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Original Research Article

Assessment of CA-125 levels and imaging findings in women with suspected malignant ovarian tumors

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ABSTRACT

Background: Ovarian cancer diagnosis is growing due to the prudent use of investigational methods. Imaging techniques and molecular biomarkers are the commonly used. A correct ovarian cancer staging assists gynecological oncologists in determining whether the patient required primary debulking surgery or neoadjuvant chemotherapy. The aim of the study was to evaluate the accuracy of CA-125 titre, USG of whole abdomen imaging and CT scan for diagnosis of ovarian malignancy.
Methods: A prospective, observational study was conducted Gynae Oncology Unit, Department of Obs and Gynae, Dhaka Medical College Hospital, Dhaka during January 2022 to December 2022. Total 96 patients who were diagnosed clinically as malignant ovarian tumor were included in the study.
Results: The sensitivity of malignant ovarian tumors by USG was calculated to be 89.4%, specificity was 76.7%, accuracy was 85.4%, PPV was 89.4%, and NPV was 76.7%. The validity of CA-125 in malignant ovarian tumors was demonstrated by calculating sensitivity of 75.8%, specificity of 90.0%, accuracy of 80.2%, PPV of 94.3%, and NPV of 62.8%. The sensitivity of malignant ovarian tumors by CT was calculated to be 90.9%, specificity was 86.7%, accuracy was 89.6%, PPV was 93.8%, and NPV was 81.3%. Using histology as the gold standard.
Conclusion: The results of this study demonstrate the superior diagnostic capabilities of two distinct imaging modalities (USG and CT) in determining the degree of malignant spread.

Keywords: USG, CT, CA-125, Ovarian cancer

INTRODUCTION

Ovarian cancer is a malignant tumor of the female reproductive system with the highest mortality. The incidence of ovarian cancer in recent years is getting higher due to the increasing stress on life, which poses a serious threat to the health and lives of the majority of women.[1] Ovarian cancers (OC) include a group of diseases with variable prognosis. The diagnostic imaging with particular focus in molecular biomarker has the potential for altering management plans, which can ultimately help to improve the prognosis of ovarian cancer.[2] OC occupies the seventh place between malignant tumours and the eighth place as a cause of death from cancer in women in the world accounting for over 384,000 deaths in 2018.3 Survival depends on stage at diagnosis, with five-year net survivals of 93% for stage I, 68% for stage II, 27% for

stage III, and 13.4% for stage IV disease.[4] Most women are diagnosed following a symptomatic presentation and in healthcare systems in which general practitioners (GPs) play a gatekeeping role, this initial presentation usually takes place in primary care.[5,6]

Symptoms can occur at all stages of ovarian cancer.[7] However, they are usually nonspecific and are common in women without ovarian cancer, so they only have modest positive predictive values for the disease.[8]

CA125 has been studied extensively in screening studies and in women at secondary care with pelvic masses but not in women presenting with symptoms of possible ovarian cancer in primary care. The NICE guidelines for CA125 testing in women with symptoms are derived from data gathered in secondary care and screening settings, rather than primary care.[9]

The effectiveness of a test can differ based on factors such as the prevalence of the disease, its severity, and the occurrence of other conditions that might raise CA125 levels. Therefore, assessing CA125 within the specific population for which it is intended is crucial.[10]

CA125 is a protein that is found in greater concentration in ovarian cancer tumor cells than in other cells of the human body. Therefore, a simple blood test, using a sample taken from a peripheral vein, makes it possible for it to be used as a marker to detect the presence of ovarian cancer.

However, CA125 is not specific to ovarian cancer, as elevated levels can also be observed in other cancers, such as breast, lung, colon, and pancreatic cancers, as well as in non-cancerous conditions like endometriosis, pelvic inflammatory disease, and ovarian cysts.[11] CA125 has a high positive predictive value (PPV) of >95%, but a low negative predictive value (NPV) ranging from 50 to 60%, for the detection of OC.12 Some studies have advocated the use of a single CA125 level measurement, frequently quoting the value 35 IU/ml as a cut-off point to indicate the presence of malignancy.[13,14] Levels above this have a good positive predictive value, however many actual cancers may have lower levels of CA125 and can be missed.[15]

As people's awareness of tumor markers has increased, the combined detection of tumor markers has become an important issue.[16] Ultrasound is the most commonly used method in gynecological investigations and plays a very important screening role in diagnosis because of non-invasiveness and high efficiency.

Computed tomography (CT), especially contrast enhanced scanning, has been widely used in the diagnosis of ovarian cancer in recent years, and certain achievements have been obtained.[17] The objective of this study was to evaluate the accuracy of CA-125 titre, USG imaging and CT scan for diagnosis of ovarian malignancy.

METHODS

Study place

This prospective, observational study was conducted in the Gynae Oncology Unit, Department of Obstetrics and Gynaecology at Dhaka Medical College Hospital, Dhaka.

Study duration

The study period was from January 2022 to December 2022.

Sample size

A total of 96 patients, clinically diagnosed with malignant ovarian tumors, were purposively sampled.

Inclusion criteria

Patients with elevated CA-125 levels, complex adnexal masses on ultrasound, or CT scan findings indicating complex ovarian tumors and metastasis were included.

Exclusion criteria

Exclusion criteria comprised patients who had undergone radiotherapy or chemotherapy, had cognitive or communication disorders, severe liver or kidney dysfunction, or were unwilling to participate.

Ethical approval

Ethical approval was obtained from the Dhaka Medical College Hospital's Ethical Committee, and informed consent was taken from all participants.

Data collection

The data collection process involved taking fasting venous blood samples (5 ml) from each participant for CA-125 estimation, with a CA-125 level above 35 U/ml considered positive. Ultrasound examinations were performed, followed by contrast-enhanced CT scans of the abdomen using 90 ml of contrast agent intravenously injected at 2.8 ml/sec. Clinically suspected ovarian malignancy cases underwent laparotomy, and specimens were sent for histopathological analysis to differentiate between benign and malignant tumors. The preoperative findings from CA-125 levels, ultrasound, and CT scans were compared with the histopathological outcomes to assess the diagnostic value of each method.

Statistical analysis

Data were analyzed using SPSS version 23.0, where mean values were calculated for continuous variables and frequencies for categorical variables. The Chi-Square test was used for categorical variables, and the sensitivity,

specificity, accuracy, positive predictive value, and negative predictive value of CA-125, ultrasound, and CT scan for ovarian malignancy diagnosis were calculated. A p value of less than 0.05 was considered statistically significant. Throughout the study, privacy, confidentiality, and patients' rights were strictly maintained, with no experimental drugs used. Participants were informed about the study's purpose, had the right to withdraw at any time, and their participation did not affect their treatment.

RESULTS

Table 1 According to age all patients were divided in seven groups. Among them almost one third (33.33%) patients belonged to age 51-60 years. The mean age was found 53.7±14.5 years with range from 19 to 73 years. The majority (38.54%) patients completed primary education. The majority (91.7%) patients were housewives and 8 (8.3%) were service holder. Eighty-six patients (89.6%) were from lower middle-class families, seven (7.3%) from low families, and three (3.1%) were from upper middle-class families.

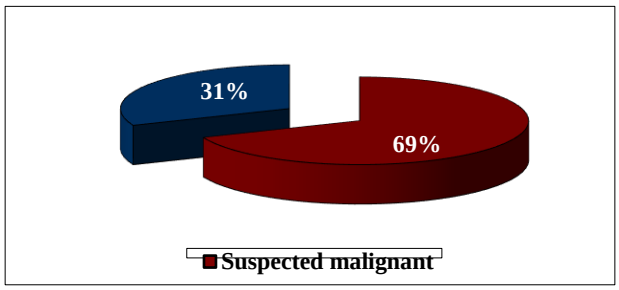

Figure 1: USG diagnosis of the study patients.

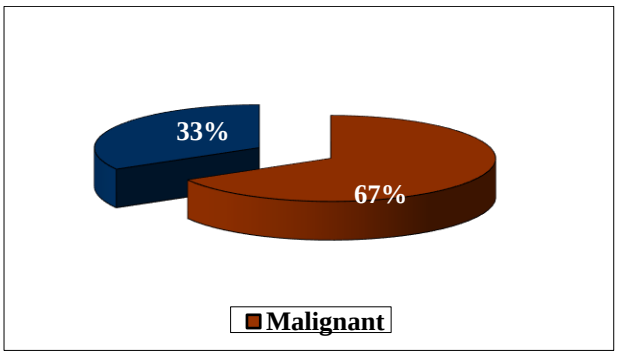

Figure 2: CT diagnosis of the study patients.

Table 2 shows the background history and risk factors among the study subjects. Menstrual status, parity, risk factors and nutritional status (BMI) were taken into account. Majority of the patients were multiparous and premenopausal 87.5% and 57.29% respectively. Chewing tobacco habit, hypertension, diabetes, dyslipidaemia, family history of ovarian disease, sedentary lifestyle, and obesity were found in 5.21%, 33.33%, 20.83%, 15.63%, 4.17%, 9.38%, and 75% respectively.

Table 1: Socio-demographic characteristics of the study subject (n=96).

Characteristics	Number of patients	%
Age in years		
≤20	2	2.08
21-30	10	10.42
31-40	11	11.46
41-50	24	25.00
51-60	32	33.33
61-70	15	15.63
>70	2	2.08
Mean ±SD	53.7±14.5	
Educational status		
Illiterate	24	25.00
Primary	37	38.54
Secondary	30	31.25
Graduate	5	5.21
Occupational status		
Housewife	88	91.70
Service	8	8.30
Socio-economic status		
Low income	7	7.30
Lower-middle income	86	89.60
Upper-middle	3	3.10

*Low-income =≤7400 TK, Lower-middle income =7401-29000 TK, Upper-middle (29001-89920 TK, High income =>89920 TK (World Bank Data Team, 2022).

Table 2: Background history and risk factors among the study subjects (n=96).

Factors	Number of patients	%
Gynaecological history menstrual status		
Premenopausal	55	57.29
Postmenopausal	41	42.71
Parity		
Nulliparous	12	12.50
Multiparous	84	87.50
Risk factors		
Smoking/chewing tobacco	5	5.21
Hypertension	32	33.33
Diabetes mellitus	20	20.83
Dyslipidaemia	15	15.63
Family history of ovarian disease	4	4.17
Sedentary lifestyle	9	9.38
BMI (kg/m2)		
<25	24	25.00
≥25	72	75.00

Table 3: Distribution of the study patients according to USG findings (n=96).

USG findings	Number of patients	%
Morphology characteristic		
Cystic	22	22.9
Solid	15	15.6
Partly cystic, partly solid	59	61.5
Largest diameter		
<100 mm	24	25.0
>100 mm	72	75.0
Surface and locularity		
Irregular and multilocular	56	58.3
Smooth and unilocular	40	41.7
Papillary projections		
Present	32	33.3
Absent	64	66.7
Associated findings		
Ascites	33	34.4
Peritoneal deposits	22	22.9
Omental thickening	7	7.3
Lymphadenopathy	2	2.1
Acoustic shadows	14	14.6
Colour score		
No blood flow	40	41.7
Very strong blood flow	56	58.3

Table 3 shows that 22 (22.9%) tumors were cystic, solid 15 (15.6%) and partly cystic, partly solid 59 (61.5%), 72 (75.0%) had largest diameter >100 mm, 56 (58.3%) tumors had irregular & multilocular, 32 (33.3%) had papillary projections, 33 (34.4%) was ascites, 22 (22.9%) was peritoneal deposits, 7 (7.3%) was omental thickening, 2 (2.1%) was lymphadenopathy, acoustic shadows were 14 (14.6%) and 56 (58.3%) had very strong blood flow.

Table 4: Detection of serum CA-125 of the study population (n=96).

CA-125 (U/ml)	Number of patients	%
≤35	43	44.80
>35	53	55.20
Mean ±SD	175.04±173.48	
Range (min-max)	23-620	

Figure 1 shows that more than two third 66 (68.8%) patients were found suspected malignant and 30 (31.2%) benign identified by USG.

Table 4 shows that more than half (55.2%) of the patients were found CA-125>35 U/ml. The mean CA-125 was found 175.04±173.48 U/ml with range from 23.0 to 620 U/ml.

Table 5 reveals that 20 (20.83%) of the tumors were cystic, 18 (18.75%) were solid, and 58 (60.42%) were mixed. 77 (80.2%) tumors had septation, 38 (39.6%) had papillary projections, 37 (38.5%) tumors had heterogeneous enhancement, 19 (19.8%) was peritoneal deposits, 43 (44.8%) was ascites, 8 (8.3%) was omental thickening, 4(4.2%) was lymphadenopathy and calcification was 26 (27.1%).

Figure 2 shows that two third (66.7%) patients were found malignant and 32 (33.3%) benign identified by CT.

In Table 6 out of 96 study patients 66(68.8%) was diagnosed as malignant ovarian tumors among them 34(51.5%) patients had high grade serous cystadenocarcinoma, 15 (22.7%) had low grade serous cystadenocarcinoma, 6 (9.1%) had mucinous cystadenocarcinoma, 6 (9.1%) had dysgerminoma, 1 (1.5%) had immature teratoma and 4 (6.1%) had borderline ovarian tumor. Thirty (31.2%) patients were diagnosed as benign tumors among them 10 (33.3%) had endometriosis, 10 (33.3%) had mucinous cystadenoma, 6 (20.0%) had dermoid cyst and 4 (13.3%) had serous cystadenoma.Table 7 shows that USG diagnosis evaluation for ovarian malignancy, true positive 59 cases, false positive 7 cases, false negative 7 cases and true negative 23 cases in identification by histopathological diagnosis.

Table 8 the validity of malignant ovarian tumors by USG was represented by calculating sensitivity was 89.4%, specificity was 76.7%, accuracy was 85.4%, PPV was 89.4% and NPV was 76.7% taken into account histopathology as gold standard.

Table 5: Distribution of the study patients according to CT findings (n=96).

CT findings	Number of patients	%
Densities		
Cystic	20	20.83
Solid	18	18.75
Mixed	58	60.42
Septation		
Present	77	80.2
Absent	19	19.8
Papillary projections		
Present	38	39.6
Absent	58	60.4
Pattern of enhancement		
Homogenous	12	12.5
Heterogeneous	37	38.5
Non enhancing	47	49.0
Associated findings		
Peritoneal deposits	19	19.8
Ascites	43	44.8
Omental thickening	8	8.3
Lymphadenopathy	4	4.2
Calcification	26	27.1

Table 6: Distribution of the study patients according to histopathological finding (n=96).

Histopathological finding	Number of patients	%
Malignant	66	68.8
High grade serous cystadenocarcinoma	34	51.5
Low grade serous cystadenocarcinoma	15	22.7
Mucinous cystadenocarcinoma	6	9.1
Dysgerminoma	6	9.1
Immature teratoma	1	1.5
Borderline ovarian tumor	4	6.1
Benign	30	31.2
Dermoid cyst	6	20.0
Endometriosis	10	33.3
Mucinous cystadenoma	10	33.3
Serous cystadenoma	4	13.3

Table 7: Comparison between histopathological diagnosis and USG diagnosis evaluation for ovarian malignancy (n=96).

USG diagnosis	Histopathological diagnosis		P value
	Positive (n=66)	**Negative (n=30)**	
Positive (n=66)	59 (True positive)	7 (False positive)	0.001[s]
Negative (n=30)	7 (False negative)	23 (True negative)	

s=significant, p value reached chi square test.

Table 8: Sensitivity, specificity, accuracy, positive and negative predictive values of the USG, CT and CA-125 diagnosis evaluation for prediction of ovarian malignancy.

Validity test	USG	CA-125	CT
Sensitivity	89.4	75.8	92.42
Specificity	76.7	90.0	89.66
Accuracy	85.4	80.2	91.58
Positive predictive value	89.4	94.3	94.31
Negative predictive value	76.7	62.8	83.87

The validity of malignant ovarian tumors by CA-125 was represented by calculating sensitivity was 75.8%, specificity was 90.0%, accuracy was 80.2%, PPV was 94.3% and NPV was 62.8% taken into account histopathology as gold standard. The validity of malignant ovarian tumors by CT was represented by calculating sensitivity was 90.9%, specificity was 86.7%, accuracy was 89.6%, PPV was 93.8% and NPV was 81.3% taken into account histopathology as gold standard.

DISCUSSION

In this study observed that almost one third (33.33%) patients belonged to age 51-60 years. The mean age was found 53.7±14.5 years with range from 19 to 73 years. Moideen et al found majority of patients included were above 40 years. The mean age was found 47.5±15.5 years with range from 11 to 73 years.[18] Guo et al reported 40.19% patients belonged to age >45 years in malignant, 25 (40.98%) in benign and 54.08% in normal groups.[1] The difference was not statistically significant (p>0.05). Funston et al, reported the mean patient age was 56 years (range: 18–102 years).[19] Another study by Ahmed et al, at BIRDEM hospital found mean age of patient with ovarian cancer was 47.5 years (range: 20–50 years) which was also nearly similar to this study.[20]

In this study menstrual status, parity, risk factors and nutritional status (BMI) were taken into account. 84 (87.5%) patients were found multipara and 12 (12.5%) was nulliparous. Moideen et al, reported majority (70.3%) of patients were multiparious, 10 (18.5%) were nulliparious and 6 (11.1%) were grand multi parous.[18]

Chewing tobacco habit, hypertension, diabetes, dyslipidaemia, family history of ovarian disease, sedentary lifestyle, and obesity were found in 5.21%, 33.33%, 20.83%, 15.63%, 4.17%, 9.38% and 75% respectively. Moideen et al, observed 38 (70.3%) patients were multiparus and 59.3% was premenopausal.[18] Jacobs et al reported postmenopausal was found 48.0% in benign and 80.5% in malignant group.[16] Timmerman et al, discovered the family history of ovarian cancer was 4.31%.[21]

In this study observed that 22 (22.9%) tumors were cystic, 72 (75.0%) had largest diameter >100 mm, 56 (58.3%) tumors had irregular and multilocular, 32 (33.3%) had papillary projections, 33 (34.4%) was ascites, 22 (22.9%) was peritoneal deposits, 7 (7.3%) was omental thickening, 2 (2.1%) was lymphadenopathy, acoustic shadow was 14 (14.6%) and 56 (58.3%) had very strong blood flow. More than two third 66 (68.8%) patients were found suspected malignant and 30 (31.2%) benign identified by USG. Moideen et al reported 66.6% cases were malignant.[18] Bhimani et al observed 25 patients were found septation in benign and 35 cases in malignant tumor identified by USG.[22] Arora et al, reported presence of papillary projections in 11.1% in benign lesions and in 32.3% of malignant lesions in USG.[23] Timmerman et al, papillary projection was evident in 28.14% of cases, acoustic shadows were present in 12.7% of benign cases and 1.5% of malignant ones. The color score was recorded. Strong flow (Score 4) in malignant (36.4%) and benign (5.7%) tissue.[21]

In this study that more than half (55.2%) of the patients were found CA-125 >35 U/ml. The mean CA-125 was found 175.04±173.48 U/ml with range from 23 to 620 U/ml. Moideen et al reported CA 125 levels were low (<35 U/ml) in 15 (27.7%), mildly elevated (35-200 U/ml) in 18

(33.3%), significantly elevated in (201-1000 U/ml) in 18 (33.3%) and were very high (>1001 U/ml) in 3 (5.5%) cases.[18]

In this study showed that 47 (49.0%) tumors were cystic, 77 (80.2%) tumors had sepation, 38 (39.6%) had papillary projections, 37 (38.5%) tumors had heterogeneous enhancement, 19 (19.8%) was peritoneal deposits, 43 (44.8%) was ascites, 8 (8.3%) had omental thickening, 4 (4.2%) was lymphadenopathy and calcification was 26 (27.1%). Two third (66.7%) patients were suspected malignant and 32 (33.3%) benign identified by CT. Arora et al., reported in CT 29.4% malignant tumors had papillary projections and 5.8% benign tumors had papillary projections.[23] CT was significantly better showing lymphadenopathy in 17 malignant cases while USG could detect only 8 cases. Moideen et al, reported 87.5% cases were suspected malignant on CT.[18] In this study out of 96 patient 66 (68.8%) were diagnosed as malignant ovarian tumour among them 34 (51.5%) patients had high grade serous cystadenocarcinoma, 15 (22.7%) had low grade serous cystadenocarcinoma, 6(9.1%) had mucinous cystadenocarcinoma, 6 (9.1%) had dysgerminoma, 1 (1.5%) had immature teratoma and 4 (6.1%) had borderline ovarian tumor.

Thirty (31.2%) patients were diagnosed as benign tumors among them 10 (33.3%) had Endometriosis, 10 (33.3%) had mucinous cystadenoma, 6 (20.0%) had dermoid cyst and 4 (13.3%) had serous cystadenoma. Moideen et al reported nine cases were diagnosed as benign tumors among them 7 had mucinous cystadenoma, 1 had serous cystadenoma and 1 had mucinouscystadenoma with Brenner.[18] Funston et al reported the ovarian cancers diagnosed, 21.5% (n=98) were borderline tumors.[19] Bhimani et al, reported the most common malignant tumors in his study were serous cyst adenocarcinoma (45.6%) and mucinous cystadenocarcinoma (26%).[22]

In this study showed the validity of malignant ovarian tumors by USG was represented by calculating sensitivity was 89.4%, specificity was 76.7%, accuracy was 85.4%, PPV was 89.4% and NPV was 76.7% taken into account histopathology as gold standard. The validity of malignant ovarian tumors by CA-125 was represented by calculating sensitivity was 75.8%, specificity was 90.0%, accuracy was 80.2%, PPV was 94.3% and NPV was 62.8% taken into account histopathology as gold standard. The validity of malignant ovarian tumors by CT was represented by calculating sensitivity was 90.9%, specificity was 86.7%, accuracy was 89.6%, PPV was 93.8% and NPV was 81.3% taken into account histopathology as gold standard. Moideen et al reported USG had 90.2% sensitivity, 53.8% specific, 81.5% accuracy, 86.0% PPV and 63.6% NPV.

CA 125 had an 87.8% sensitivity, 76.9% specificity, 85.2% accuracy, 92.3% PPV and 66.7% NPV. CT had 95.1% sensitivity, 46.2% specificity, 83.3% accuracy, 84.8% PPV and 75.0% NPV.18 USG for detection of ovarian malignancy was found 91% sensitivity and 91% specificity.[24] Another study Anton et al reported that sensitivity was 90% and specificity was 88%.[25] CT for the detection of ovarian malignancy was found 91% sensitivity and 96% specificity.[26] Another study Mubarak et al reported that sensitivity was 97% and specificity was 91%.[27] Guo et al reported sensitivity, specificity, diagnostic coincidence rate, PPV and NPV of USG were 79.44, 81.97, 80.36, 88.54 and 69.44 respectively.[1] Sensitivity, specificity, diagnostic coincidence rate, PPV and NPV of CA125 was 77.57, 80.33, 78.57, 87.37 and 67.12 respectively. Sensitivity, specificity, diagnostic coincidence rate, PPV and NPV of CT was 83.18, 58.25, 83.93, 90.82 and 74.29 respectively. Funston et al reported at or above the 35 U/ml cutoff, CA125 demonstrated a PPV of 10.1% (95% CI 9.1–11.2), an NPV of 99.8% (95% CI 99.7–99.8), a sensitivity of 77.0% (95% CI 72.8–80.8%) and a specificity of 93.8% (95% CI 93.6–94.0) for ovarian cancer.[19] Priya and Kirubamani reported USG showed 88.00% sensitivity, 80.68% specificity in predicting ovarian cancer.[28] Arora et al, observed that sensitivity of USG and CT was 76.4% and 91.7%, specificity 83.3% and 77.7%, accuracy 78.8% and 86.5% respectively.[23] Moideen et al reported that USG had sensitivity of 90.2%, specificity 53.8%, PPV 86%, NPV 75%, accuracy 85.2% and CT had sensitivity 95.1%, specificity 46.2%, PPV 84.8%, NPV 75% and accuracy 94.4%.[18]

Limitations of the study was that the populations were selected from one tertiary care hospital in Dhaka city, so that the results of the study may not reflect the exact picture of the country. Small sample size was also a limitation of the present study. Therefore, in future further study may be under taken with large sample size.

CONCLUSION

The findings of this study show that USG and CT scan have excellent diagnostic capacities in detecting the amount of malignant dissemination. The addition of a third parameter, CA-125 increases precision even more. It is difficult to diagnose suspected ovarian cancer by a single investigative method. All the three modes can give a valuable direction for the evaluation of cancer patients.

Recommendations

Further studies can be undertaken by including large number of patients.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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