To Determine the Accuracy of Frozen Section in the Management of Ovarian Tumours

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ABSTRACT

BACKGROUND

Frozen section done during surgery provides a valuable tool in the diagnosis and classification of tumours into benign, borderline and malignant. In this study, we evaluated the intraoperative findings and the accuracy of the frozen section and compared it with the final histopathology report.

METHODS

A retrospective study was done in the Department of Obstetrics and Gynecology in Sri Ramachandra University and Research Centre from January 2017 to January 2020, for a period of 3 years and data was taken from the patients who underwent surgery-staging laparotomy for ovarian masses along with frozen section in the diagnosis of their tumor. The final histopathology report is the gold standard for detection of ovarian tumours. The accuracy of the frozen section was compared with the final histopathological report on paraffin section.

RESULTS

There was a total of 109 cases during the study period of 3 years. Out of the total, frozen section showed 55 malignancy cases, 7 cases were borderline, and 47 cases were benign tumors; whereas the final histopathology report showed 51 malignant cases, 9 borderline cases, and 49 cases were benign tumors. This shows that frozen section has almost 97 % accuracy.

CONCLUSIONS

Frozen section is a very good tool in the diagnosis of tumour whether benign, borderline or malignant and when compared with the final histopathological report gives good accuracy. The diagnosis given during surgery is helpful in the further management of patients according to the stage of the tumour.

KEY WORDS

Frozen Section, Benign, Borderline, Malignant tumours, Final Histopathological Report

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DOI: 10.14260/jemds/2021/170

How to Cite This Article:

Murugesan S, Nadar AN. To determine the accuracy of frozen section in the management of ovarian tumours. J Evolution Med Dent Sci 2021;10(11):793-797, DOI: 10.14260/jemds/2021/170

Submission 10-11-2020,

Peer Review 23-01-2021,

Acceptance 30-01-2021,

Published 15-03-2021.

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BACKGROUND

Frozen section has been used for than 100 years as it was published by Louis B Wilson in the Journal of the American Medical Association (JAMA) article in December 1905.¹ Risk of malignancy index (RMI) was the most commonly used technique to predict malignant risk of ovarian masses in many national guidelines. However, newer models such as the assessment of different neoplasia in the adnexa model (ADNEX) perform better than the RMI.² Frozen sections are a diagnostic tool which can prevent unnecessary second operation and adjuvant chemotherapy. The clinical diagnosis of ovarian tumours is difficult and can be done accurately by staging laparotomy and with Federation of Obstetrics and Gynecology (FIGO) staging both surgical and pathological staging.^{3,4}

The management depends on the category and the histological diagnosis of the tumour. In case of ovarian tumours, both benign and borderline tumours, fertility conserving surgeries omitting the lymph node sampling can be done, whereas in malignant tumours complete surgical staging with total abdominal hysterectomy with bilateral salpingo-oophorectomy with partial omentectomy and retroperitoneal lymph node sampling is done.⁵ Frozen section is an important tool in the diagnosis of category of the tumour.⁶ A good communication is necessary between the surgeon and the pathologist.⁷ In this study, we evaluated the intraoperative findings of the frozen section and compared it with the final histopathology report and we tried to know the accuracy of frozen section.

METHODS

A retrospective study was done in the Department of Obstetrics and Gynecology in Sri Ramachandra University and Research Centre from January 2017 to January 2020, a period of 3 years, and data was taken from those patients who underwent surgery-staging laparotomy for ovarian masses along with frozen section in the diagnosis of their tumour whether benign or malignant. The accuracy of the frozen section was compared to that of the final histopathological report on paraffin section. The frozen section, clinical data, preoperative cancer antigen-125 (CA-125) levels in mIU / l, operative details and final histopathology reports were reviewed. For patients planned for staging laparotomy, the gynaecologist team had informed the pathologist in advance for the frozen section. The pathologists in duty took the tissue and processed it for frozen section. The diagnosis of the tumour was informed to the surgeon on phone within 30 minutes, during the surgery. The management varies depends on the category of the frozen section. The specimen was then fixed in 10 % formalin overnight and sampled for routine histopathology. Diagnosis of ovarian tumour was done according to the World Health Organization (WHO) and FIGO (Federation of Obstetrics and Gynecology) classification.⁸

Statistical Analysis

Accuracy, sensitivity, specificity, positive predictive value and negative predictive value were calculated for frozen section

and final histopathological diagnosis. The P-value was calculated by Fischer's exact test. The cases with different diagnosis between frozen section and final histopathology were reviewed in detail by special pathologists.

RESULTS

The total number of benign, borderline and malignant cases diagnosed by frozen section and their accuracy, sensitivity, specificity, positive predictive value and negative predictive value were compared with final histopathological reports.

Frozen Section Diagnosis	Frozen Section Diagnosis			Total
	Malignant	Borderline	Benign	
Malignant	50	2	3	55
Borderline	0	7	0	7
Benign	0	0	47	47
Total	50	9	50	109

Table 1. Classification of Tumours

In this study, Table 1 shows diagnosis by frozen section. Out of 109 cases, frozen section done intraoperatively showed 55 malignant cases, 7 borderline cases and 47 benign cases. It showed 2 borderline malignant cases.

Diagnostic value (%) (95 % CI)	Benign	Borderline	Malignant	Borderline / Malignant
Accuracy	95.41 % (89.71 - 98.03)	98.17 % (93.56 - 99.5)	97.25 % (92.22 - 99.06)	95.41 % (89.71 - 98.03)
Sensitivity	100 % (92.87 - 100)	77.78 % (45.26 - 93.68)	94 % (83.78 - 97.94)	91.53 % (81.65 - 96.33)
Specificity	91.53 % (81.65 - 96.33)	100 % (96.3 - 100)	100 % (93.89 - 100)	100 % (92.87 - 100)
PPV	90.91 % (80.42 - 96.06)	100 % (64.57 - 100)	100 % (92.45 - 100)	100 % (93.36 - 100)
NPV	100 % (93.36 - 100)	98.04 % (93.13 - 99.46)	95.16 % (86.71 - 98.34)	90.91 % (65.55 - 110.93)

Table 2. Accuracy, Sensitivity, Specificity, PPV and NPV of Frozen Section

Histopathological Diagnosis	HPE Diagnosis			Total
	Malignant	Borderline	Benign	
Malignant	50	0	1	51
Borderline	0	9	0	9
Benign	0	0	49	49
Total	50	9	50	109

Table 3. Histopathological Diagnosis

In this study, Table 2 shows the accuracy, sensitivity, specificity, positive predictive value and negative predictive value of frozen section. The benign cases had 95.41 % (89.71 % - 98.03 %) accuracy, 100 % (92.87 % - 100 %) sensitivity, 91.53 % (81.65 % - 96.33 %) specificity, 90.91 % (80.42 % - 96.06 %) positive predictive value and 100 % (93.36 % - 100 %) negative predictive value. The borderline cases had 98.17 % (93.56 % - 99.5 %) accuracy, 77.78 % (45.26 % - 93.68 %) sensitivity, 100 % (96.3 % - 100 %) specificity, 100 % (64.57 % - 100 %) positive predictive value and 98.04 % (93.13 % - 99.46 %) negative predictive value. The malignant cases had 97.25 % (92.22 % - 99.06 %) accuracy, 94 % (83.78 % - 97.94 %) sensitivity, 100 % (93.89 % - 100 %) specificity, 100 % (92.45 % - 100 %) positive predictive value and 95.16 % (86.71 % - 98.34 %) negative predictive value. The borderline malignant cases had 95.41 % (89.71 % - 98.03 %) accuracy, 91.53 % (81.65 % - 96.33 %) sensitivity, 100 % (92.87 % - 100 %)

%) specificity, 100 % (93.36 % - 100 %) positive predictive value and 90.91 % (65.55 % - 110.93 %) negative predictive value with 95 % confidence interval (CI).

In this study, Table 3 shows diagnosis by final histopathology report. Out of 109 cases, 51 cases were malignant, 9 cases were borderline, and 49 cases were benign.

Diagnostic Value (%) (95 % CI)	Benign	Borderline	Malignant	Borderline / Malignant
Accuracy	99.08 % (94.99 - 99.84)	100 % (96.6 - 100)	99.08 % (94.99 - 99.84)	99.08 % (94.99 - 99.84)
Sensitivity	100 % (92.87 - 100)	100 % (70.09 - 100)	98 % (89.51 - 99.65)	98.31 % (91.01 - 99.7)
Specificity	98.31 % (91.01 - 99.7)	100 % (96.3 - 100)	100 % (93.89 - 100)	100 % (92.87 - 100)
PPV	98.04 % (89.7 - 99.65)	100 % (70.09 - 100)	100 % (92.73 - 100)	100 % (93.79 - 100)
NPV	100 % (93.79 - 100)	100 % (96.3 - 100)	98.33 % (91.15 - 99.71)	98.04 % (69.41 - 119.94)

Table 4. Accuracy, Sensitivity, Specificity, PPV and NPV of Final Histopathological Diagnosis

In this study, Table 4 shows the accuracy, sensitivity, specificity, positive predictive value and negative predictive value of the final histopathological diagnosis. The benign cases had 99.08 % (94.99 % - 99.84 %) accuracy, 100 % (92.87 % - 100 %) sensitivity, 98.31 % (91.01 % - 99.7 %) specificity, 98.04 % (89.7 % - 99.65 %) positive predictive value and 100 % (93.79 % - 100 %) negative predictive value. The borderline cases had 100 % (96.6 % - 100 %) accuracy, 100 % (70.09 % - 100 %) sensitivity, 100 % (96.3 % - 100 %) specificity, 100 % (70.09 % - 100 %) positive predictive value and 100 % (96.3 % - 100 %) negative predictive value. The malignant cases had 99.08 % (94.99 % - 99.84 %) accuracy, 98 % (89.51 % - 99.65 %) sensitivity, 100 % (93.89 % - 100 %) specificity, 100 % (92.73 % - 100 %) positive predictive value and 98.33 % (91.15 % - 99.71 %) negative predictive value. The borderline malignant cases had 99.08 % (94.99 % - 99.84 %) accuracy, 98.31 % (91.01 % - 99.7 %) sensitivity, 100 % (92.87 % - 100 %) specificity, 100 % (93.79 % - 100 %) positive predictive value and 98.04 % (69.41 % - 119.94 %) negative predictive value with 95 % CI.

In this study, Table 5 shows the age, marital status, parity, previous deliveries, menopausal status, associated comorbidities and CA-125 value, histological classification and lymph node metastasis.

In women more than 40 years of age, out of 71 (65.1 %) cases, diagnosis was correct in 69 cases (97.2 %) and mismatched diagnosis in 2 cases (2.8 %). In women < / = 40 years, out of 38 cases (34.9 %), diagnosis was correct in 35 cases (92.1 %) and 3 cases (7.9 %) had mismatched diagnosis with P value not significant.

In unmarried females, out of 13 cases (11.9 %) 11 cases (84.6 %) had correct diagnosis and 2 cases (15.4 %) had mismatched diagnosis. In married females, out of 96 cases (88.1 %), 93 cases (96.9 %) had correct diagnosis and 3 cases (3.1 %) had mismatched diagnosis with P-value not significant.

16 cases (16.7 %) were nulliparous women in whom 15 cases (93.8 %) had correct diagnosis and 1 case (6.3 %) had mismatched diagnosis. 59 women (61.5 %) had < / = 2 children in whom 58 cases (98.3 %) had correct diagnosis and 1 case (1.7 %) had mismatched diagnosis. 21 women (21.9 %) had > 2 children, in whom 20 cases (95.2 %) had correct

diagnosis and 1 case (4.8 %) had mismatched diagnosis with P-value not significant.

		Diagnosis				P-Value	Total	
		Correct		Mismatched			Total	
		Count	%	Count	%		Count	%
Age	> 40 years	69	97.2 %	2	2.8 %	0.179	71	65.1 %
	< = 40 years	35	92.1 %	3	7.9 %		38	34.9 %
Marital status	Unmarried	11	84.6 %	2	15.4 %	0.095	13	11.9 %
	Married	93	96.9 %	3	3.1 %		96	88.1 %
Parity	Nulliparous	15	93.8 %	1	6.3 %	0.366	16	16.7 %
	< = 2	58	98.3 %	1	1.7 %		59	61.5 %
	> 2	20	95.2 %	1	4.8 %		21	21.9 %
Previous delivery	LSCS	20	100.0 %	0	0.0 %	0.56	20	25 %
	NVD	58	96.7 %	2	3.3 %		60	75 %
Menopausal status	Post-menopausal	52	96.3 %	2	3.7 %	0.32	54	49.5 %
	Pre-menopausal	52	94.5 %	3	5.5 %		55	50.5 %
Co-morbidities	Present	56	98.2 %	1	1.8 %	0.132	57	52.3 %
	Nil	48	92.3 %	4	7.7 %		52	47.7 %
CA125	< = 35	74	94.9 %	4	5.1 %	0.378	78	71.6 %
	> 35	30	96.8 %	1	3.2 %		31	28.4 %
Histological types	Serous	14	93.3 %	1	6.6 %	0.168	15	13.8 %
	Mucinous	28	93.3 %	2	6.6 %		30	27.5 %
	Endometrioid	13	92.8 %	1	7.2 %		14	12.8 %
	Metastatic	48	96 %	2	4 %		50	45.9 %
Lymph node metastasis	Present	16	94.1 %	1	5.9 %	0.132	17	15.6 %
	Absent	90	97.8 %	2	2.2 %		92	84.4 %
Table 5. Age, Marital Status, Parity, Previous Deliveries, Menopausal Status, Associated Comorbidities and CA-125 Value, Histological Classification and Lymph Node Metastasis								
P value – Fisher’s Exact test								

Table 5. Age, Marital Status, Parity, Previous Deliveries, Menopausal Status, Associated Comorbidities and CA-125 Value, Histological Classification and Lymph Node Metastasis

P value – Fisher's Exact test

20 cases (25 %) had previous caesarian section in whom all 20 cases (100 %) had correct diagnosis. 60 cases (75 %) had previous normal delivery in whom 58 cases (96.7 %) had correct diagnosis and 2 cases (3.3 %) had mismatched diagnosis with P-value not significant.

54 women (49.5 %) were postmenopausal in whom 52 cases (96.3 %) had correct diagnosis and 2 cases (3.7 %) had mismatched diagnosis. 55 women (50.5 %) were premenopausal, in whom 52 cases (94.5 %) had correct diagnosis and 3 cases (5.5 %) had mismatched diagnosis with P value not significant.

57 women (52.3 %) had associated comorbidities like diabetes, hypertension, heart problems, bronchial asthma, anemia etc., in whom 56 cases (98.2 %) had correct diagnosis and 1 case (1.8 %) had mismatched diagnosis. 52 women (47.7 %) had no comorbidities in which 48 cases (92.3 %) had correct diagnosis and 4 cases (7.7 %) had mismatched diagnosis with P value not significant.

78 women (71.6 %) had CA-125 values < / = 35 IU in whom 74 cases (94.9 %) had correct diagnosis and 4 cases (5.1 %) had mismatched diagnosis. 31 women (28.4 %) had CA-125 value > 35 IU in whom 30 cases (96.8 %) had correct diagnosis and 1 (3.2 %) case had mismatched diagnosis with P value not significant.

Histological classification included, 15 women (13.8 %) with serous tumours out of which 14 cases (93.3 %) had correct diagnosis and 1 case (6.6 %) had mismatched diagnosis, 30 women (27.5 %) with mucinous tumour in whom 28 cases (93.3 %) had correct diagnosis and 2 cases (6.6 %)

%) had mismatched diagnosis, 14 women (12.8 %) with endometrioid tumour in whom 13 cases (92.8 %) had correct diagnosis and 1 case (7.2 %) had mismatched diagnosis and 50 women (45.9 %) had metastatic tumour in whom 48 cases (96 %) had correct diagnosis and 2 cases (4 %) had mismatched diagnosis with P value not significant.

Lymph node metastasis was present in 17 women (15.6 %) in whom 16 cases (94.1 %) had correct diagnosis and 1 case (5.9 %) had mismatched diagnosis. 92 women (84.4 %) had no lymph node metastasis in whom 90 cases (97.8 %) had correct diagnosis and 2 women (2.2 %) had mismatched diagnosis with P value not significant.

DISCUSSION

In this study, out of 109 cases, frozen section done intraoperatively showed, 55 malignant cases, 7 borderline cases and 47 benign cases. 2 cases were borderline malignant. Whereas in the retrospective study done by A-BF Mohammed et al.⁹ intraoperative frozen section assessment between January 2009 and December 2012 analysed in the Middle East Fertility Society, where 4 cases had the diagnosis at the time of frozen section were deferred. In the remaining 56 patients, the frozen section (FS) diagnoses were benign in 24 cases, borderline in 9 cases, and malignant in 23 cases. In the study done by Fred Yau-Lung Kung,¹⁰ there were 1149 ovarian lesions sent for intraoperative frozen section reporting from January 2006 to December 2016, Six cases were excluded as the diagnosis was deferred from the time of the intraoperative frozen section (0.5 %). In frozen section, there were 748 benign, 154 borderline and 241 malignant cases.

In this study, in the final histopathology report, out of 109 cases, 51 cases were malignant, 9 cases were borderline and 49 cases were benign. Whereas in A-BF Mohammed et al.⁹ the final histopathology diagnosis was benign in 23 cases, borderline in 11 cases, and malignant in 26 cases. The final histopathology report in the Fred Yau-Lung Kung et al.¹⁰ study comprised 1143 cases, with 716 benign, 133 borderline, and 294 malignant.

In this study, the frozen section showed that the benign cases had 95.41 % accuracy, 100 % sensitivity, 91.53 % specificity, 90.91 % positive predictive value and 100 % negative predictive value. The borderline cases had 98.17 % accuracy, 77.78 % sensitivity, 100 % specificity, 100 % positive predictive value and 98.04 % negative predictive value. The malignant cases had 97.25 % accuracy, 94 % sensitivity, 100 % specificity, 100 positive predictive value and 95.16 % negative predictive. Whereas in the A-BF Mohammed et al.⁹ study, the overall accuracy of intraoperative frozen section diagnosis was 95.5 %. The sensitivity for frozen section diagnosis was 100 % for benign, 72.7 % for borderline and 88.4 % for malignant category, whereas the specificity was 97.3 %, 97.9 %, and 100.0 %, respectively. The positive predictive value was 95.8 % for benign, 88.8 % for borderline, and 100.0 % for malignant group, and the negative predictive values were 100 %, 94.1 %, and 91.8 %, respectively. In the Fred Yau-Lung Kung et al.¹⁰ study for benign diagnoses, the intraoperative frozen section diagnostic accuracy sensitivity and specificity were 97.20 %, 100 %, and 92.51 %, respectively, positive predictive value was 95.72 % and

negative predictive value was 100 %. For borderline diagnoses, the intraoperative frozen section diagnostic accuracy, sensitivity, and specificity, PPV and NPV were 95.19 %, 87.22 %, and 96.24 %, 75.32 % and 98.28 % respectively. For malignant diagnoses, the intraoperative frozen section diagnostic accuracy, sensitivity and specificity, PPV and NPV were 97.20 %, 81.29 %, and 99.76 %, 99.17 % and 93.90 % respectively.

According to Rhett Morton et al.¹¹ retrospective review was conducted for intraoperative frozen section of adnexal lesions from 2008 to 2013, diagnoses classified as benign, borderline or malignant. The overall sensitivity for diagnosing malignant disease was 75.9 % and the specificity was 100 % out of 277 cases. With a benign intraoperative frozen section result, there was a 6.25 % chance that the final diagnosis would be malignant and a 7.6 % chance that the final diagnosis would be borderline. The predictive values for benign, borderline and malignant intraoperative frozen section (IFS) results were 86.1 %, 66.6 % and 100 %, respectively. For a borderline intraoperative frozen section result, there was a 33.3 % chance that the final diagnosis would be malignant disease.

In this study, 71 cases (65.1 %) were > 40 years in whom the diagnosis was correct in 69 cases (97.2 %). 38 cases (34.9 %) were < / = 40 years in whom the diagnosis was correct in 35 cases (92.1 %) with P value not significant. In the study by A-BF Mohammed et al.⁹ the mean age was between 19 - 57 years. In the Fred Yau-Lung Kung et al.¹⁰ study 79.4 % were aged 40+ years out of which 79.2 % had correct diagnosis and 20.6 % of women were < 40 years, out of which, 20.4 % had correct diagnosis with P value not significant. In the study by A-BF Mohammed et al.⁹ the mean age was between 19-57 years.

In this study, 54 women (49.5 %) were postmenopausal in whom 52 cases (96.3 %) had correct diagnosis with P value not significant. In the study by A-BF Mohammed et al.⁹ 28 women (46.7 %) were postmenopausal. In the Fred Yau-Lung Kung et al.¹⁰ study 46.4 % were post-menopausal in whom 45.4 % had correct diagnosis with P value not significant.

In this study 16 cases (16.7 %) were nulliparous women, 59 women had < / = 2 children and 21 women (21.9 %) had > 2 children. In the study by A-BF Mohammed et al.⁹ 12 women (20 %) were nulliparous, and 48 women were multiparous.

In this study, 57 women (52.3 %) had associated comorbidities like diabetes, hypertension, heart problems, bronchial asthma, anemia etc. Whereas in the study by A-BF Mohammed et al.⁹ 34 women (56.6 %) had associated comorbidities like diabetes, hypertension, heart problems, bronchial asthma, anemia etc.

In this study, 31 women (28.4 %) had CA-125 value > 35 IU in whom 30 cases (96.8 %) had correct diagnosis with P value not significant. In the Fred Yau-Lung Kung et al.¹⁰ study the CA-125 value was higher than 35 IU / mL in 72.2 % of cases out of which 71.4 % had correct diagnosis with P value not significant.

Histological classification showed 15 women (13.8 %) with serous tumours in whom 14 cases (93.3 %) had correct diagnosis, 30 women (27.5 %) had mucinous tumour in whom 28 cases (93.3 %) had correct diagnosis, 14 women (12.8 %) had endometrioid tumour in whom 13 cases (92.8 %) had correct diagnosis and 50 women (45.9 %) had metastatic

tumour in whom 48 cases (96 %) had correct diagnosis with P value not significant.

In the Fred Yau-Lung Kung et al.¹⁰ study epithelial tumours accounted for 79.6 % of cases, 15.7 % serous tumours, out of which, 17.2 % had correct diagnosis; 29 % mucinous tumours, out of which, 27.3 % had correct diagnosis and 17.1 % endometrioid tumours, out of which, 16.9 % had correct diagnosis with P-value not significant.

CONCLUSIONS

Frozen section is a very good tool in the diagnosis of tumour whether benign, borderline or malignant, and when compared with the final histopathological report gives good accuracy. The diagnosis given intraoperatively is helpful in the further management of patients according to the stage of the tumour.

Data sharing statement provided by the authors is available with the full text of this article at jemds.com.

Financial or other competing interests: None.

Disclosure forms provided by the authors are available with the full text of this article at jemds.com.

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