The Diagnostic Accuracy of Intraoperative Frozen Section Biopsy - A Study at A Tertiary Care Centre in Western Maharashtra

Running title: The Diagnostic Accuracy of Intraoperative Frozen Section Biopsy

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Abstract

Background: A Frozen section is a rapid diagnostic procedure performed on tissues obtained intraoperatively, which helps the operating surgeon make immediate decisions during surgery, primarily to distinguish between benign and malignant neoplasms. It plays a significant role in guiding intra- and perioperative patient management and reduces the need for re-operation.

Methods: The present study aims to evaluate the diagnostic accuracy, sensitivity and specificity of the frozen section. Analysis of 49 frozen sections was conducted in the Pathology department from September 2022 to May 2024. The frozen section diagnoses were compared to those of the routine paraffin sections. The results were classified as concordant and discordant. Diagnostic accuracy, sensitivity, and specificity were calculated.

Results: Out of 49 cases, the diagnosis was concordant with routine histopathology in 47 cases, while 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 is a reliable, accurate and rapid technique for intraoperative consultation. Several factors can affect the accuracy of Frozen Section diagnosis, including sampling error, technical error and interpretation error.

Key Words: Frozen section, Diagnostic accuracy, Concordant, Discordant

Introduction

The frozen section technique was first used by William H. Welch from Johns Hopkins Hospital in 1891 for intraoperative consultation. (1) Since then, this practice has developed rapidly. There are many reasons for performing a frozen section, such as 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 the frozen section is to assist the surgeon in making immediate decisions during surgery, mainly to distinguish 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 differ across various organs. (2,5) The accuracy of frozen section diagnosis can be assessed by comparing it with the final diagnosis on permanent sections. Since only a small amount of tissue is sampled during frozen section examination, and because of technical differences between frozen and permanent sections, discrepancies between the two diagnoses may happen. (4,6-9) Periodic review of the correlation between frozen section and final diagnoses is helpful for identifying potential causes of errors, enabling measures to prevent similar issues and is an integral part of quality assurance in surgical pathology (2,4)

This study aims to analyze the indications and turnaround time for intraoperative frozen section consultations at our institution, examine the spectrum of cases, and evaluate the diagnostic accuracy across different anatomical sites. Additionally, we will review discordant cases to identify underlying causes, which will help improve our diagnostic skills and ultimately enhance patient care.

Methods

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

After approval from the Institutional Ethics Committee (IEC/MIMER/2022/825 dated 26/9/22), a valid informed consent was obtained. Fresh specimens received for intra-operative Frozen Section consultations from surgical departments irrespective of age, sex and anatomical site were included in the present study. Fresh tissue samples were received in a clean container properly labelled along with a requisition form, which carries necessary clinical details and indication for frozen section consultation.

Inclusion criteria: Fresh Surgical specimens received for Intraoperative Frozen section Consultation in Histopathology Laboratory of our Institute irrespective of age, sex and 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 were grossly examined and appropriate sections were taken. Frozen sectioning was done on the cryostat (Leica, CM 1520). The sections were immediately stained by Toluidine blue & rapid H & E stain and examined. A diagnosis was made and was immediately conveyed to the operating surgeon. The turnaround time (TAT) was noted down from the time of receipt of the specimen to the time of delivery of the report to the surgeon. The remaining gross specimen and the frozen bits were fixed overnight in 10% neutral buffered formalin and processed in an automated tissue processor (Leica TP1020),

paraffin-embedded, and stained with H&E stain. The Frozen Section diagnosis, as given to the surgeon at the time of surgery, was compared to the final Histopathological diagnosis of the permanent sections.
The results were categorized into concordant & discordant. Diagnoses were considered as concordant if there was agreement and discordant if there was disagreement with permanent section diagnoses. The slides of the discordant cases were reviewed, and the causes of the discrepancy were analyzed. The diagnostic accuracy and discordant rates were calculated.

Results

The present study is a cross-sectional (September 2022 to May 2024) study of 49 consecutive frozen section specimens from 46 patients of various organs received in the department of pathology of our college.
The highest numbers of frozen sections were done in patients between 41 and 51 years and 61 and 70 years, followed by 21 to 30 years and 31-40 years. The lowest incidence was seen in the age group of 11-20 years, followed by 71-80 years. There were 34 female patients and 12 male patients, the Female: male ratio being 2.8:1

Table 1. Indication-wise distribution of Frozen section cases

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%

The most common indication for frozen section diagnosis was Primary diagnosis or to rule out malignancy, followed by to rule out metastasis and assessment of margin involvement (Table 1).
Turnaround time (TAT) varied from a minimum of 15 minutes to a maximum of 35 minutes. The highest number of cases, i.e, in 30 cases, TAT was in between 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.

Table 2. Department-wise distribution of cases

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

Out of the 49 cases, the Surgery department contributed the maximum number of frozen sections, followed by the department of Obstetrics and Gynaecology and Orthopaedics (Table 2).
Out of the 49 cases, the maximum number of cases were from the female genital system, followed by the lymph node, breast, oral cavity, and skeletal system.
Out of the 49 cases that were received for frozen section evaluation, 47 cases were concordant with paraffin section diagnosis, giving a concordance rate of 95.92% and 2 cases were discordant with paraffin section diagnosis, giving a discordance rate of 4.08%.

After final histopathological examination, 2 cases were found to be discordant out of the 49 cases that were received for frozen section examination. The first case was from the endometrial polypoidal lesion, which on frozen section showed histological features suggestive of endometrial polyp with a single focus showing back-to-back arrangement of endometrial glands with mild to moderate cytologic atypia. So, it was 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. So, the diagnosis offered was Endometrioid carcinoma NOS, FIGO grade 1

The second case was from the Pancreas, where the diagnosis was given as "Suspicious for malignancy (Adenocarcinoma)" on frozen section. Whereas the diagnosis given on routine paraffin section was "Chronic Pancreatitis". Glandular structures lined by cells with visibly enlarged nuclei and hyperchromasia were misinterpreted as a malignant feature in frozen section, and Glands were seen within areas of fibrosis, which was misinterpreted as invasion. However, routine Paraffin on extensive sectioning showed that the glandular structures were identified as normal pancreatic tissue infiltrated by chronic inflammatory cells and fibrous tissue. So, the diagnosis offered was Chronic Pancreatitis.

Out of the 49 cases, 47 cases turned out to be concordant, and 2 were discordant. The number of true positive cases was 24 (96%). The number of true negative cases was 23 (95.43%). The number of False positives (4 %) and false negatives (4%) cases was 1 each.

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

Table 3 shows the comparative diagnosis of each case on frozen section and paraffin section.

Table 3. Comparison of frozen section and paraffin section diagnosis

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
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

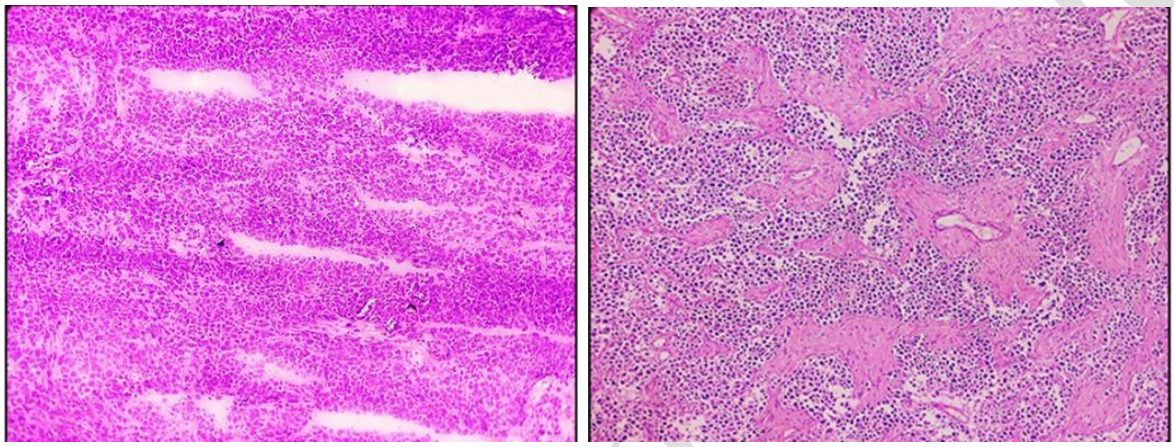

Figure 1. Photomicrograph of ovarian mass showing malignant germ cell tumor on frozen section of (H and E, 10x). and dysgerminoma of ovary on HPE (H and E, 10x)

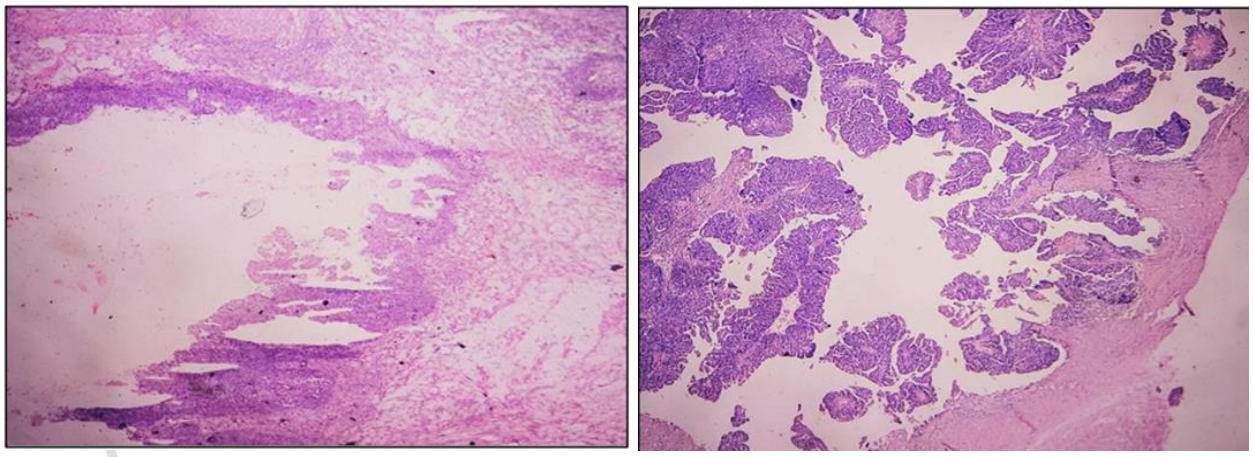

Figure 2. Photomicrograph of ovarian cystic mass showing serous papillary cystadenocarcinoma on frozen section (H and E, 10x) and HPE (H and E, 10x)

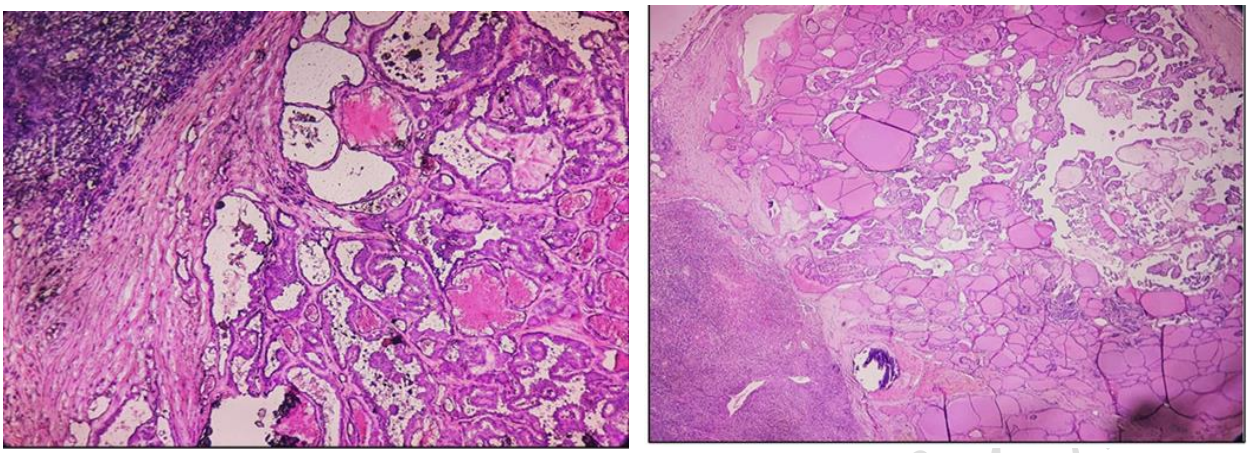

Figure 3. Photomicrograph of cervical lymph node showing metastatic deposits from papillary carcinoma of thyroid on frozen section (H and E,10x) and HPE (H and E,10x).

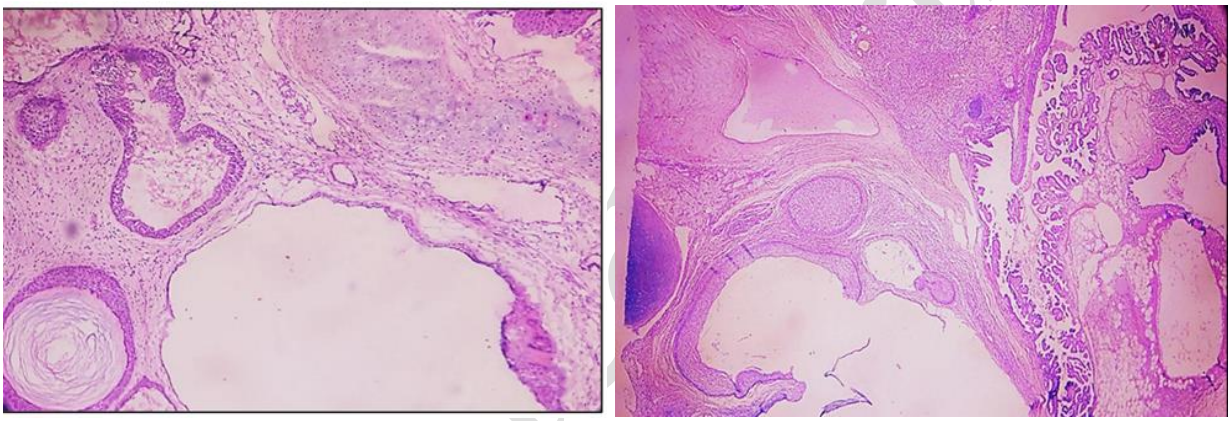

Figure 4. Photomicrograph of ovarian mass showing Mature cystic teratoma on Frozen section of (H and E, 10x) and HPE (H and E, 10x)

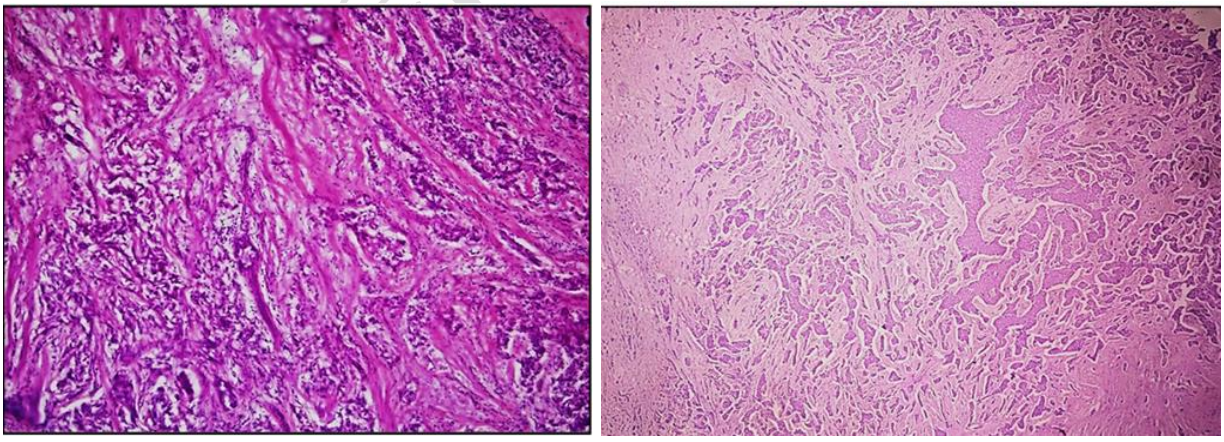

Figure 5. Photomicrograph of breast mass showing Invasive ductal carcinoma (NOS) on frozen section (H and E, 10x) and HPE (H and E, 10x)

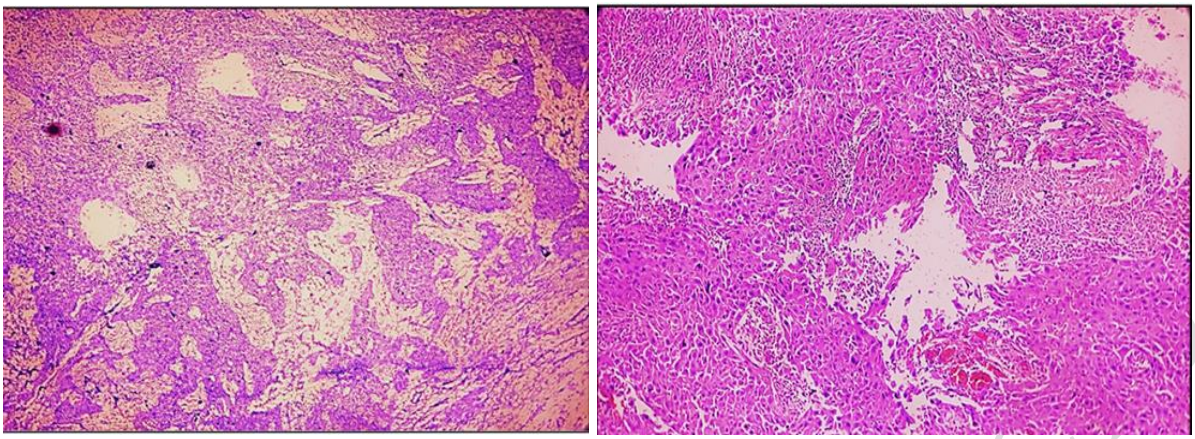

Figure 6. Photomicrograph of mass from oral cavity showing squamous cell carcinoma (Moderately differentiated) on frozen section (H and E, 10x) and HPE (H and E 10x)

Discussion

The present study was done at our tertiary care center on 49 cases to establish the diagnostic accuracy of frozen section of different anatomical sites, to know the turnaround time, discordance rates of Frozen section, and to analyze the causes of discordance. The findings of this study showed that overall concordance rate was notably high, indicating that frozen section analysis provides an accurate reflection of the underlying pathology in most cases. This high concordance suggests that the frozen section technique is effective in delivering timely and accurate diagnostic information, which is essential for guiding surgical procedures particularly in oncological and complex surgical procedures**.**

In our study, most of the cases were between 41 and 50 years of age. This is comparable to the studies of Prajapati Jagdish et al (6) and Mohite S et al (10).

In the present study, Female preponderance was seen, female to male ratio being 2.8:1. This is comparable to the studies of Diwagar N et al (11) and Farinaz Shahmoradi et al (12).

The most common indication for frozen section diagnosis was Primary diagnosis or to rule out malignancy, followed by to rule out metastasis, and assessment of margin involvement, which is comparable with a study done by Tangade A et al (13) and Ahmad Z et al (14)

In the present study, the average turnaround time (TAT) was found to be 23 min. This is comparable to the studies of Farinaz Shahmoradi et al (12) and Gidwani RK et al (4).

In our present study, the largest number of cases for frozen section examination came from the Female genital system, which can be compared with studies of Farinaz Shahmoradi et al (12), Diwagar N et al (11), and Mohite S et al (10).

The present study focused on evaluating 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 in 47 out of 49 cases, the frozen section diagnosis matched the final diagnosis made after paraffin section analysis. This high level of accuracy is consistent with previous studies that have reported concordance rates in the range of 91.5% to 97.4% as seen in the studies of 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 study findings confirm that frozen section analysis remains a dependable diagnostic method in surgical pathology.

In the present study, the Discordant rate was found to be 4.08%. This is comparable to the studies of 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 error, gross sampling error and

technical errors such as 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 difficulties in interpreting certain tissues can lead to diagnostic discrepancies. As a result, these findings emphasize the need for continuous quality improvement and training for pathologists to minimize such errors. Moreover, they suggest that in cases where there is significant uncertainty, extensive sampling should be done to ensure accurate diagnosis. This careful approach could help improve diagnostic accuracy even further, thereby enhancing patient outcomes. (16-18). Rabb SS noted that regular audit of frozen-permanent section is linked with enhanced diagnostic accuracy (19).

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

Challenges and limitations

Few technical challenges were encountered during the study. One of the primary technical issues was deviation in temperature of the cryostat or blade sharpness, which resulted in poor-quality sections that were difficult to interpret. Achieving the correct balance between speed and quality of staining is another important technical issue that can lead to difficulties in interpretation. (19,20) The limitations of the study were a relatively small sample size of 49 cases, the study being conducted within a single institution, and the majority of cases belonging to specific organ systems, particularly the female genital system.

Conclusion

The frozen section is regarded as a reliable, precise and quick method of intraoperative consultation. When performed with all of its limitations in mind, frozen sections can be extremely beneficial to the surgeon and play a crucial role in surgical care by preventing the need for repeat procedures. In this situation, a thorough understanding between the pathologists and surgeons is essential. The limitations of frozen sections should be recognized and utilized appropriately by both the pathologist and the surgeon. Misinterpretation, inadequate slide preparation, or sample errors may be the cause of the diagnostic errors during the frozen section. Careful macroscopic inspection, evaluation of several sections, together with radiological and clinical findings, might help minimize these inaccuracies. Regular audit and analysis of methodology, technical skills, clinicopathological discussion, adequate sectioning, and diagnostic expertise are essential factors to improve frozen section reliability. Evaluation of discordant rates regularly with an experienced pathologist will increase the diagnostic accuracy of frozen section and thus patient management.

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No additional funding was required as the frozen section is advised for the cases where it is indicated as a part of treatment protocol.

Ethical Approval

It was taken from Institutional Ethical Committee. IEC No is IEC/MIMER/2022/825 dated 19/09/2022

Conflict of Interest

No conflict of interest.

Authors Contributions

SW: Data Collection, Data Analysis and Writing Original Manuscript Draft. SB: helped in data analysis, Supervision, Validation and Reviewing and Editing the Manuscript.

Data Availability Statement

Data is available from the records of the Histopathology Laboratory of MIMER Medical College Talegaon Dabhade Pune India

AI Statement

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

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