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Original Research Article

Diagnostic accuracy of frozen section: an institutional observational study

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ABSTRACT

Background: Frozen section is an important tool in rapid intra-operative diagnosis. It is commonly used during surgical procedures to detect malignancy so that modifications of surgery can be decided at the time of surgery on the table. Frozen section is also performed for evaluation of surgical margins and detection of lymph node metastasis. In addition, it is applied for detection of unknown pathological processes. The objective of this study was to assess the accuracy of frozen section diagnosis in comparison to gold standard histopathological diagnosis and to find concordance and discordance rate of frozen section with histopathological report. Aim of the study was comparison between frozen section and routine formalin fixed paraffin sections in various tissues.
Methods: This is a retrospective cross-sectional study of 272 frozen section samples done in the department of pathology in Bharati Medical College and Research Centre, Dhankawdi- Pune and Excel diagnostics Pune, in Maharashtra from January 2022 to April 2023. The study included all frozen section samples with their permanent tissue samples received for final histopathological evaluation.
Results: Out of 272 cases, 268 had concordant diagnosis on frozen section and permanent paraffin embedded section. Out of 4 discordant cases, 3 showed false negative result and definite diagnosis of one case could not be given on frozen section. The overall diagnostic accuracy of frozen section was 98.52%.
Conclusions: Frozen section is a reliable intra operative diagnostic tool. Intra-operative diagnosis helps surgeon to take important intra-operative decision to avoid second surgery. Accuracy of frozen section can be improved by avoiding sampling errors and experience of the histopathologist.

Keywords: Intra-operative consultation, Frozen section, Accuracy

INTRODUCTION

Frozen section helps in rapid intra-operative diagnosis. It was first used by William H Welch from John Hopkin Hospital in 1891. This technique was further improved in 1905 at Mayo clinic by Wilson and McCarty. This practice became more popular after the development of cryostat in 1959.[1,2]

Intra operative consultation includes gross and microscopic examination of the tissue to guide the surgeon to diagnose and determine the nature of the lesion whether it is benign or malignant, identify the metastatic disease and assess the surgical margins. It is rapid method of intra operative consultation. The procedure is done while patient is under anesthesia on operating table. The frozen section is studied with the help of cryostat machine at -20 to -30^0 C. The diagnostic accuracy of frozen section varies from organ to organ.[3]

Frozen section report is conveyed to the surgeon within specific time, so as to make quick intra operative decision. It requires clinical details and good communication between pathologist and operating surgeon. The final

report is given after studying formalin fixed paraffin embedded samples, to exclude misinterpretation errors due to procedural artifacts and sampling errors.[4]

Even though frozen section provides rapid intra operative diagnosis, it cannot replace the conventional paraffin embedded tissue diagnosis because of its limitations. The frozen section diagnosis can be deferred in challenging situations.[5] The results of frozen sections varies from organ to organ due to freezing artifacts, sampling errors, staining quality and interpretation errors. Discrepancies are common in organs like thyroid, breast, skin and uterine cervix.[6]

In present study, we compared the diagnosis on frozen section and permanent sections of various organs over the period of 1.3 years to determine its accuracy and any discrepancy.

METHODS

The present study is retrospective study done in the department of pathology at Bharati Medical College and Research Centre, Dhankawdi- Pune and Excel diagnostics Pune, from January 2022 to April 2023. All the sample received from various surgical departments for frozen section analysis with their permanent paraffin embedded tissue were included in the study. There were no exclusion criteria. Total 272 samples were analyzed in the present study. Frozen section samples received in normal saline were immediately grossed, frozen at -20 to -30^0 C and sectioned on cryostat machine at 3-6 mm thickness. The sections were stained using Toluidine blue and also with rapid hematoxylin and eosin stains. The microscopic diagnosis was given after 20-30 minutes after the submission of samples.

For permanent sections, the remaining tissue was fixed in 10% formalin for 24 hours. Adequate representative sections were taken and processed for routine paraffin embedding. After conventional hematoxylin and eosin stain, they were reported and compared with the frozen section tissue slides. Special stains and immunohistochemistry were performed wherever needed.

In discordant cases, the slides of frozen section and permanent section were reviewed by 2 pathologists to determine the cause and report was informed to surgeon.

RESULTS

Total 272 cases were studied from January 2022 to April 2023. Out of 272 cases diagnosis was accurate in 268 cases and 3 cases were diagnosed false negative, while diagnosis was inconclusive in one case. The overall accuracy was 98.52% with false negative rate of 1.11%. There were no false positive cases in present study.

In present study, the most common indication was definitive diagnosis (39.80%), followed by margin status in previously biopsy diagnosed malignant cases (31.40%) and other indications were to rule out malignancy (16.20%), to know the status of lymph node (10.70%) and to know the presence of ganglion cells in Hirschsprung's disease (1.90%) of the cases (Table 1).

Table 1: Distribution of cases based on indication for frozen section.

S. no.	Indication for frozen section	Percentage	Number of cases
1	Definitive diagnosis	39.80	109
2	Status of lymph nodes	10.70	29
3	To rule out malignancy	16.20	44
4	Status of margin in a known case of malignancy	31.40	86
5	Presence of ganglion cells in Hirschsprung's disease	1.90	4
6	Total	100	272

Most common organ received for frozen section was ovary, followed by CNS, lymph nodes, breast, uterus, endocrine and others. The accuracy in margin status, ovary, breast, uterus, endocrine was 100%. Accuracy in central nervous system was 97.05%, lymph node 96.42%, oral cavity 83.33% and colon was 80% (Table 2).

Amongst the ovarian lesion, one of the commonest lesion was benign sex cord stromal tumor, fibroma. Young female presented with abdominal mass, ultrasonography (USG) showed solid ovarian mass of size 5×4 cm. Since the mass was solid intraoperative frozen was done to rule out malignancy. Grossly lesion was solid, well circumscribed and yellowish cut surface. Intraoperative frozen section was reported as benign sex cord stromal tumor which was then confirmed after paraffin embedded section as fibroma (Figures 1 and 2).

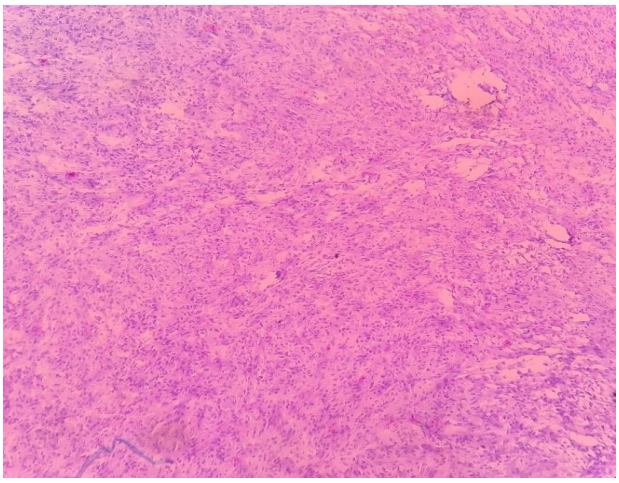

Figure 1: Fibroma on rapid H&E staining.

Table 2: Organ wise distribution of cases.

S. no.	Sites	No. of cases	Concordant cases	Discordant cases	Accuracy (%)
1	Margins (oral cavity, tongue, breast, eye mass, cystic duct, colon)	86	86	00	100
2	Ovary	42	42	00	100
3	CNS	34	33	01	97.05
4	Lymph node	28	27	01	96.42
5	Breast	26	26	00	100
6	Uterus	22	22	00	100
7	Endocrine	13	13	00	100
8	Oral cavity	6	5	01	83.33
9	Colon	5	4	01	80
10	Other	10	10	00	100
11	Total	272	268	04	

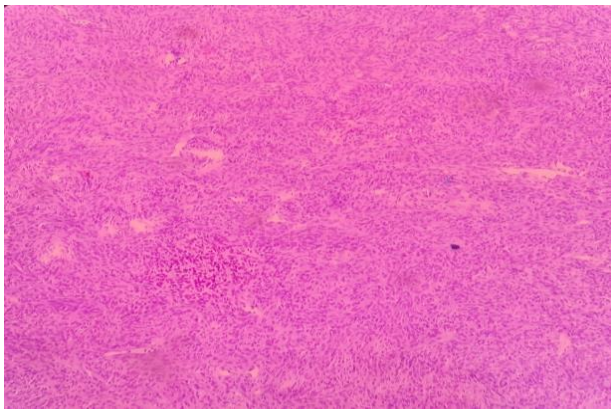

Figure 2: Fibroma on routine H&E staining.

Table 3: False negative cases.

S. no.	Site	Frozen diagnosis	Final paraffin diagnosis
1	Lymph node	No metastasis	Metastatic deposit of moderately differentiated adenocarcinoma
2	Oral cavity	Moderate dysplasia	Moderately differentiated squamous cell carcinoma
3	Colon	No dysplasia	Severe dysplasia

In present study, 3 cases showed false negative result. Out of 3 cases, 1 case was of lymph node, 1 case was of oral cavity and 1 was of colon (Table 3).

In all the cases malignancy/metastatic deposit was not visualized on frozen section, but it was seen on routine paraffin embedded sections. Reason for discrepancy in all the 3 cases is limitations to assess multiple deeper sections on intraoperative frozen section.

Table 4: Deferred diagnosis.

S. no.	Site	Frozen diagnosis	Final paraffin diagnosis
1	CNS	No opinion possible	Pituitary apoplexy

DISCUSSION

Frozen section is rapid diagnostic technique which helps the surgeon to take intra operative decision by avoiding second surgery. It helps the surgeon when there is good communication with pathologist to understand surgical implications and limitations of the case. Frozen section is costly technique and also it requires technical as well as interpretation skills to avoid errors in diagnosis. Therefore, this facility is available in major institutes and tertiary health care centers.

Present study was carried out from January 2022 to April 2023 in department of pathology in private institute. Total 272 cases were reviewed; overall accuracy of frozen section was 98.52% with false negative rate of 1.11%. The accuracy of frozen section varies from organ to organ. Present study was comparable with similar studies for accuracy, concordance and discordance (Table 5).

Table 5: Comparison of present study with various similar studies.

S. no.	Authors	Study period (years)	No. of cases	Concordance (%)	Discordance (%)
1	Patil et al[5]	2	100	96.9	3.1
2	Chbani et al[7]	1	261	95	5
3	Roy et al[8]	9 months	327	97.6	2.4
4	Mishra et al[9]	2	52	96.2	3.8

Continued.

S. no.	Authors	Study period (years)	No. of cases	Concordance (%)	Discordance (%)
5	Shrestha et al[10]	5	404	94.6	5.4
6	Peter et al[11]	1	1952	96.5	3.5
7	Present study	1.4	272	98.52	1.48

Deferred diagnosis on frozen section is also an important parameter in quality assurance. In present study single case was deferred for diagnosis, which is comparable to other studies with deferral rate ranging from 0.04 to 6.7%.[5] The deferral rate may change according to nature of specimen and clinical details. In present study deferred case was of pituitary gland.

In present study, diagnostic accuracy of ovarian, breast, endocrine and uterine lesion was 100%. The diagnostic accuracy of ovarian lesion on frozen section was comparable with the study done by Abdelgehany et al.[12] The diagnostic accuracy of endocrine and uterine lesion on frozen section was comparable with the study done by Gidwani et al.[13] Because frozen section is multistep process which includes surgical resection, intraoperative slide preparation, microscopic examination along with communicating frozen diagnosis to surgeon and then processing the remaining tissue for formalin fixed paraffin embedded tissue and special studies if required. Errors in any of the above steps causes false results.[14] There are many factors which can affect the accuracy of intraoperative frozen section diagnosis, including sampling error, technical errors like freezing artifacts, lack of clinical details, limitations to assess multiple sections and interpretation error. In present study false negative rate was 1.11%, in all the 3 cases the malignant focus was missed because of limitations of frozen section to assess the multiple deep sections. The false negative rate is present study is comparable with the studies done by Gidwani et al 6.84% and Patil et al 2.04%.[5,13]

Quality assurance depends upon various parameter one of which is deferral of cases in frozen section diagnosis. In present study, diagnosis was deferred in one cases which is comparable to previously published studies with a deferred rate ranging from 0.04% to 6.7%.[7] The deferred case was of previously operated case of pituitary adenoma, the lesion was recurred so frozen section was performed, which showed only haemorrhage.

CONCLUSION

Frozen section is very useful and accurate procedure which can be highly beneficial for the proper management of patients if careful sampling of the specimen, proper communication with the surgeon is maintained. Limitations of this technique should be kept in mind by both surgeon and pathologist when ordering and performing the procedure.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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