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Accuracy of peritoneal carcinomatosis extent diagnosis by initial FDG PET CT in epithelial ovarian cancer: a multicentre study of the FRANCOGYN research group

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1

2 **Introduction**

3

4 Ovarian cancer (OC) is the seventh leading cause of female cancer with 4,615 new cases in
5 2012 and 3,140 deaths in France. In parallel with the aging population, the incidence of
6 ovarian cancer has also been increasing (1,2). The average age of diagnosis is approximately
7 63 years old (1). The most important risk factor for ovarian cancer is genetic: about 10% of
8 ovarian cancers occur in a context of genetic predisposition (mainly BRCA 1/2 mutation) and
9 then occur before the age of 60 years. Unlike for breast or colon cancer, there is no organised
10 screening programme, because no diagnostic test is sufficiently sensitive and specific for the
11 detection of OC especially at an early-stage.

12 The majority of ovarian cancers are of the epithelial type (90%). Other types, includes stromal
13 tumours (granulosa/sex cords) and germ cell tumours (3). Since diagnosis is often late, three
14 quarters of these cancers are diagnosed at an advanced stage (stages IIIB to IV). Its prognosis
15 remains poor. 5-year overall survival, all stages combined, is approximately 45% with poorer
16 prognosis for stages III and IV (between 20-40% and around 10%, respectively) (1,4).

17 The diagnostic approach, in case of discovery of a pelvic mass, includes performing
18 abdominal and pelvic ultrasounds, determining serum tumour marker levels (CA 125, CA 19-
19 9 and ACE) and thoracic-abdominal-pelvic computerised tomography (CT) to characterise the
20 lesion. This exploration can be completed to determine the mass and extent of lesions by
21 pelvic imaging such as MRI (Magnetic Resonance Imaging) or 2-[18F]-fluoro-2-deoxy-D-
22 glucose (FDG)-positron-emission tomography (PET) CT according to ASCO
23 recommendations (5). The standard evaluation is based on surgical staging as recommended
24 by the International Federation of Gynaecology and Obstetrics (FIGO).

25 The primary surgery must be a complete cytoreduction surgery with no macroscopic residual
26 disease whenever feasible because it determines the patient 's survival: a residual tumour <1
27 cm is associated with a worse prognosis when compared to surgery without macroscopic
28 residual disease (4,6,7). PET CT appears sensitive using the Standardised Uptake Value
29 (SUV) to diagnose peritoneal carcinomatosis or the presence of lymphatic or visceral
30 metastases (8-10), but the initial assessment of disease extension remains difficult since the
31 tumour volume is hard to assess and is still performed during exploratory laparoscopy (6).

32 The main objective of the present study was to evaluate the diagnostic reliability of FDG PET
33 CT for peritoneal carcinomatosis extent in epithelial ovarian cancer (EOC), performed before
34 any treatment and to compare it with peroperative observations/ histology samples obtained
35 during upfront laparotomy/ laparoscopy in the setting of a multicentre study.

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48 **Material and methods**

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50 Patients

51 We conducted a retrospective study using maintained databases from 7 French referral
52 gynaecologic oncology institutions from a research group network. The databases registered
53 all patients diagnosed with ovarian cancer at any stage between January 2000 and December
54 2016. The research protocol was approved by our Institutional Review Board.

55

56 Inclusion

57 All patients treated for EOC, who underwent FDG PET CT at the beginning of management,
58 were included, irrespective of whether the surgical treatment was a frontline cytoreduction
59 surgery or a laparoscopy followed by neoadjuvant chemotherapy. Please note that all PET
60 CTs were performed with 18 Fluorodeoxyglucose (18 FDG). The extension of peritoneal
61 carcinomatosis was given by peroperative findings/ histological results in case of frontline
62 cytoreductive surgery or peroperative findings of exploratory laparoscopy. For lymph node
63 involvement, it was analysed only in women who underwent lymphadenectomy.

64 Exclusion criteria: All patients who did not undergo surgery at diagnosis be it laparotomy
65 with cytoreductive surgery or an exploratory laparoscopy before chemotherapy.

66 Procedures

67 All patients underwent clinical examination. Preoperative workup included at least a
68 PET CT and for most of them a standard abdominal – pelvic computed tomography scan (CT
69 – scan).

70 PET images were obtained using a combined 16-section PET/computed tomography (CT)
71 camera 60 minutes following the intravenous injection, with 2 minutes per bed position. The
72 field of view was the whole body. CT images were obtained with contrast media injection and
73 interpreted by experienced radiologists.

74 Experienced nuclear physicians in each participant centre independently estimated FDG
75 uptake while blinded to the clinical characteristics of each subject.

76 PET images were classified as positive if there was focal or multifocal FDG uptake and
77 negative if there was no uptake or residual physiological FDG uptake. A quantitative analysis
78 was also performed, in which a maximum standardised uptake value (SUVmax)

79 All surgeries were performed by a qualified gynaecologic oncologist. Initial
80 management consisted in explorative surgery (laparoscopy) to confirm the diagnosis,
81 determine the extent of the peritoneal spread and the resectability of the disease. Decision to
82 proceed to either primary frontline cytoreductive surgery or neoadjuvant chemotherapy
83 followed by interval debulking surgery was at the discretion of the surgeon. This decision was
84 based on the extent of the disease, surgical experience and on patient comorbidities and the
85 ability to withstand a radical procedure. Cytoreductive surgeries were always performed with
86 intent to achieve no macroscopic residual disease. It included at least a midline laparotomy,
87 total hysterectomy, bilateral salpingo – oophorectomy and infragastric omentectomy. A more
88 extensive surgery was performed when indicated and could involve digestive tract resections,
89 upper abdominal resections such as diaphragmatic resection, splenectomy, lymph node
90 dissection and any other gesture to obtain no residual disease.

91

92 The initial stage of the disease was determined according to the classification of the
93 International Federation of Gynaecology and Obstetrics (FIGO) and TNM seventh edition
94 (12, 13).

95 In order to obtain an exhaustive collection, the histological types of ovarian tumours collected
96 were those described by WHO (14, 15).

97

98 Statistical analysis

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100 Descriptive parameters were expressed as the mean (\pm Standard Deviation [SD]) and median
101 [range] when indicated. Frequencies were presented as percentages. Demographic, clinical,
102 biological, and radiological characteristics are summarised by continuous variables and
103 categorical variables and were analysed using the Student's test.

104

105 For continuous variables, we used t-tests. Overall survival time was calculated in months
106 from the date of diagnostic to death or the date of last follow-up for surviving patients. The
107 Kaplan-Meier method was used to estimate the survival distribution. Patients alive at the end-
108 point have been censored. Effects were expressed as hazard ratios (HRs) with 95% confidence
109 intervals as appropriate. A p-value of <0.05 was considered statistically significant. Data were
110 managed in an Excel database (Microsoft, Redmond, WA, USA) and analysed using software
111 R 3.1.2 Package Hmisc, Design and Survival libraries (16).

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115 **Results**

116 During the study period, 980 women were treated for an epithelial ovarian cancer within our
117 research group centres. Ninety patients (9.2%) were included in the present study and
118 received a PET CT scan before surgery or any treatment.

119 The characteristics of the study population are summarised in Table 1.

120 At diagnosis, 80% of the patients had advanced stage III or IV disease (47 and 25 patients
121 respectively). There were nine cases (10%) where the stage was not specified but described as
122 locally advanced (III or IV). Table 2.

123

124 Regarding the management, 3 patients did not have cytoreductive surgery but only one or
125 more laparoscopies (3/90 or 3.3%), 41 patients underwent frontline cytoreductive surgery
126 (41/90 i.e. 45.6%) followed on average by 4 courses of adjuvant chemotherapy. Thirty-two
127 patients underwent interval surgery considered as complete (35.6%) and 14 were operated on
128 interval surgery considered as incomplete (15.5%). On average, the number of neo-adjuvant
129 courses was 4.

130 In our population, epithelial ovarian tumours were mostly serous (66/90, 73.3%),
131 endometrioid (8/90, 8.9%) and undifferentiated adenocarcinoma (8/90, 8.9%).

132 To differentiate ovarian, unilateral or bilateral involvement, PET CT was reliable for the
133 serous type in 69.6% of the cases, for the mucinous type in 66.6% and for the endometrioid
134 type in 66.7% of the cases. For an extension to the cupola, PET CT was reliable in 57.1% for
135 the serous type. For omentum invasion, the prediction was 66.7% for the mucinous type and
136 48.1% for the serous type. Small intestine disease was confirmed in 75% of cases for the
137 endometrioid, 75% for the mucinous 75% and 47.5% for the serous type. The involvement of

138 the colon was found in 87.5% of the cases for the endometrioid, 75% for the mucinous and
139 58% for the serous types. For the serous type, there were 53 cases of high grade, and 5 low
140 grade.

141 The prediction accuracy of peritoneal carcinomatosis on the initial PET by comparing the
142 histological data of the surgical specimens is presented on table 3

143 There was no link between the value of CA 125 and the reliability of PET CT.

144 Eighty patients had a standard CT scan at diagnosis that was evaluated for diagnostic
145 reliability and compared to PET CT. The accuracy of prediction of peritoneal carcinomatosis
146 extent on the initial CT is presented on table 4

147

148 The mean follow-up in our population was 28 months (1- 342). Overall survival for the entire
149 population was 60% at 5 years.

150

151

152 **Discussion**

153 The aim of our study was to evaluate the diagnosis reliability of PET CT for peritoneal
154 carcinomatosis extent in EOC, performed before any treatment and to compare it with
155 histology samples obtained during laparotomy and/ or per-operative observations during
156 laparoscopy in the framework of a multicentre study conducted by the FRANCOGYN
157 research group.

158 EOC prognosis is strongly related to its local and regional extension: the FIGO and TNM
159 classifications take into account peritoneal carcinomatosis in staging (1,2). Tumours without
160 peritoneal carcinomatosis may be considered to be at lower risk of recurrence taking into
161 account tumour volume and abdominopelvic extension. In addition, size and capsular rupture
162 of lymph nodes are important prognostic factors significantly associated with both overall and
163 recurrence-free survival (1,4,7,17,18).

164 According to the European Society for Medical Oncology (ESMO), PET CT is not
165 recommended for the initial management of EOC (19). The recommendations of the
166 American Society of Cancerology and Oncology (ASCO) regarding the evaluation of
167 peritoneal carcinomatosis and the neoadjuvant chemotherapy response, unchanged since then,
168 are:

169 - The initial evaluation is based on imaging with injected time, if possible abdominal-pelvic
170 CT with chest sections in order to evaluate any possible diaphragmatic extension, in order to
171 specify tumour involvement, laparoscopic evaluation may be considered or second-line
172 imaging such as PET CT or pelvic MRI,

173 - Histological evidence of ovarian origin should be provided, failing that the follow-up will be
174 performed on the fluctuations of CA 125 and the ratio CA 125 / ACE: a value greater than 25
175 evokes a gynaecological origin (20).

176 The French recommendations (HAS) remain vague concerning the indication of PET CT in
177 this context, it evokes it in the pre-therapeutic assessment in case of a disease difficult to
178 characterise or when NAC is scheduled. In his meta-analysis, Lee shows that CT scans are a
179 good tool for evaluating tumour mass during preoperative evaluation and that the value of
180 hypermetabolism is associated with early recurrence (6). These data are included in the study
181 by Klumpp et al, which preoperatively evaluated the location and extent of peritoneal
182 carcinomatosis, but this study concerned a very small population (n = 15), suggesting a
183 probable reading of the images by only one professional (21). This examination can be used
184 as part of protocols, within nomograms, for the prediction of incomplete cytoreduction
185 (22,23). The combination of abdominopelvic CT / PET CT provides the best assessment of
186 carcinomatosis extent, although surgical exploration allows the most reliable findings with
187 possible pathological confirmation (24).

188 PET CT is a recent nuclear imaging technique with good sensitivity (Se) and specificity (Sp)
189 for the diagnosis of peritoneal carcinomatosis extent, reported at around 90% for both
190 parameters in the literature (21,25). The strength of this imaging technique lies in its positive
191 predictive value (PPV) greater than 95% and a correct negative predictive value (NPV) close
192 to 75%. These data are concordant with the meta-analysis of Limei in 2013, although the
193 diagnosis performance is heterogeneous according to the studies (26). The results are similar
194 in the meta-analysis by Li in 2015 with a Specificity greater than 85% and a Sensitivity close to
195 95% (27). Thus, these two meta-analyses tend to define PET CT as a good diagnostic tool for
196 peritoneal carcinomatosis extent diagnosis, without separating the initial diagnosis and

197 recurrence situations. Diagnosis accuracy is reported to be close to 90% in both of these
198 studies, Suppiah et al's meta-analysis reported in 2017 a value of 87% (28).

199 PET CT are presented as imaging that can be used to abstain from interval laparoscopic re-
200 evaluation in the case of NAC when detecting peritoneal carcinomatosis implants **less than 2**
201 **cm in size and positive lymph nodes or persistent diaphragmatic lesions** (28). The study by De
202 Iaco, which concerned peritoneal carcinomatosis – all comers – highlights a good correlation
203 between PET CT and surgical exploration for lesions greater than 5 mm, with no interest in
204 metastatic lymphadenopathy (29). These data are to be taken with caution since the authors
205 are equally interested in peritoneal carcinomatosis during the initial diagnosis and during
206 recurrence, on digestive pathologies with a significant proportion of male patients mixing
207 different cancers and situations.

208 By combining data from two different situations, the prediction of lesions artificially
209 increases as well as the Sensitivity and Specificity of the examination. In addition, the
210 definition of peritoneal carcinomatosis was multimodal and does not rely solely on PET CT: it
211 contrasts with other imaging or histological analysis or operative findings (6,26,28).

212 The advantage of PET CT lies in the diagnosis of diaphragmatic localisations and metastatic
213 recurrence, at an undeveloped stage since all parasitic signals are excluded and only implants
214 linked to the disease are visualised (28,30-32). This detection capacity seems to increase with
215 the CA 125 level and when the conventional imaging techniques are taken in default:
216 identification of the areas of interest (33). However, in the previously mentioned meta-
217 analyses, neither pelvic lymph node nor para-aortic involvement was assessed (6,26,28).

218 The correlation between the size measured in PET CT and the histological size varies
219 according to the tumour phenotype (34). Thus, SUVs are lower for ovarian mucinous cancers
220 than digestive tumours but with higher diffusion coefficients (35,36). In our study, the

221 correlation was better for the endometrioid and mucinous types, which is consistent with the
222 studies on digestive neoplasia but is contradictory for the serous type. In the literature, the
223 histological type influences SUVs: values are higher for serous or endometrioid profiles.

224 PET CT in the context of the NAC make it possible to evaluate the efficacy of the treatment,
225 and to guide the clinician in evaluating the tumour residue at the end of treatment (37).
226 Regarding surgical management, primary surgery with adjuvant chemotherapy appears to
227 improve the overall survival of patients compared to a NAC (17,38,39). The major criterion,
228 however, remains the presence of a macroscopic residual disease (40).

229 The strength of our study lies in its multicentre nature and the number of patients included.
230 However, we cannot rule out inherent retrospective bias. The first cytoreduction or NAC
231 indications were at the discretion of the surgeon in each centre and may represent a
232 recruitment bias. However, all participating centres are regional reference centres that apply
233 French / European standards after discussion in multidisciplinary consultation committee.

234 During the data collection period, there was little change in the classifications (FIGO and
235 TNM) and in the surgical techniques (digestive resection, resection or peritoneal fulguration).
236 On the other hand, the PET technique and especially the machines used are constantly
237 evolving: this results in a better current definition of lesions. In older studies, lesions could be
238 "forgotten" because of insufficient detection. Current machines tend to cuts of smaller
239 thickness but still thicker than those of CT (41).

240 The sensitivity and specificity values of our study may appear low compared to recent meta-
241 analyses as shown in table 5 (21,26-28). Our endpoint was stricter: initial assessment of
242 peritoneal carcinomatosis extent for an epithelial ovarian tumour, without defining minimum
243 detection size and excluding digestive causes and other causes of peritoneal carcinomatosis.
244 In the end, the diagnosis of peritoneal carcinomatosis is often obtained by histological

245 samples taken during surgery since the imaging techniques are often inaccurate for lesions of
246 small sizes.

247

248 **Conclusion**

249

250 The rates of false positives and false negatives in PET CT and abdominopelvic CT are not
251 negligible rendering laparoscopy a mandatory tool to evaluate the extent of peritoneal
252 carcinomatosis in case of advanced epithelial ovarian cancer. PET CT does not seem to be the
253 most efficient test for assessing the initial tumour extent. We should prefer abdominal-pelvic
254 CT as indicated in the current French recommendations. This test is better than the clinical
255 examination and abdominal-pelvic ultrasound to assess the extent of the disease, with a lower
256 price and shorter examination time and easier accessibility. The performance of PET CT
257 varies according to the nature of the tumour, the location of peritoneal carcinomatosis but also
258 the devices used. The correlation between histology and imaging is not perfect: it is an
259 examination to be reserved to supra diaphragmatic extension. The evolution of the techniques
260 will allow us to consider an improvement of the diagnostic performances and an evolution of
261 our surgical care.

262

263 **Declarations of interest:** none

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409 **Table 1** - Characteristics of the population.

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Characteristics of the population.	n = 90
Age (years) mean \pm SD [range]	58.1 \pm 11.8 [30-85]
BMI (kg/m²) mean \pm SD [range]	24.4 \pm 5.2 [16.4-44]
Parity mean \pm SD [range]	1.6 \pm 1 [0-8]
Nulliparous (%)	23/90 (25.6%)
Post-Menopausal (%)	62 (68.9%)
Hormone replacement therapy (%)	20 (32.2%)
Follow up (month)	64.5 \pm 91 (6-264)
CA 125 at diagnosis	1158 (12-10 400)
CA 19-9 at diagnosis	157 (0-3093)
History of	
- appendectomy	21 (23.3%)
- unilateral adnexectomy	3 (3.3%)
Diabetes (%)	5/90 (5.5%)
HBP (%)	16/90 (17.8%)

411 SD: Standard Deviation; HTM: hormonal treatment of menopause; BMI: body index mass;

412 HBP: High Blood Pressure

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420 **Table 2** – FIGO stage.

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FIGO stage	n = 90
I	7 (7.8%)
II	2 (2.2%)
III	47 (52.2%)
IV	25 (27.8%)
Unspecified	9 (10%)

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438 **Table 3** – Accuracy of peritoneal carcinomatosis diagnosis by FDG PET CT

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	Omentum	SI	Colonic	Cupola	Ovary	Pelvic nodes	LA nodes	Global
Se	25%	7.3%	26.3%	44.4%	54.05%	30%	30.8%	60%
Sp	75%	97.4%	92.9%	75%	90.9%	83.3%	92.3%	97.2%
PPV	66.7%	75%	76.9%	50%	90.9%	50%	80%	96.3%
NPV	66.7%	50.7%	41.8%	29.4%	45.9%	33.3%	42.8%	34%
Accuracy	41.7%	50.6%	61.25%	64%	67.8%	62.9%	61.5%	76.25%

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441 Se: Sensibility; Sp: Specificity; PPV: Positive predictive value; NPV: Negative predictive value; LA: lumbar aortic; SI: small
 442 intestine

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456 **Table 4** – Accuracy of peritoneal carcinomatosis diagnosis by CT

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	Omentum	SI	Colic	Cupola	Ovary	Pelvic nodes	LA nodes
Se	60%	9%	21%	45.8%	80%	43%	40%
Sp	81%	97%	91.2%	93.3%	53%	78.6%	91%
PPV	85.7%	75%	70%	84.6%	77.8%	50%	80%
NPV	48.5%	54%	47%	31.7%	43.75%	27%	37.5%
Accuracy	67.2%	50%	56%	72.2%	71.1%	66.7%	67%

458 Se: Sensibility; Sp: Specificity; PPV: Positive predictive value; NPV: Negative predictive value; LA: lumbar aortic; SI: small
 459 intestine

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473 **Table 5** – Diagnosis value of PET CT in literature

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Reference	Se	Sp	PPV	NPV	Accuracy	PC / n
Lee et al (9)	72	65	-	-	-	61/61
Klumpp et al.(24)	93	96	98	84	94	15/15
Risum et al.(26)	97	90	-	-	-	26/40
Pfannenbergl et al.(27)	63	89	93	52	-	22/22
Kim et al.(28)	96	90	93	95	94	26/40
Limei et al.(29)	89	90	-	-	-	1198/1747
Li et al.(30)	84	94	-	-	-	1291/1291
Suppiah et al.(31)	86,8	-	-	-	-	184/184
De Iaco et al.(32)	78,9	68,4	-	-	-	308/346

475 PC peritoneal carcinomatosis

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