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Diagnostic accuracy of intraoperative frozen section biopsy - A study at a tertiary care Centre in western Maharashtra

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Abstract

Background: A frozen section is a rapid diagnostic procedure performed on tissue obtained intraoperatively that helps the operating surgeon make immediate decisions during surgery, primarily by distinguishing between benign and malignant neoplasms. It plays a significant role in guiding intraoperative and perioperative patient management and reduces the need for re-operation.

Methods: The present study aimed to evaluate the diagnostic accuracy, sensitivity, and specificity of frozen section examination. An analysis of 49 frozen sections was conducted in the Pathology Department from September 2022 to May 2024. The frozen section diagnoses were compared with those obtained from routine paraffin sections. The results were classified as concordant or discordant. Diagnostic accuracy, sensitivity, and specificity were calculated.

Results: Of the 49 cases, the diagnosis was concordant with routine histopathology in 47 cases, whereas 02 cases were discordant. The overall diagnostic accuracy, sensitivity, specificity, positive predictive value, and negative predictive value were 95.92%, 96%, 95.43% ,96%, and 95.43%, respectively. The discordance rate was 4.08%.

Conclusion: Frozen section examination is a reliable, accurate, and rapid technique for intraoperative consultation. Several factors can affect the accuracy of frozen section diagnosis, including sampling, technical, and interpretation errors.

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Introduction

The frozen section technique was first used by William H. Welch of Johns Hopkins Hospital in 1891 for intraoperative consultation (1). Since then, this practice has developed rapidly. Frozen sections are performed for several reasons, including determining the nature and extent of a lesion, identifying lymph node metastasis, evaluating surgical margins, and assessing tissue adequacy for diagnosis (2,3). However, the primary purpose of frozen section examination is to assist the surgeon in making immediate decisions during surgery, mainly by distinguishing between benign and malignant neoplasms. It plays an important role in guiding intraoperative and perioperative patient management and reducing the need for re-operation (4). The indications and limitations of frozen section diagnosis vary among organs (2,5). The accuracy of frozen section diagnosis can be assessed by comparison with the final diagnosis based on permanent sections. Because only a small amount of tissue is sampled during frozen section examination and technical differences exist between frozen and permanent sections, discrepancies may occur between the two diagnoses (4,6-9). Periodic review of the correlation between frozen section and final diagnoses helps identify potential causes of errors, enables measures to prevent similar issues, and is an integral component of quality assurance in surgical pathology (2,4).

This study aimed to analyze the indications and turnaround time for intraoperative frozen section consultations at our institution, examine the spectrum of cases, and evaluate diagnostic accuracy across different anatomical sites. In addition, discordant cases were reviewed to identify their underlying causes, thereby helping to improve diagnostic skills and ultimately enhance patient care.

Methods

The present study included 49 fresh specimens received from surgical departments between September 2022 and May 2024 for intraoperative frozen section consultation, irrespective of age, sex, or anatomical site. The frozen section diagnoses were compared with those obtained from routine paraffin sections. The results were categorized as concordant or discordant. Diagnostic accuracy, sensitivity, specificity, positive predictive value, and negative predictive value were calculated.

Following approval by the Institutional Ethics Committee (IEC/MIMER/2022/825 dated 26/9/22), valid informed consent was obtained. Fresh specimens received from surgical departments for intraoperative frozen section consultation, irrespective of age, sex, or anatomical site, were included in the present study. Fresh tissue samples were received in properly labelled clean containers, together with requisition forms containing the necessary clinical details and the indication for frozen section consultation.

Inclusion criteria: Fresh surgical specimens received for intraoperative frozen section consultation in the Histopathology Laboratory of our institute, irrespective of age, sex, or anatomical site, were included in the present study.

Exclusion criteria: Formalin-fixed surgical specimens were excluded from the present study.

Fresh, unfixed tissue received in the Histopathology Laboratory was grossly examined, and appropriate sections were obtained. Frozen sectioning was performed using a cryostat (Leica, CM 1520). The sections were immediately stained with Toluidine blue and rapid H & E stain and then examined. A diagnosis was established and immediately communicated to the operating surgeon. Turnaround time (TAT) was recorded from receipt of the specimen to delivery of the report to the surgeon. The remaining gross specimen and frozen tissue fragments were fixed overnight in 10% neutral buffered formalin, processed in an automated tissue processor (Leica TP1020), embedded in paraffin, and stained with H and E stain. The frozen section diagnosis communicated to the surgeon at the time of surgery was compared with the final histopathological diagnosis based on the permanent sections.

The results were categorized as concordant or discordant. Diagnoses were considered concordant when they agreed with the permanent section diagnoses and discordant when they did not. Slides from the discordant cases were reviewed, and the causes of the discrepancies were analyzed. Diagnostic accuracy and discordance rates were calculated.

Results

The present cross-sectional study (September 2022 to May 2024) included 49 consecutive frozen section specimens from various organs obtained from 46 patients and received in the Department of Pathology at our college.

The largest numbers of frozen sections were obtained from patients aged 41 to 51 years and 61 to 70 years, followed by those aged 21 to 30 years and 31-40 years. The lowest incidence occurred in the 11-20-year age group, followed by the 71-80-year age group. There were 34 female patients and 12 male patients, corresponding to a female-to-male ratio of 2.8:1.

The most common indication for frozen section diagnosis was primary diagnosis or exclusion of malignancy, followed by exclusion of metastasis and assessment of margin involvement (Table 1).

Table 1. Distribution of frozen section cases by indication

Indication for frozen	No. of cases	Percentage
Primary diagnosis / Rule out malignancy	39	79.59%
Margin involvement	8	16.32%
To rule out metastasis	2	4.08%
Total	49	100.00%

Turnaround time (TAT) ranged from a minimum of 15 minutes to a maximum of 35 minutes. The largest number of cases, i.e, 30 cases, had a TAT of 21-25 minutes, followed by 15-20 minutes for 12 cases, 26-30 minutes for 6 cases, and 31-35 minutes for a single case. The average TAT was 23 minutes.

Of the 49 cases, the Department of Surgery contributed the largest number of frozen sections, followed by the Departments of Obstetrics and Gynaecology and Orthopaedics (Table 2).

Table 2. Distribution of cases by department

Department	No. of patients	Percentage
Surgery	24	51.02 %
Obstetrics and Gynaecology	22	44.90 %
Orthopaedics	03	5.77 %
Total	49	100%

Of the 49 cases, the largest number involved the female genital system, followed by the lymph nodes, breast, oral cavity, and skeletal system.

Of the 49 cases received for frozen section evaluation, 47 were concordant with the paraffin section diagnosis, yielding a concordance rate of 95.92%, whereas 2 were discordant, yielding a discordance rate of 4.08%.

Following final histopathological examination, 2 of the 49 cases received for frozen section examination were found to be discordant. The first involved an endometrial polypoidal lesion that, on frozen section, showed histological features suggestive of an endometrial polyp, with a single focus demonstrating a back-to-back arrangement of endometrial glands with mild-to-moderate cytologic atypia. It was therefore diagnosed as an endometrial polyp with a focus of endometrial intraepithelial lesion (EIN). Routine paraffin sections from the hysterectomy specimen showed complex endometrial glands with moderate cytologic atypia invading the upper 1/3rd of the myometrium. The diagnosis rendered was therefore endometrioid carcinoma NOS, FIGO grade 1.

The second case involved the pancreas, for which the frozen section diagnosis was "Suspicious for malignancy (Adenocarcinoma)." In contrast, the routine paraffin section diagnosis was "Chronic Pancreatitis." Glandular structures lined by cells with visibly enlarged nuclei and hyperchromasia were misinterpreted as malignant features on frozen section, while glands within areas of fibrosis were misinterpreted as evidence of invasion. However, extensive examination of routine paraffin sections showed that the glandular structures represented normal pancreatic tissue infiltrated by chronic inflammatory cells and fibrous tissue. The diagnosis rendered was therefore chronic pancreatitis.

Of the 49 cases, 47 were concordant and 2 were discordant. The number of true-positive cases was 24 (96%), whereas the number of true-negative cases was 23 (95.43%). The numbers of false-positive (4 %) and false-negative (4%) cases were 1 each.

For all 49 cases in the present study, diagnostic accuracy was 95.92%, sensitivity was 96%, specificity was 95.43%, the positive predictive value was 96%, and the negative predictive value was 95.43%.

Table 3 presents the comparative diagnoses of each case based on frozen and paraffin sections.

Table 3. Comparison of frozen section and paraffin section diagnoses

Sr. No.	Frozen diagnosis	Paraffin section diagnosis
1	Adult granulosa cell tumor of ovary	Adult granulosa cell tumor of ovary
2	Adult granulosa cell tumor of ovary	Adult granulosa cell tumor of ovary
3	Malignant ovarian tumor	Adult granulosa cell tumor of ovary
4	Malignant ovarian tumor	Adult granulosa cell tumor of ovary
5	Benign ovarian stromal tumor	Benign Fibroma of ovary
6	Benign ovarian stromal tumor	Benign Thecoma of ovary
7	Benign epithelial tumor of ovary	Serous cystadenofibroma of ovary
8	Benign epithelial tumor of ovary	Mucinous cystadenoma of ovary
9	Borderline seromucinous tumor of ovary	Borderline seromucinous tumor of ovary
10	Mature cystic teratoma of ovary	Mature cystic teratoma of ovary
11	Mature cystic teratoma of ovary (Figure 4)	Mature cystic teratoma of ovary (Figure 4)
12	Serous papillary cystadenocarcinoma of ovary (Figure 2)	Serous papillary cystadenocarcinoma of ovary (Figure 2)
13	Borderline serous tumor of ovary	Borderline serous tumor of ovary
14	Mucinous cystadenoma of ovary	Mucinous cystadenoma of ovary
15	Mucinous cystadenoma of ovary	Mucinous cystadenoma of ovary
16	Serous cystadenoma of ovary	Serous cystadenoma of ovary
17	Malignant epithelial tumor of ovary	Primary ovarian endometrioid carcinoma
18	Malignant germ cell tumor of ovary (Figure 1)	Dysgerminoma of ovary (Figure 1)
19	Normal ovarian tissue, Negative for malignancy	Normal ovarian tissue, Negative for malignancy
20	Normal ovarian tissue, Negative for malignancy	Normal ovarian tissue, Negative for malignancy
21	Endometrial polyp with a focus of endometrial intraepithelial neoplasia	Endometrioid carcinoma NOS, FIGO grade I of endometrium
22	Benign endometrial polyp	Benign endometrial polyp
23	Benign Phylloides tumor of breast	Benign Phylloides tumor of breast

Table 3 (Continued)

24	Malignant tumor of breast	Apocrine carcinoma of breast
25	Malignant tumor of breast	Invasive carcinoma of breast with mixed ductal and lobular features
26	Invasive ductal carcinoma of breast, NOS (Figure 5)	Invasive ductal carcinoma of breast, NOS
27	Giant cell tumor of bone	Giant cell tumor of bone
28	Giant cell tumor of bone	Giant cell tumor of bone
29	Negative for malignancy - Bony lesion	Negative for malignancy - Bony lesion
30	Squamous cell carcinoma - Oral cavity	Squamous cell carcinoma (Conventional), Moderately differentiated - Oral cavity
31	Squamous cell carcinoma - Oral cavity	Squamous cell carcinoma (Keratinizing), Well differentiated - Oral cavity
32	Squamous cell carcinoma - Oral cavity (Figure 6)	Squamous cell carcinoma (Conventional), Moderately differentiated - Oral cavity (Figure 6)
33	Squamous cell carcinoma - Penis	Squamous cell carcinoma usual type, moderately differentiated - Penis
34	All margins are negative for malignancy - Oral cavity	All margins are negative for malignancy - Oral cavity
35	Positive for metastatic deposits - Lymph Nodes	Positive for metastatic deposits from Invasive ductal carcinoma of breast
36	Positive for metastatic deposits - Lymph Nodes	Positive for metastatic deposits from Invasive ductal carcinoma of breast
37	Positive for metastatic deposits - Lymph Nodes	Positive for metastatic deposits from Invasive ductal carcinoma of breast
38	Positive for metastatic deposits - Lymph Nodes	Positive for metastatic deposits from Adenocarcinoma
39	Positive for metastatic deposits - Lymph Nodes (Figure 3)	Positive for metastatic deposits from Papillary thyroid carcinoma (Figure 3)
40	Lymphoproliferative lesion	High grade B cell Lymphoma
41	Papillary lesion, high suspicion of malignancy	Thyroid Papillary thyroid carcinoma
42	Multinodular Goiter	Thyroid Multinodular Goiter
43	Suspicious for malignancy (Adenocarcinoma) - Pancreas	Chronic Pancreatitis
44	All margins are negative for malignancy - Pancreas	All margins are negative for malignancy - Pancreas
45	Renal oncocytic tumor - suspicious for malignancy	Chromophobe renal cell carcinoma, WHO Grade2
46	High grade glioma	High grade glioma, IDH mutant, WHO grade IV
47	Chronic Sialoadenitis	Chronic Sialoadenitis
48	All margins are negative for malignancy - Soft tissue mass	All margins are negative for malignancy - Soft tissue mass
49	Necrotising granulomatous inflammatory lesion of Omentum	Tuberculous inflammatory lesion of Omentum

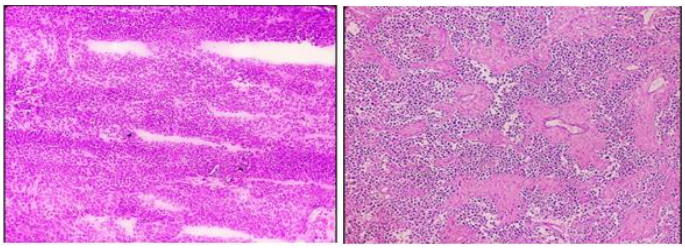

Figure 1. Photomicrograph of an ovarian mass showing a malignant germ cell tumor on frozen section (H and E, 10x) and dysgerminoma of the ovary on HPE (H and E, 10x)

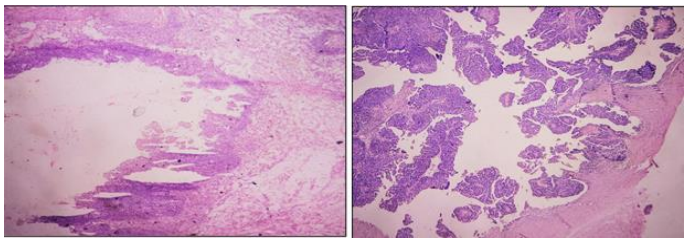

Figure 2. Photomicrograph of an ovarian cystic mass showing serous papillary cystadenocarcinoma on frozen section (H and E, 10x) and HPE (H and E, 10x)

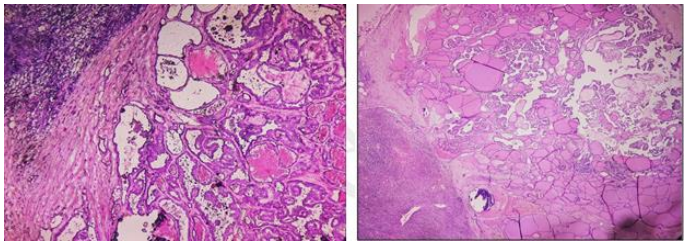

Figure 3. Photomicrograph of a cervical lymph node showing metastatic deposits from papillary carcinoma of the thyroid on frozen section (H and E,10x)

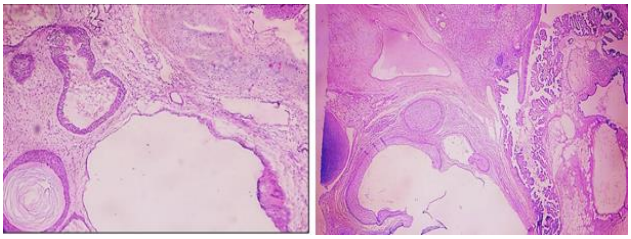

Figure 4. Photomicrograph of an ovarian mass showing a mature cystic teratoma on frozen section (H and E, 10x) and HPE (H and E, 10x)

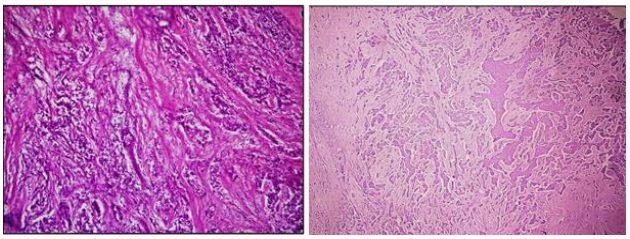

Figure 5. Photomicrograph of a breast mass showing invasive ductal carcinoma (NOS) on frozen section (H and E, 10x) and HPE (H and E, 10x)

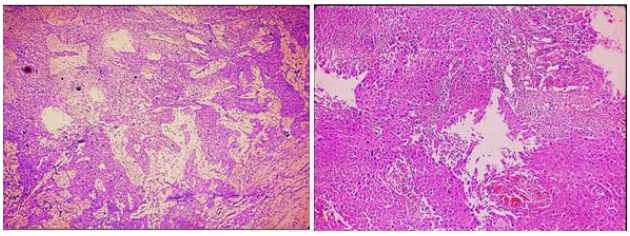

Figure 6. Photomicrograph of a mass from the oral cavity showing moderately differentiated squamous cell carcinoma on frozen section (H and E, 10x) and HPE (H and E 10x)

Discussion

The present study was conducted at our tertiary care center using 49 cases to determine the diagnostic accuracy of frozen section examination across different anatomical sites, assess turnaround time and frozen section discordance rates, and analyze the causes of discordance. The findings demonstrated a notably high overall concordance rate, indicating that frozen section analysis accurately reflects the underlying pathology in most cases. This high concordance suggests that frozen section examination effectively provides timely and accurate diagnostic information, which is essential for guiding surgery, particularly oncological and complex surgical procedures.

In our study, most cases involved patients between 41 and 50 years of age. This finding is comparable to those reported in the studies by Prajapati Jagdish et al (6) and Mohite S et al (10).

In the present study, female predominance was observed, with a female-to-male ratio of 2.8:1. This finding is comparable to those reported in the studies by Diwagar N et al (11) and Farinaz Shahmoradi et al (12).

The most common indication for frozen section diagnosis was primary diagnosis or exclusion of malignancy, followed by exclusion of metastasis and assessment of margin involvement, which is comparable to the findings of studies conducted by Tangade A et al (13) and Ahmad Z et al (14).

In the present study, the average turnaround time (TAT) was 23 min. This finding is comparable to those reported in the studies by Farinaz Shahmoradi et al (12) and Gidwani RK et al (4).

In the present study, the largest number of cases submitted for frozen section examination involved the female genital system, which is comparable to the findings of studies by Farinaz Shahmoradi et al (12), Diwagar N et al (11), and Mohite S et al (10).

The present study evaluated the diagnostic accuracy of frozen section analysis based on its concordance with the final paraffin section diagnoses. The overall concordance rate was 95.92%, indicating that the frozen section diagnosis matched the final diagnosis established by paraffin section analysis in 47 of 49 cases. This high level of accuracy is consistent with previous studies, which reported concordance rates ranging from 91.5% to 97.4%, as observed in the studies by Diwagar N et al (11), Farinaz Shahmoradi et al (12), Gidwani RK et al (4) Prajapati Jagdish et al (6), Mohite S et al (10), and Hatami H et al (15). Therefore, our findings confirm that frozen section analysis remains a reliable diagnostic method in surgical pathology.

In the present study, the discordance rate was 4.08%. This finding is comparable to those reported in the studies by Diwagar N et al (11), Farinaz Shahmoradi et al (12), Selvakumar AS et al (16), and Mayura VP et al (8). The most common causes of discordance are interpretation, gross sampling, and technical errors, such as those related to sectioning and staining. These discordant cases underscore the importance of recognizing the potential pitfalls of frozen section analysis. They illustrate how sampling limitations and the inherent difficulty of interpreting certain tissues can lead to diagnostic discrepancies. Consequently, these findings emphasize the need for continuous quality improvement and training for pathologists to minimize such errors. Moreover, they suggest that extensive sampling should be performed in cases involving substantial uncertainty to ensure an accurate diagnosis. This careful approach may further improve diagnostic accuracy and thereby enhance patient outcomes (16-18). Rabb SS noted that regular audits of frozen-permanent sections are associated with improved diagnostic accuracy (19).

In our study, sensitivity was 96%, which is comparable to the findings of studies by Farinaz Shahmoradi et al (12) and Prajapati Jagdish et al (6). Specificity was 95.4%, which is comparable to the findings of studies by Diwagar N et al (11) and Mohite S et al (10). The negative predictive value was 95.43%, which is comparable to the findings of studies by Farinaz Shahmoradi et al. (12) and Prajapati Jagdish et al. (6). The positive predictive value was 96%, which is comparable to the findings of studies by Farinaz Shahmoradi et al (12) and Mohite S et al (10).

Challenges and limitations

Several technical challenges were encountered during the study. One of the primary technical issues was variation in the cryostat temperature or insufficient blade sharpness, which resulted in poor-quality sections that were difficult to interpret. Achieving an appropriate balance between the speed and quality of staining is another important technical issue that can create interpretive difficulties. (19,20) The study limitations included the relatively small sample size of 49 cases, its single-institution design, and the predominance of cases from specific organ systems, particularly the female genital system.

Conclusion

Frozen section examination is regarded as a reliable, precise, and rapid method of intraoperative consultation. When performed with full consideration of its limitations, it can be extremely beneficial to the surgeon and play a crucial role in surgical care by preventing the need for repeat procedures. In this context, effective communication between pathologists and surgeons is essential. The limitations of frozen sections should be recognized and appropriately considered by both the pathologist and the surgeon. Misinterpretation, inadequate slide preparation, or sampling errors may cause diagnostic errors during frozen section examination. Careful macroscopic inspection and evaluation of several sections, together with radiological and clinical findings, may help minimize these inaccuracies. Regular audits and analyses of methodology, technical skills, clinicopathological discussions, adequate sectioning, and diagnostic expertise are essential for improving the reliability of frozen section examination. Regular evaluation of discordance rates by an experienced pathologist will improve the diagnostic accuracy of frozen section examination and, consequently, patient management.

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No additional funding was required because frozen section examination is advised for cases in which it is indicated as part of the treatment protocol.

Ethical Statement

Approval was obtained from the Institutional Ethics Committee. IEC No is IEC/MIMER/2022/825 dated 19/09/2022.

Conflicts of Interest

No conflict of interest.

Author Contributions

SW: Data Collection, Data Analysis, and Writing of the Original Manuscript Draft. SB: assisted with data analysis, Supervision, Validation, and Review and Editing of the Manuscript.

Data Availability Statement

Data are available from the records of the Histopathology Laboratory of MIMER Medical College, Talegaon Dabhade, Pune, India.

Use of Artificial Intelligence

AI tools were not used in the preparation of this manuscript.

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