effusion is present there must be positive cytology for it to be classed as stage IV disease
Para-aortic lymph node metastases are considered regional lymph nodes (stage IIIC)

consultant radiologist reported all the cases, thus avoiding interobserver bias.

Reporting of histopathological specimens was carried out by one of the two consultant histopathologists with particular interest in gynaecology. In order that false-negative and false-positive results are not overlooked, all histopathology reports were reviewed for women with ovarian pathology who had undergone 3T MRI prior to surgery. For the few women where FIGO staging was not already stated, staging was determined from the text of the pathology report according to FIGO recommendations (Table 1).

Those women identified from 3T MRI and histopathology as being suspected to have or having ovarian malignancy all underwent review of the surgical findings as recorded in the patient's case notes. The surgical staging was then compared with both MR and histopathological staging of disease. All women found to have ovarian malignancy who had also undergone 3T MRI were operated on by one of the two experienced gynaecologists with a special interest in gynaecological oncology.

Results

Over the time period, 191 women identified as having ovarian pathology underwent 3T MRI. Of the 191 women, 172 had ovarian disease as their primary diagnosis on histology. There were a further 19 women in whom the main diagnosis was uterine pathology, with incidental findings of ovarian disease (13 with endometrial adenocarcinoma, 3 with uterine sarcoma and 3 with benign leiomyoma).

In the case of both benign and malignant ovarian disease occurring in the same woman, the malignant disease was noted as the primary diagnosis.

Primary ovarian malignancy was diagnosed in 77 women (20 of whom had borderline malignancies). These individuals had undergone primary debulking surgery and subsequent histopathological staging and formed the study group for whom staging data was calculated. There were a further 18 women in whom malignancy was suspected or could not be excluded on MRI, but were found to have benign disease on histology. Of these 18 women of suspected ovarian cancer, 5 were thought to have borderline disease on MRI, 2 of which were surgically staged as Ic disease. On histopathological examination, the majority of these tumours were either mucinous cystadenomas or serous adenofibromas with a further two cases of ovarian torsion.

There were six women who were not thought to have malignancy on MRI, but were subsequently found to have ovarian tumours on histopathological examination (false negative). Five of these were stage Ia borderline tumours with a single case of squamous cell cancer arising in a pre-existing mature cystic teratoma.

Metastatic ovarian disease was found in further seven women, and in one woman there was an extragastrointestinal stromal tumour arising in the broad ligament. This was not included in the results due to its rare nature and there being no recognised staging for this particular tumour. There was also a case of a gonadoblastoma arising in a woman with androgen insensitivity syndrome (testicular feminisation), which was excluded from the final data. In those women found to have benign disease, there were three women with ovarian torsion, 22 benign teratomas and a further 52 women with benign ovarian tumours, predominantly cystadenoma and fibroma. A summary of the gynaecological pathologies can be found in Table 2.

The mean age of women undergoing surgery for a suspected ovarian malignancy was 59 years, with a range of 27–90 years. The mean age of those diagnosed with ovarian cancer was 56 years (range 26–89) with a slightly higher mean of 65 years (range 35–90) for those women found to have benign disease following surgery.

The ability to detect ovarian malignancy with 3T MRI was comparable with other studies, with a sensitivity of 92% and a specificity of 76%. The overall accuracy in detecting malignancy with 3T MRI was 84%, with a positive predictive value was 80% and negative predictive value of 90%.

Direct comparisons of surgical, histopathological and MR staging was achieved by allotting an incremental score for

Table 2. Summary of gynaecological pathologies, both benign and malignant, in whom 3T MRI was performed

Ovarian neoplasms					
Total ovarian malignancies	Primary malignancy	Borderline malignancy	Metastatic	Recurrence	Secondary debulking
98	57	20	7	3	11
Total benign	Dermoid	Cystadenoma	Fibroma	Other	Torsion
74	22	37	10	5	3
Uterine neoplasms					
	Total	Adenocarcinoma	Sarcoma	Leiomyoma	
	19	13	3	3	

Table 3. Showing the incremental scores assigned to each FIGO stage for ovarian cancer

FIGO stage	Assigned score
Ia	1
Ib	2
Ic	3
IIa	4
IIb	5
IIc	6
IIIa	7
IIIb	8
IIIc	9
IV	10

each of the stages of disease, thus producing linear data (Table 3). This was then analysed using weighted kappa statistical test.

Weighted kappa is a test for interobserver agreement, in which a *K* value of 1 amounts to perfect agreement, and value of 0 is complete disagreement. The weighting of the differences allows for the fact that there are degrees of disagreement between observers. The *K* value is interpreted as follows:[25]

Value of *K*	Strength of agreement
<0.20	Poor
0.21–0.40	Fair
0.41–0.60	Moderate
0.61–0.80	Good
0.81–1.00	Very good

Statistical analysis of the two methods of staging when compared with the stage obtained by histopathological examination using weighted kappa, gave a *K* value of 0.926 (SE ±0.121) for surgical staging and 0.866 (SE ±0.119) for MR staging (Tables 4 and 5). Comparison of the MR stage and surgical stage with the histopathological stage revealed there was no significant difference between the two. Due to the high proportion of borderline tumours in our final data, we performed a further analysis of the staging data for ovarian cancers alone after removing the borderline tumours. This resulted in a *K* value of 0.931 (SE ±0.136) for histopathological staging versus MR staging (Table 6) and a *K* value of 0.958 (±0.140) for histopathological stage versus surgical staging (Table 7).

Discussion

3T high-field MRI has been used in a number of areas with particular applications in neurology, with other applications for whole body imaging also under investigation.[26–32] MRI at this field strength allows us to double the SNR, which is fundamental in the quality of the final image. The signal determines the brightness of each image pixel and is proportional to the radio frequency (RF) emitted by the tissue. The noise is due to random RF emissions, mainly from the patient. In simple terms, 3T MRI has twice the strength of 1.5T MRI and provides more information about structure and function of tissues, in half the time of the 1.5T machines.

A review of the literature revealed that previously published papers comparing surgical staging with staging determined by MRI have analysed the data in the broad categories of stages I, II, III and IV diseases. We have compared the different

Table 4. Weighted kappa table for histopathological stage versus MRI stage

	Observer A (histopathological stage)									%
Observer B (MRI stage)	1	2	3	4	5	6	7	8	9	
1	11	0	5	1	1	1	0	0	0	26.8
2	0	1	1	0	0	0	0	0	0	2.8
3	5	0	11	0	0	1	0	0	0	23.9
4	0	0	0	1	0	0	0	0	0	1.4
5	0	0	0	1	1	1	1	0	0	5.6
6	1	0	2	0	0	1	1	1	1	9.9
7	0	0	0	0	0	1	0	0	0	1.4
8	0	0	0	0	0	0	0	0	1	1.4
9	0	0	0	0	1	0	0	3	15	26.8
%	23.9	1.4	26.8	4.2	4.2	7.0	2.8	5.6	23.9	

Weighted kappa = 0.866; standard error (Kw′ = 0) = 0.119.

Table 5. Weighted kappa table for histopathological stage versus surgical stage

	Observer A (histopathological stage)									%
Observer B (surgical stage)	1	2	3	4	5	6	7	8	9	
1	15	0	2	0	0	0	0	0	0	25.0
2	1	1	0	0	0	0	0	0	0	2.9
3	0	0	14	0	1	0	0	0	0	22.1
4	0	0	0	2	0	0	0	0	0	2.9
5	0	0	0	1	0	3	0	1	0	7.4
6	0	0	1	0	1	2	0	0	0	5.9
7	1	0	0	0	0	0	1	0	1	4.4
8	0	0	0	0	0	0	1	1	2	5.9
9	0	0	0	0	1	0	0	2	13	23.5
%	25.0	1.5	25.0	4.4	4.4	7.4	2.9	5.9	23.5	

Weighted kappa = 0.926; standard error (Kw′ = 0) = 0.121.

Table 6. Weighted kappa table for histopathological stage versus MRI stage with borderline tumour data removed

	Observer A (histopathological stage)									%
Observer B (MRI stage)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	
1	9	0	4	0	1	0	0	0	0	25.9
2	0	1	1	0	0	0	0	0	0	3.7
3	4	0	10	0	0	0	0	0	0	25.9
4	0	0	0	1	0	0	0	0	0	1.9
5	0	0	0	1	0	2	0	0	0	5.6
6	0	0	0	0	0	0	0	1	0	1.9
7	0	0	0	0	0	1	0	0	0	1.9
8	0	0	0	0	0	0	0	0	1	1.9
9	0	0	0	0	1	0	0	3	13	31.5
%	24.1	1.9	27.8	3.7	3.7	5.6	0.0	7.4	25.9	

Weighted kappa = 0.931; standard error (Kw′ = 0) = 0.136.

modalities of staging like-for-like, using the full FIGO classification, that is stage Ia, b and c, stage IIa, b and c, stage IIIa, b and c, a situation more relevant to the clinical setting.

Whichever method is used, the correct initial diagnosis and staging of ovarian cancer is important in determining appropriate referral and treatment to optimise survival.[33] Thus, accurate preoperative staging with 3T MRI and subsequent multidisciplinary discussion may prevent inappropriate and suboptimal surgery such that tumours deemed inoperable at presentation may be treated initially with chemotherapy followed by interval debulking surgery. Unfortunately, less than half of the women with ovarian cancer are treated by gynaecological oncologists. A recent review of imaging of ovarian cancer quoted long acquisition times as another reason to use CT instead of MR; however, our acquisition time for routine MRI of both pelvis and abdomen is 45 minutes in total.

Table 7. Weighted kappa table for histopathological stage versus surgical stage with borderline tumour data removed

	Observer A (histopathological stage)									%
Observer B (surgical stage)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	
1	12	0	1	0	0	0	0	0	0	25.5
2	1	1	0	0	0	0	0	0	0	3.9
3	0	0	12	0	1	0	0	0	0	25.5
4	0	0	0	1	0	0	0	0	0	2.0
5	0	0	0	1	0	1	0	1	0	5.9
6	0	0	0	0	0	2	0	0	0	3.9
7	0	0	0	0	0	0	0	0	1	2.0
8	0	0	0	0	0	0	0	1	1	3.9
9	0	0	0	0	1	0	0	2	11	27.5
%	25.5	2.0	25.5	3.9	3.9	5.9	0.0	7.8	25.5	

Weighted kappa = 0.958; standard error (Kw′ = 0) = 0.140.

Our results show that it is possible to use 3T MRI not only in the diagnosis of ovarian malignancy but also to stage the disease, achieving results comparable with those seen with surgical staging. However, as with all imaging modalities, there will be both false-positive and false-negative results especially with regard to the microscopic disease often associated with borderline malignancies. The borderline group of malignancies is particularly difficult to diagnose without histopathological assessment and even then can exhibit only very subtle cellular changes amounting to no more than slight cyst wall thickening (Figure 3). Of the six women in whom malignancy was not suspected, five were borderline tumours exhibiting no obvious stigmata of malignancy on macroscopic examination (e.g. vegetations on the capsular surface) with only microscopic areas of disease found on further examination. All were staged as Ia tumours. Interestingly, of the 13 women with borderline tumours that were identified as suspicious of malignancy on MR examination, over half were stated as being likely borderline tumours in the MR report, the remainder were considered to be stage I cystadenomas. Such subtleties of tumour characterisation are only possible because of the improved image quality obtained with 3T MR techniques, allowing better visualisation of the cyst wall and abnormal areas associated with it. However, this does mean that subtle changes in benign cysts may be construed as suspicious on MR investigation, thus raising the possibility of malignancy. It is important to consider the clinical picture

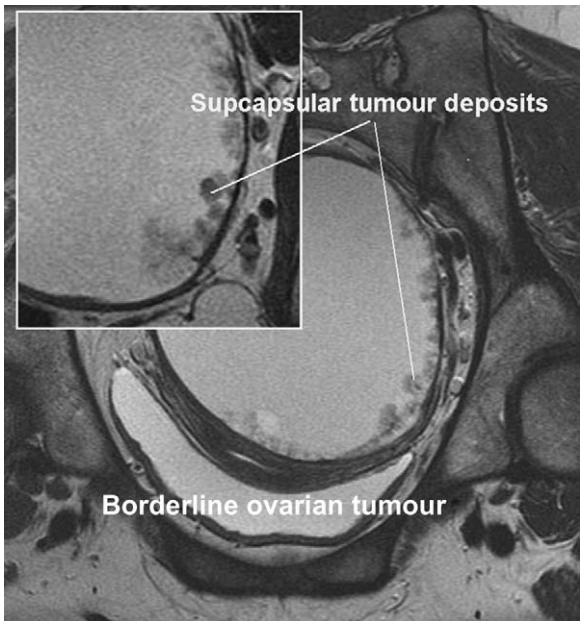

Figure 3. Oblique 3T MR image of a borderline ovarian malignancy showing details of subcapsular tumour deposits.

and tumour markers (if available) when interpreting these images. Nevertheless, if malignancy cannot be excluded on MR investigation, it should be treated as such until proven otherwise. This may lead to an overtreatment of some individuals who are later found to have benign disease but ensures that as manywomen as possible are treated by the appropriate specialist surgeon. In our study, the number of false-positive cases was comparable to similar studies, which employed other methods of imaging and assessment in terms of their sensitivity, specificity, positive and negative predictive values. The 18 women in whom malignancy was suspected or could not be excluded and were later found to be benign were mainly serous or mucinous cystadenomatous lesions.

Although the numbers within this study are small, the results are positive. The *K* values obtained from our data including and excluding the group of borderline tumours show very good levels of agreement. The continued growth in the use of 3T MRI for the staging of ovarian cancer should be pursued. Future considerations to improve the technique include the use of 16- or 32-channel phased array coils. Phased array coils are used where possible to improve the signal-to-noise levels and hence produce clearer MR images. We currently use an eight-channel phased array coil in clinical practice, but we may wish to consider using 16- or 32-channel phased array coils to improve image quality and staging accuracy. In addition, further detail of pelvic and abdominal disease may be achieved with the routine use of ultrathin three-dimensional (3D) sequences enhanced with intravenous gadodiamide contrast.

The quality of the 3T MRI and the results of this study and are encouraging, providing clinicians with further evidence of the merits of this technique. Where facilities allow, we would encourage the use of 3T MRI in the assessment of cases of ovarian cancer as it can provide staging accuracy comparable with that obtained with surgical intervention.

Contribution to authorship

S.J.B. was responsible for study design, collection of all data, data analysis, literature search and article drafting. L.W.T. was responsible for study concept, interpretation of data and critical appraisal of article. D.R.P. was responsible for information regarding surgical staging of ovarian disease and revision of article. I.R. was responsible for histopathological information regarding tumour type and stage.

Ethics approval

All database searches were carried out by staff acting according to Good Clinical Practice guidelines. Patient data were kept to a minimum and stored in a secure manner on a database under the control of the University of Hull to which only the corresponding author has access.

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