Original Article

Surgical Pathology and Intraoperative Consultation: An Audit

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Abstract

***Background*: While intraoperative consultation has been used in Bangladesh for a long period of time, to date, there has been no published reporting on the performance of frozen sections. The current audit evaluates the performance of frozen sections in a well reputed medical center in Bangladesh, Anowara Medical Services.**

***Objective*: This retrospective study has been designed to measure the accuracy of frozen section diagnosis in a medical center in a third-world country, where many surgical procedures rely on intraoperative consultation.**

***Methods:* A series of 1379 intra- and peri-operative frozen section cases, from 2007 to 2014, was reviewed. Intraoperative tissue specimens received at Anowara Medical Services were processed for frozen sections. After examination of the frozen section that yielded the initial frozen section diagnoses, the frozen tissues were reprocessed for regular paraffin sectioning. These paraffin sections were examined by a second pathologist, and a final diagnosis was issued. The frozen section diagnosis and final diagnoses of all cases were retrospectively analysed to determine the accuracy of frozen section examination.**

***Results:* Overall, accurate diagnosis was made on frozen sections in 98.2% of the cases. The discrepant diagnoses were all clinically significant, i.e., there were discrepancies between benign and malignant diagnoses on frozen and paraffin sections. In 1% of the cases, diagnosis was deferred. Fifty percent of the deferred cases were benign. Two cases, received in formalin, were excluded. In both cases, the diagnosis was positive for malignancy. The number of false negative results (4 false negatives) was slightly lower than that of false positives (5 false positives). Specificity and sensitivity of 99.3% and 99.4% were achieved, respectively. In this study, the positive predictive value was 99.2% and the negative predictive value was 99.5%. Over the years, the number of discrepant diagnoses remained fairly constant.**

***Conclusion:* The present method has a satisfactory rate of accuracy of frozen section diagnosis, which is comparable to other remote and recent published series. The results of this study offer a testament to the reliability of frozen section diagnosis rendered by qualified pathologists in Bangladesh and may serve as evidence in building confidence among the surgeons who use this service for improved patient care.**

Keywords: *pathology, surgery, frozen sections, diagnosis, carcinoma*

Introduction

Frozen sections are used to provide rapid gross or microscopic diagnoses that can guide surgeons during intra- or peri-operative management of a patient. Intraoperative consultations are sought by surgeons for various reasons, including diagnosis of a previously undiagnosed lesion (mainly benign vs. malignant), assessment of margin status, detection of spread of disease, e.g. lymph nodes metastases, instant evaluation of adequacy of lesional tissue, and collection of fresh frozen tissue that requires additional testing and identification of tissue origin (1). Frozen section diagnosis of surgically resected tumours and tissues has become a regular practice over the past 60 years (2,3). Reviews on frozen section diagnoses have been widely published from 1929 to the present day. The accuracy rates of frozen sections have been reported to range from 94% to 99% (2,4–8). These parameters have been useful in ensuring the quality and technique, and assessing the usefulness of frozen section diagnoses, as well as improving surgical quality and patient care.

While frozen sectioning has long been used in Bangladesh, to date, there has been no published report on the performance of frozen sections. From the point of view of quality control, and to measure the performance of a laboratory, frozen sections may serve as an indicator of quality assurance for the laboratories that perform frozen

sectioning in Bangladesh. Hence, it is important to review the results through an audit. This paper also presents a picture of how intraoperative consultation is used in third-world countries, like Bangladesh.

The aim of this study is to evaluate the accuracy of frozen section examination for routine diagnostic use in surgical pathology, and to provide a platform for comparison of intraoperative consultation in a third-world country like Bangladesh.

Dhaka, the capital of Bangladesh, is a megacity, with more than 500 small and large government-owned and private hospitals/clinics. Most of these medical centers (about 99%) do not have frozen section facilities. Anowara Medical Services, located in Dhanmondi, a central area in Dhaka, offers frozen section facilities to nearby clinics and hospitals, where surgeries are performed. Usually, it takes about 30 minutes for samples to reach the pathologist. The surgeon sends the sample by a pre-informed messenger to Anowara Medical Services, and after the assessment, the result is conveyed to the surgeon by the pathologist over the telephone (the whole procedure takes about 20–30 minutes). The patient remains under anaesthesia until the surgeon is informed of the results. Then the surgeon uses the results from the frozen section test to guide the next steps of the operation.

The current audit, the first of its kind in the country, evaluates the results of frozen sections from the files of a reputable medical center in Bangladesh, Anowara Medical Services. As all the frozen sections were performed by a single pathologist, the result will serve as a testament of the reliability of the pathologist. This also reflects a very typical situation in Bangladesh, where many laboratories depend on a single consulting pathologist, who is in charge of the frozen and paraffin section diagnoses.

Material and Methods

The histopathology reports of the specimens received for intra- and peri-operative frozen section at Anowara Medical Services from January 2007 to May 2014 were retrieved.

During the six and a half years, 1379 frozen section cases were entered in the database. The 1379 frozen sections received, processed, and diagnosed by this center had been referred by surgeons from other nearby hospitals and clinics where the operations had taken place. The results of the frozen sections were conveyed to the surgeons over the telephone during the operations, and formal reports were issued later.

Intraoperative tissue specimens sent by the surgeons were wholly processed for frozen sections if the specimen was small. If the specimen was large, representative sections of the tissue were processed for frozen sections. After examination of the frozen sections, which yielded the initial frozen section diagnoses, the frozen tissues were reprocessed for regular paraffin sections. These paraffin sections were examined by a second pathologist, and final diagnoses were issued.

These case files were reviewed. The data from the case files were used to calculate the number of discrepancies between the initial frozen section diagnoses and the final histological diagnoses, which were made from sections of the tissue embedded in paraffin blocks.

The three ovarian cases where the paraffin section diagnosis of papillary serous tumour with borderline potential was achieved; they had been considered negative for paraffin section diagnosis to simplify the method. Among the gastrointestinal (GI) tract cases that were examined for absence of ganglion cells and presence of hypertrophic nerve bundles to identify Hirschsprung's disease, the ones that showed aganglionic segments were considered positive for simplification. If Hirschsprung disease was detected on the specimen, the surgeon started resectioning of the aganglionic portion. A second sample was sent for frozen section diagnosis. Resectioning continued through aganglionic and transitional segments until healthy segments were reached. In the rest of the GI tract cases, frozen sectioning was undertaken to identify if resection margins were tumour free. In case of a positive result, the surgeon continued resectioning of margins. For the rest of the specimens, a diagnosis of malignancy prompted surgeons to undertake a more aggressive operation to surgically remove the malignant lesion and its margins more completely.

The patient demographics were recorded. The specimens were separated according to site of origin. The data were then analysed to assess accuracy parameters of the frozen section diagnoses compared with the diagnoses obtained from paraffin sections. The overall accuracy, sensitivity, specificity, and positive and negative predictive values for frozen section diagnosis were determined.

Results

The age range of the patients was from 0.1 years to 100 years, but 79% of the specimens were from patients aged between 28 and 70 years. The majority of the patients were between the fourth and fifth decades (39.3%). The proportion of malignant lesions increased with advancing age. Of the 515 patients aged 50 years or older, 344 (66.8%) had malignant lesions (diagnosed in the paraffin sections), whereas only 294 malignant lesions were found among the 864 patients aged younger than 50 years (34.0%). Overall, the female to male ratio was 1.6:1. The number of cases sent to this laboratory for frozen section diagnosis varied from 133 to 228 per year over the designated time period (Table 1). In total, 14 (1.0%) cases were deferred for paraffin section diagnosis over the past six and a half years (Table 1).

Table 1: Annual accessions of frozen section cases for intraoperative diagnosis, numbers of diagnostic errors, and deferred diagnoses

Figures year	No. of cases	Discrepancies (%)	Deferred diagnoses (%)
2007	147	1 (0.7)	0 (0)
2008	150	0 (0)	2 (1.3)
2009	133	0 (0)	5 (3.8)
2010	173	1 (0.6)	0 (0)
2011	195	2 (1.0)	0 (0)
2012	213	2 (0.9)	1 (0.5)
2013	228	1 (0.4)	1 (0.4)
2014	140+	2 (1.4)	5 (3.6)
Total	1379	9 (0.7)	14 (1.0)

+ only January to May considered

Table 2: Results from frozen section and paraffin section diagnoses

Frozen section diagnosis	Paraffin section diagnosis		Total (%)
	Positive (%)	Negative (%)	
Positive	671* (48.7)	5 (0.4)	676 (49.0)
Negative	4 (0.3)	683** (49.5)	687 (49.8)
Deferred	7 (0.5)	7 (0.5)	14 (1.0)
Unsuitable for assessment	2 (0.1)	0 (0)	2 (0.1)
684 (49.6)	695 (50.4)		1379

*GI tract cases positive for Hirschsprung's disease were considered positive.
**The three borderline diagnoses on ovarian sections were considered negative.

Table 3: Frozen and paraffin section diagnoses from the 110 large intestine cases looking for Hirschsprung's disease

Frozen section diagnosis		Paraffin section diagnosis	
Negative for ganglion cells	Positive for ganglion cells	Positive for Hirschsprung's disease	Negative for Hirschsprung's disease
46	64	46	64

Diagnoses on the frozen sections and the subsequent paraffin sections were identical in 1354 of the 1363 cases. Clinically significant differences, i.e., discrepancies between benign and malignant diagnoses on frozen and paraffin sections, were found in nine cases (Table 2). Non-significant discrepancies (where both diagnoses are benign or malignant, but there is a difference in the exact typing of the tumour or tissue) were not encountered. Diagnosis on the frozen sections was deferred for assessment until paraffin sections in 14 cases.

Of the 110 cases of the GI tract that were examined for the presence of ganglion cells, 46 were positive for Hirschsprung's disease in both frozen section and paraffin section, and the rest were healthy specimens (Table 3).

Clinically significant differences in diagnosis were encountered mostly (three of the nine cases) in the breast specimens (Table 4). In two of the thyroid cases, difference between frozen section and paraffin section diagnosis occurred. Discrepancies also arose in lesions from the tongue, gallbladder, kidney, and pancreas (Table 4). Of the nine discordant diagnoses, false negative results occurred in four cases; that is, lesions designated as benign by frozen section diagnosis turned out to be malignant when paraffin sections were examined, while the rest of the five were false positives (Table 2).

In this series, false negative diagnosis was made in four cases (Table 5). In the two thyroid cases, papillary carcinoma and papillary microcarcinoma were both misdiagnosed as negative for malignancy due to poor quality of the sections. Colloid carcinoma of the breast was diagnosed negatively since the tumour cells in the frozen section resembled well-differentiated cells and the colloid component was not very prominent. The pancreatic adenocarcinoma tissue resembled reactive pancreatic tissue associated with inflammation on frozen section, and thus a false negative diagnosis was made.

There were five cases in this series where false positive diagnoses were made (Table 6). In the breast, atypical florid ductal hyperplasia, which is closely related to malignant lesions and is difficult to identify even in permanent sections, was misidentified as malignant. In the second breast case where discrepancy occurred, the reactive histocytes of fat necrosis were misinterpreted as carcinoma. As for the discrepant gallbladder case, glands were observed in the muscle layer, which were thought to be malignant but later on turned out to be reactive glands. Clear cell carcinoma of the kidney, which has tremendous morphological resemblance to adrenocortical adenoma, was falsely diagnosed in a renal tissue specimen. In this case, the surgeon had also been unable to distinguish tissue from adrenal gland and renal tissue. The false positive case of the tongue arose from surgical margins of a previously diagnosed stromal cell carcinoma, where presence of squamous hyperplasia with mild atypia was misinterpreted as malignant.

Table 4: Summary of discrepancies between frozen section and paraffin section diagnoses

Organs	No. of discrepancies (%)
Tongue	1 (11.1)
Breast	3 (33.3)
Gallbladder	1 (11.1)
Kidney	1 (11.1)
Pancreas	1 (11.1)
Thyroid	2 (22.2)
Total	9 (100)

Table 5: List of false negative frozen section diagnoses

Sex	Age	Organ examined	Frozen section diagnosis	Paraffin section diagnosis
F	42	Breast	Negative for malignancy	Colloid carcinoma, degenerated with good chemotherapeutic response
F	60	Pancreas	Negative for malignancy	Adenocarcinoma, moderately differentiated
M	36	Thyroid	Negative for malignancy	Papillary carcinoma, follicular variant
F	27	Thyroid	Negative for malignancy	Papillary microcarcinoma, follicular variant

Table 6: List of false positive frozen section diagnoses

Sex	Age	Organ examined	Frozen section diagnosis	Paraffin section diagnosis
F	34	Breast	Positive for malignancy	Fat necrosis; no residual tumour is seen.
F	31	Breast	Positive for malignancy; atypical cell seen compatible with inter-duct cell malignancy	Atypical florid ductal hyperplasia
M	53	Gallbladder	Positive for malignancy	Adenomyoma with acute and chronic cholecystitis with xanthogranuloma
F	50	Kidney	Positive for malignancy (margins are free of the tumour)	Adenocortical adenoma
M	43	Tongue	Positive for malignancy	Negative for malignancy

Table 7: Accuracy parameters of diagnoses made on frozen sections compared to the final diagnoses made on paraffin sections of resected tissues

Parameters	Percentage (%)
Sensitivity	99.4
Specificity	99.3
Positive predictive value	99.2
Negative predictive value	99.5
Accuracy	98.2
Prevalence of deferred diagnosis	1.0

Excluding the 14 cases where frozen section diagnoses were deferred and the two cases that were unsuitable for assessment because of prefixation in formalin when received, the accuracy in this series of frozen sections was 99.3%. A specificity and sensitivity of 99.3% and 99.4% were achieved, respectively (Table 7).

The breast constituted the single most frequent specimen received for frozen sectioning, accounting for 226 (16.4%) of the cases (Table 8). The gallbladder and thyroid were the next most frequent, followed by the ovaries, oral cavity and kidneys, accounting for more than 50 cases in each category. Gastrointestinal tract specimens tested for Hirschsprung's disease accounted for 110 (8.0%) of the frozen section cases.

The likelihood of encountering a malignant diagnosis varied among the different organs; the liver ranked the highest (100%) and the colon the lowest (0%). The colon specimens were sent for advice on margin resection and were all diagnosed as benign. Specimens from the oral cavity, eyelid, cheek, and tongue were more likely to be malignant, whereas rectal and ovarian specimens were less frequently malignant (Table 8). Intermediate malignancy rates were shown by the testis, ureter, gallbladder, and the pouch of Douglas specimens (63%, 55%, 46%, and 43%, respectively)

Discussion

Discrepancies between diagnoses on frozen and paraffin sections

Diagnoses on the frozen sections and the subsequent paraffin sections were identical in 1354 of the 1363 cases. Diagnosis on the frozen sections was deferred for assessment of subsequent paraffin sections in 14 cases.

There were no discrepancies in the 110 cases that were examined for Hirschsprung's disease (Table 3). There did not seem to be any important change in the accuracy of frozen section diagnosis over the six and a half years (Table 1), as well as in the proportion of deferred diagnoses.

Table 9 enumerates the deferred cases categorized by organs. The 14 deferred diagnoses concerned the gallbladder (four cases), the thyroid (three cases), and the breast, bile duct, ovary, testis, ampullary tissue, rectum, kidney, and pancreas (one case each). Seven of these 14 proved to be malignant in later paraffin sections, and the rest were non-malignant (Table 2). Table 10 shows the final diagnosis of the deferred cases on paraffin sections.

Table 8: Organs submitted for frozen section diagnosis and the distribution of malignancies diagnosed on paraffin sections

Organ examined	Total cases (no.)	Malignancy (no. [%])
Ampullary tissue	32	22 (68.8)
Breast	266	186 (69.9)
Cheek	19	14 (73.7)
Colon	29	0 (0)
Eye lid	27	20 (74.1)
Gallbladder	162	75 (46.3)
Liver	15	15 (100)
Kidney	84	59 (70.2)
Pancreas	28	7 (25.0)
Pouch of Douglas	14	6 (42.9)
Ovary	137	28 (20.4)
Oral cavity	101	88 (87.1)
Rectum	43	10 (23.3)
Testis	30	19 (63.3)
Tongue	21	15 (71.4)
Thyroid	149	41 (27.5)
Ureter	11	6 (54.5)
GI tract**	110	46 (41.8)**
Others*	101	27 (26.7)
Total	1379	684 (49.6)

*Abdomen [(3), 0.2%], adrenal gland [(2), 0.1%], anus [(2), 0.1%], axilla [(1), 0.1%], bone [(4), 0.3%], brain [(2), 0.1%], chest wall [(2),0.1%], duodenum [(5), 0.4%], epididymis [(6), 0.4%], fallopian tube [(4), 0.3], foot [(3), 0.2], forearm [(2), 0.1], gastric body [(2), 0.1], leg [(2), 0.1], lung [(3), 0.2%], lymph node [(9), 0.7%], mediastinal mass [(1), 0.1%], myoma [(3), 0.2%], neck [(1), 0.1%] nose [(4), 0.3%], omentum [(4), 0.3%], orbit [(4), 0.3%], parathyroid [(3), 0.2%], parietal wall [(1), 0.1%], parotid [(1), 0.1%], penis [(2), 0.1%], pleura [(2), 0.1%], prostate [(1), 0.1%], retrobulbar tissue [(1), 0.1%], retroperitoneum [(2), 0.1%], salivary gland [(4), 0.3%], scrotum [(1), 0.1%], skin [(4), 0.3%], terminal ileum [(1), 0.1%], thumb [(1), 0.1%], urinary bladder [(1), 0.1%], urethra [(2), 0.1%], uterus [(5), 0.4%].
**Gastrointestinal tract cases looking for Hirschsprung's disease; positive for Hirschsprung's (aganglionic).

Table 9: Deferred frozen section cases categorised by organs

Organ	No. of cases (%)
Gallbladder	4 (28.6)
Thyroid	3 (21.4)
Testis	1 (7.1)
Breast	1(7.1)
Ovary	1(7.1)
Ampullary tissue	1(7.1)
Rectum	1(7.1)
Kidney	1(7.1)
Bile duct	1(7.1)
Total	14 (100.0)

Table 10: Permanent section diagnosis of the deferred frozen section cases

Organ	Diagnosis on paraffin section
Ampullary tissue	Adenocarcinoma, moderately differentiated
Bile duct	Chronic inflammation
Breast	Chronic breast abscess with epithelial hyperplasia
Gallbladder	Acute and chronic cholecystitis
Gallbladder	Chronic cholecystitis with atypia
Gallbladder	Chronic cholecystic
Ovary	Immature teratoma
Rectum	Positive for malignancy
Kidney	Renal cell carcinoma
Testis	Granuloma
Thyroid	Multinodular goiter with cystic change
Thyroid	Anaplastic carcinoma, spindle cell type
Thyroid	Follicular variant of papillary carcinoma

The number of malignancies was more frequent in the fifth and sixth decades, as expected. The highest number of specimens was received from the breast, which is consistent with the results from other such studies (9,10) and points to the high prevalence of breast diseases in the country and the necessity for urgent tissue diagnosis.

Background and role of frozen section diagnosis in a low-income country like Bangladesh

Even though frozen sectioning is extensively used to provide an immediate decision during a surgical procedure in differentiating between benign and malignant neoplasms in developed countries (11), its use is limited in low socioeconomically developed countries, like Bangladesh, by the number of centers that provide the diagnostic test. In Bangladesh, there are only a few centers that offer the test; most hospitals, where surgical procedures are offered, do not have facilities for frozen section diagnosis on site. As a result, a preoperative appointment with the pathologist at the nearest medical center that offers the test has to be obtained beforehand and the intraoperative specimen has to be sent to the center. A diagnosis is obtained over the phone to or from the pathologist and a detailed report is issued later on.

This has an important implication since time is a crucial factor in the test. The process is facilitated by careful preparation by both the surgeon and pathologist, which includes a reliable delivery system and effective communication between the two parties.

Importance of reliability of frozen section diagnosis

With the increasing use of conservative surgical procedures and declining width of surgical margins, histologic evaluation of the margins is essential to assessing the extensiveness of excisions of a malignant tumour or in Hirschsprung's disease. A rapid procedure, frozen sectioning is intraoperative, and thus helps to reduce the number of surgeries, which has implications financially as well on the physical and mental state of the patient. The procedure offers assistance in determining the approach to surgery, including the type or extent of surgery to be performed on the patient. Frozen section diagnosis can also have a role in deciding the type of management for the patient.

Since intraoperative frozen sectioning helps to shape the course of surgical procedures, it is of vital importance that the diagnostic results offered by the pathologist to the surgeon are reliable.

Comparison of results with other frozen section reports

Excluding the 14 cases where frozen section diagnoses were deferred and the two cases that were unsuitable for assessment because of prefixation in formalin when received, the accuracy in this series of frozen sections was 99.3%. The result of the study is better than the reported diagnostic accuracy of 98.6% obtained from a series of 3000 cases reviewed by Nakazawa et al. (1968) (6). The accuracy found in this study is also superior to that reported by Ackerman et al. (1959) in a case series of 1269, that described by Dankwa and Davies (1985) in a case series of 1000, that in a series of 404 cases reported by Shreshtha et al. (2009), that found in a series of 240 cases by Evans and Suvarna (2006), and that from a series of 433 cases reported by da Silva et al. (2011) in which the diagnostic accuracies were 98%, 97.8%, 94.3%, 98.7% 93.3%, respectively (4, 9, 12–14) (Table 11).

The accuracy of frozen section diagnosis in breast cases was found to be 98.7%, which is higher than the rate found by Desai (1966) in breast biopsies (97%) (10), Dankwa and Davies in 1985 (98%) (9), Gonzalez et al. in 1985 (72.7%, 81.4%) (15), and Bellolio et al. in 2007 (86%) (11). The overall prevalence of deferred diagnoses (1.0%) was significantly less than that reported in other such audits.

Table 11: Accuracy of frozen section diagnosis found in other similar studies

Study	Number of cases	Accuracy (%)
Nakazawa et al. (1968) (6)	3000	98.6
Ackerman et al. (1959) (4)	1269	98.0
Dankwa and Davies (1985) (9)	1000	97.8
Shreshtha et al. (2009) (12)	404	94.3
Evans and Suvarna (2006) (13)	240	98.7
Da Silva et al. (2011) (15)	433	93.3

Overall, the frozen section diagnostic performance over the past six and a half years at Anowara Medical Services appears satisfactory, as the proportion of discrepancies and deferred diagnoses were comparable with, or even lower than, that in most other similar studies published in the literature.

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Conflict of Interest

None.

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Authors' Contributions

Conception and design, analysis and interpretation of the data, critical revision of the article for important intellectual content, final approval of the article, and provision of study materials or patients: MGM
Drafting of the article, statistical expertise, and collection and assembly of data: ZQ

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