

## Utility of Frozen Section Study in Quality Control of Surgical Pathology Laboratory

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### Abstract

*Background:* Quality assurance is an integral part of modern laboratory services. Quality control is relatively easy in hematology and biochemistry laboratories however, similar quality standards are difficult to analyze in surgical laboratories. Comparing the diagnostic accuracy of frozen section with gold standard histopathology can be used for this purpose. *Methodology:* The data for this two and a half year (January 2014- June 2016) retrospective analysis was retrieved from the records of Department of Pathology, Dayanand Medical College and Hospital Ludhiana, Punjab. The routine protocol of intraoperative consultations in the Department included prior intimation (at least 2 hours before expected sampling) with relevant clinical details and indication of frozen section. The sample was received in normal saline and representative sections were submitted for frozen section after thorough gross examination of the tissue. *Results:* A total of 200 cases were retrieved from the archives of Department of Pathology during this retrospective analysis. Majority (34.5%) of the intraoperative consultations were sought from the Gynaecology unit {Uterus 53 cases (26.5%) and ovary 16 (8%) cases}. Overall concordance rate was 95% (190/200) with sensitivity of 96.4% and specificity of 100%. *Conclusion:* The intra-operative consultations using frozen section is a very useful in assessing the quality assurance and the prospective analysis of these methods with routine histopathology can yield adequate quality assessment of a laboratory.

**Keywords:** Quality Assurance; Surgical Laboratories; Frozen Section.

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### Introduction

Quality assurance (QA) is defined as a planned and systematic activities to provide confidence that an organization fulfills requirements for quality. According to College of American Pathologists (CAP) and the Association of Directors of Anatomic and Surgical Pathology, the assessment of the correlation of the frozen section (FS) diagnosis with the final diagnosis (FD) rendered on permanent sections (PSs), is considered to be one of the cornerstones of quality assurance activities in surgical pathology laboratory. FS may be one of the most important and most difficult

procedures performed by the pathologist during his practice [1]. The pathologist has to arrive at a correct decision in a shorter duration under pressure based on his experience, judgement and the knowledge of his specialty and clinical medicine. The surgeon and pathologist should be aware of the limitations of the method as the patient's life is often dramatically influenced by the report. Even though FS provides rapid diagnosis, it is still inferior to paraffin embedded tissue technique due to its limitations. The sampling of specimen is limited and there are technical difficulties of getting good quality sections and staining of tissue; which will all influence the interpretation of the section by the pathologist. Most centers reported an accuracy rate of 92% to 98% depending on type of cases studied. A large center like Mayo Clinic Rochester, USA reported an overall accuracy of 97.8% on reviewing 24,880 frozen cases in a year [1,2]. However, the published data from India

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is scarce hence the present analysis was done with an aim to emphasize the importance of frozen section as an indicator of quality assurance in a tertiary care centre.

The data retrieved was analyzed to evaluate concordant, discordant and deferred cases.

**Methodology**

The data for this two and a half year (January 2014-June 2016) retrospective analysis was retrieved from the records of Department of Pathology, Dayananad Medical College and Hospital Ludhiana, Punjab.

- The routine protocol of intraoperative consultations in the Department included prior intimation (at least 2 hours before expected sampling) with relevant clinical details and indication of frozen section.
- The sample was received in normal saline and representative sections were submitted for frozen section after thorough gross examination of the tissue.
- The tissue was frozen at -20°C using cryostat (Cryotome; Thermo Scientific) and. The sections of 2- 3µm thickness were stained with Toluidine blue and Hematoxylin & Eosin stain.
- The frozen sections were reported by three pathologists independantly. The final diagnosis was produced from one to several days after the intraoperative consultations had occurred.
- The pathologist reporting the final diagnosis had access to the frozen section results.

**Results**

A total of 200 cases were retrieved from the archives of Department Of Pathology during this retrospective analysis. Of these 72 (36%) were males while 138 (64%) were females. Majority (34.5%) of the intraoperative consultations were sought from the Gynaecology unit {Uterus 53 cases (26.5%) and ovary 16 (8%) cases} followed by Pancreaticobiliary region { 55(27.5%) cases}. Overall concordance rate was 95% (190/200) while only 2% (4/200) were discordant. A total of 6 cases (3%) were deferred due to technical reasons. The discordant cases comprised 2 cases from pancreaticobiliary region where common bile duct margins were sent and were reported as suspicious of malignancy as nuclei which appear hyperchromatic with irregular margin however histopathology it turned out be benign biliary epithelium. One case of ovarian cyst was reported as simple cyst on frozen section but histpathology confirmed it to be serous cystadenoma. The remaining one case was of a lymphnode which did not show tumor deposits on frozen section while metastatic deposits were clearly evident on histopathology.

Six cases were deferred as marked freezing artifacts caused poor morphological details which were

**Table 1:** Concordant, discordant and deferred cases

	Concordant	Discordant	Deferred	Total
Pancreaticobiliary	52 (27.3%)	2(50%)	1(16.6%)	55(27.5%)
Hepatic	8(4.2%)	-	1(16.6%)	9(4.5%)
Uterus	52(27.3%)	-	1(16.6%)	53(26.5%)
Ovary	14(7.3%)	1(25%)	1(16.6%)	16(8%)
Breast	4(2.1%)	-	-	4(2%)
Lymphnode	15(7.8%)	1(25%)	1(16.6%)	17(8.5%)
Thyroid	3(1.5%)	-	-	3(1.5%)
Brain	9(4.5%)	-	-	9(4.5%)
Respiratory	1(0.5%)	-	-	1(0.5%)
Head and neck	7(3.6%)	-	-	7(3.5%)
Urinary	14(7.3%)	-	-	14(7.0%)
GIT	7 (3.6%)	-	1(16.6%)	8(4%)
Bone and Soft tissue	4(2.1%)	-	-	4(2%)
Total	190 (95%)	04(2%)	6(3%)	200 (100%)

**Discordant**

	Frozen section diagnosis	Histopathological examination
Pancreaticobiliary	Suspicious of malignancy	Benign Biliary epithelium
Pancreaticobiliary	Suspicious of malignancy	Benign biliary epithelium
Ovary	Simple cyst	Serous Cyst adenoma
Lymphnode	No tumor	Metastatic deposits

considered difficult to be deciphered by all the pathologists unanimously.

The frozen section technique was 96.94% sensitive and 100% specific with positive predictive value of 100% and 40% negative predictive value.

## Discussion

Quality control in histopathology is not easy as its output is wholly qualitative rather than quantitative. Quality analysis are well-established in the departments such as clinical biochemistry and hematology where numerical data is obtained compared to histopathology laboratory where reports contain interpretations, explanations, evaluations of probability and clinical judgments. Comparing the histopathology diagnosis with frozen sections or cytopathology can be used as reliable tool to assess the quality assurance in surgical pathology laboratories [3]. Frozen section provides rapid gross or microscopic diagnoses that can guide intra- or peri-operative management of a patient, including identification of an unknown pathologic process, evaluation of adequacy of margins, identification of lymph nodes metastases and identification of tissue. Both the surgeon and pathologist should be fully aware of the indications for FS. Frozen sections are routinely used to establish the nature/presence/benign nature/grade of a lesion [3,4].

Most centers reported an accuracy rate of 92% to 98% depending on type of cases studied. A large center like Mayo Clinic Rochester, USA reported an overall accuracy of 97.8% on reviewing 24,880 frozen cases in a year. A comparative overall accuracy of 97.56% was noted at a general hospital in Malaysia involving 215 FS specimens over 4 years duration. Other reported cases include accuracy rate of 94% in central nervous lesion, 98.4% for tumors of the testis and 91.1% for basal and squamous cell carcinoma of the skin. Accuracy of FS in gynaecological cases can be as high as 97.5%. However, if we look at borderline cases of ovarian tumours, this accuracy rate will fall due to diagnostic difficulty [5,6].

The limitations of frozen section study which can hamper its diagnostic utility include poor sampling of tissue by surgeons/ inappropriate selection of appropriate tissue after grossing by pathologist/ tumour degeneration or necrosis/ inadequate assessment of capsular or vascular invasion. Thus the pathologist and surgeon should have adequate communication before and after the sampling is done. The technical issues like freezing artefacts, bloated

cell morphology, poor sections and bad staining can lead to diagnostic difficulties and lead to reporting errors. Sometimes the heterogeneity of some tumors can also limit the pathologist to give a correct diagnosis. We believe that it is always sensible to defer the diagnosis if a pathologist is not confident due to any of the above limitations [3,5].

Recently, intraoperative cytology has been considered a useful adjunct to frozen section. Samples are obtained by touch imprint of fresh specimen, crush smear preparation and squash preparation. These can add a great deal of information to frozen section. Strong indications for this technique include lymphoproliferative lesions, central nervous system lesions and thyroid nodules. It can also be used for minute specimens and to sample tissue that would be difficult to cut with the cryostat. However, the frozen sections provide better architectural details hence, many histopathologists prefer frozen section over cytological methods [6,7].

The limitations of this study are its retrospective nature therefore precludes using this approach on a routine basis, which is one of the aims of quality assurance. The use of a searchable database that maintains the textual information present in the usual surgical pathology report may allow a routine query for intraoperative consultations and final diagnosis correlation studies. Another limitation is that we did not attempt to determine actual patient impact of the diagnostic disagreements. That was beyond the scope of this investigation but would be a logical extension of the project.

## Conclusion

Quality assurance is the integral part of modern day laboratory practice. Quality analysis are well-established in the clinical biochemistry and hematology laboratories but the histopathology laboratory where reports contain interpretations, explanations, evaluations of probability and clinical judgments are difficult to analyse. The intra-operative consultations using frozen section is a very useful in this aspect as prospective analysis of these methods with routine histopathology can yield adequate quality assessment of a laboratory.

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