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Evaluation of the Effectiveness of our Intraoperative Pathology Consultations in a Five-Year Period: A Total of 2.179 Cases

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Abstract: Intraoperative consultations (IOCs), which meet the urgent need for diagnosis during an operation, are widely used for the management of surgical operations. Inquiries that are most frequently made in IOCs include the presence/absence of a mass, malignant-benign differentiation of the mass. IOC is the most urgent and difficult area of pathology. Accurate diagnosis rates and sensitivity and specificity values are important clinical quality indicators. We aimed to evaluate the IOC data of our clinic in light of the literature. The reports of IOCs requested from the Department of Pathology of Ataturk University Faculty of Medicine between 2016 and 2020 and paraffin section (PS) reports of these tissues were retrospectively analyzed. Both reports were compared. The results were classified as age, gender, organ distribution, reason for IOC request, disagreement between IOC and PS diagnoses, and paraffin follow-up. A total of 2.179 cases, 70.03% female and 29.97% male, were included in the study. In 94.81% of the cases, diagnoses made during IOCs were confirmed by the PS examination, 3.62% were deferred, and disagreement was observed between IOC and PS examination in 2.5% of cases. In our study, the sensitivity was 95.7%, specificity 99.3%, positive predictive value 99.1%, and negative predictive value 97.2%. The high agreement between IOC and PS diagnoses is an important quality indicator. However, it is inevitable to avoid certain technical and interpretation mistakes due to the nature of the process. In our study, high accuracy, sensitivity and specificity values were observed in accordance with the literature.

Keywords: Intraoperative Consultation; Frozen Section; Sensitivity; Specificity; Accuracy.

1. Introduction

Tissue samples taken from the body are usually diagnosed in the pathology laboratory after detection, sampling, processing and staining for at least one day. However, when surgeons need urgent diagnosis to guide the operation, diagnostic methods called intraoperative consultation (IOC) or frozen section (FS) have been developed, which are based on freezing the tissues during the operation and taking rapid sections. FS was first applied by Welch in 1891, and with the introduction of cryostat in 1959, it is now widely used in clinical practice (1). IOC is one of the most pressing and difficult areas of pathology practice. It is generally used to determine the presence/absence of a lesion in the tissue to be operated, the nature of the lesion (malignant-benign, if any), the presence of lesion in the surgical margins, whether the sample taken is sufficient for diagnosis and the depth of invasion of the lesion. IOC is a challenging process that requires a multidisciplinary approach, involving an absolute clinic-pathological evaluation with the patient's clinical, laboratory and radiological findings. In routine surgical practice, IOC should ideally be requested in 5-15% of the operated patients, although this number varies according to the availability of hospital beds, clinics and surgeons (1, 2). However, purpose of FS examination requests are sometimes abused for various

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reasons. Dehner and Rosai reported that the cases were urgently directed to treatment in 44% of the FS requests while the operation was completed without waiting for the FS results in 42% (3).

The necessity of making a definitive diagnosis in a short time, limited sampling, freezing, staining and folding artifacts, insufficiency of histological sections compared to routine sections, and freezing difficulties are disadvantages of the method and may lead to diagnostic errors. In studies conducted in many centers including different numbers of cases, it has been stated that the agreement rate between IOC and permanent paraffin section examination ranged from 89.1% to 99.3%. Error rates can vary according to organ type, tumor type, tumor heterogeneity, sampling adequacy, and patholog experience (1, 2, 4-7).

The agreement between IOC and the final pathology report has the potential to change treatment decisions and affect patient care. Determining this agreement is an important component of laboratory quality assurance. Therefore, we aimed to retrospectively evaluate the requested IOCs from our clinic and their results over a five-year period, compare them to the PS results in light of the literature, and identify problems encountered in practice to guide the development of measures.

2. Material and Methods

This study evaluates the IOC's requested by various surgical branches of our hospital from Atatürk University Faculty of Medicine, Department of Pathology between January 1, 2016-December 31, 2020. The areas representing the lesion were sampled from the tissues sent to our laboratory by the relevant surgical branch. After the samples taken from the tissues were frozen in Thermo Scientific Cryotome and Leica 3050 devices, at least four sections of 4-8 μm thickness were taken and fixed with 80% alcohol over 1 minute. Then, the tissues were hematoxylin-stained for 1 minute, rinsed with distilled water, differentiated with acid alcohol for 5 seconds, rinsed again, eosin-stained for 30 seconds, rinsed and dehydrated with alcohol. The samples obtained were evaluated with a light microscope. The results were reported to the relevant surgical branch. Then, the routine processing of the same tissue samples was performed after formaldehyde fixation. These tissues were re-evaluated and the results were reported after processing.

For this study, the reports of IOCs made from 2016 to 2020 and the reports of the PS examination of the same tissues were screened from the archive of our department using the automation system of our hospital and listed. Then, the diagnoses made during IOC and after PS examination were compared. The cases were classified according to year, age, gender, affected organ, benign-malignant nature, whether the diagnosis was deferred, and agreement between the IOC and PS diagnoses. Furthermore, the cases reported to be malignant in IOC and benign in PS examination were evaluated as false positive while those reported to be benign in IOC and malignant in PS examination were evaluated as false negative. Accordingly, the accuracy rate, sensitivity, specificity, positive and negative predictive values of the IOC results were calculated and compared with the literature.

This study was carried out in Atatürk University Faculty of Medicine, Department of Pathology and was approved by the Ethics Committee of the same faculty with the decision numbere 07 and dated 29.11.2018

2.1. Statistical Analyses

All measures of agreement for the entire series are reported with 95% confidence intervals (95% CI). The values and confidence intervals were calculated. Data then analysed statistically to determine overall accuracy, sensitivity and specificity of each benign and malignant group of tumours.

3. Results

The study included a total of 2.179 cases, 1.526 (70.03%) female and 653 (29.97%) male, diagnosed over a five-year period. The mean age was 49.98 ± 17.40 years, with the youngest patient being a 1-month-old male and the oldest being a 90-year-old female. In the distribution of cases according to affected organs and systems, the female genital system ranked first place with 639 (29.3%) cases. This was followed by brain and nervous system lesions with 453 (20.8%) cases, breast lesions with 352 (16.1%) and others (Table 1).

In 1.553 (71.27%) of the cases, IOCs were requested to determine the presence/absence of a lesion and make a malignant-benign differentiation of the lesion if present. This was followed by IOCs requested to inquire about the continuity of the lesion at the surgical margin (n = 349, 16.01%) and the presence/absence of a tumor in the sentinel lymph node (n = 337, 15.46%) (Table 2).

Of our cases, 93.88% of our cases received a definitive diagnosis by IOC, with the diagnoses being benign in 1.251 (57.41%) of the patients and malignant in 795 (36.48%), and these diagnoses were confirmed by PS examination.

In 54 (2.47%) cases, there was a disagreement between the diagnoses of IOC and PS examination, with brain and other nervous system lesions ranking first among these cases (n=13/54, 24.07%), followed by breast sentinel lymph node examinations (n=12/54, 22.22%) and female genital system lesions (n=8/54, 14.81%) (Tables 3 and 4).

In the remaining 79 of the 2.179 cases (3.62%), it was determined during IOC that a diagnosis would be made after the PS examination. According to the organ distribution of the cases deferred until PS examination, brain and other nervous system lesions ranked first with 32/79 cases (40.50%) and female genital system lesions ranked second with 20/79 (25.31%) cases and other systems (Figure 1).

Table 1: Number of Intraoperative Consultation Requests and Organ Distribution by Years.

Organ	**2016**	**2017**	**2018**	**2019**	**2020**	**Total**
Female genital system	107	101	127	152	152	639
Brain and other nervous system	65	78	87	116	107	453
Breast	31	61	77	89	94	352
Head and Neck	28	32	46	57	51	214
Thyroid-Parathyroid	23	25	25	41	29	143
Liver, Gallbladder	18	22	16	28	31	115
Lung, Pleura, Mediastinum	10	13	25	14	12	74
Bone and soft tissue	5	8	18	21	9	61
Intestine	4	6	9	7	5	31
Peritoneum	6	4	8	6	5	29
Stomach, duodenum	3	3	3	8	5	22
Pancreas	4	1	2	9	6	22
Kidney	6	2	2	5	2	17
Testis	2	1	1	1	2	7
Total	312	357	446	554	510	2,179

Table 2: Reasons for Intraoperative Consultation Requests by Years.

Organ	**2016**	**2017**	**2018**	**2019**	**2020**	**Total**
Presence/absence of a mass	215	268	297	397	376	1,553
Evaluation of surgical margin	47	46	72	95	89	349
Evaluation of sentinel lymph node	25	51	69	94	98	337
Thyroid-parathyroid differentiation and other lesion	23	22	34	40	28	147
Presence/absence of ganglion cells	4	7	9	8	5	33
Organ transplant	8	3	4	8	4	27
Total	322	397	485	642	600	2,446

Table 3: Comparison of IOC and PS Diagnoses by Years.

	Agreement between IOC and PS diagnoses		Deferred until PS diagnosis	Disagreement between IOC and PS diagnoses	Total
	Malign	Benign			
2016	102	201	4	5	312
2017	155	178	13	11	357
2018	164	255	14	13	446
2019	186	327	25	16	554
2020	188	290	20	12	510
Total	**795**	**1.251**	**79**	**54**	**2.179**

IOC, intraoperative consultation; PS, paraffin section.

Table 4: Organ Distribution of disagreement between IOC and PS Diagnoses.

Organ	False Positive	False Negative	Different Diagnoses	Total
Central nervous system	3	3	7	13
Breast	2	10	0	12
Uterus	1	4	3	8
Ovary	1	5	0	6
Lung	0	4	2	6
Thyroid	1	4	0	5
Tongue	0	1	0	1
Parotid	0	1	0	1
Skin	0	1	0	1
Testis	0	1	0	1

Total	**8**	**34**	**12**	**54**

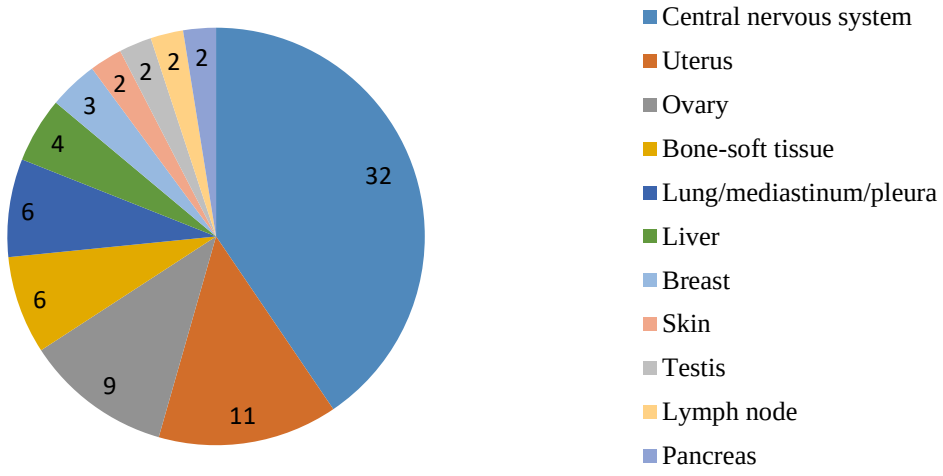

Figure 1: Organ distribution of IOCs postponed to paraffin section.

4. Discussion

IOC is one of the most important diagnostic methods in surgical case management. However, achieving an accurate diagnosis using this method requires multidisciplinary teamwork in an environment including the necessary equipment. The most important stakeholders of this team are surgeons, pathologists, and surgical and pathology technicians. Responsibility for establishing a definitive diagnosis and guiding the operation in a limited time increases the probability of error. Therefore, it is necessary to inform the pathology team to perform IOC about the case in advance and undertake an adequate preoperative clinic-pathological evaluation.

IOC's are usually made in emergency situations, such as malignant-benign mass differentiation, presence of tumor at the surgical margin, presence of sentinel lymph node metastasis, and tumor invasion depth, but they may also be needed if an unexpected situation occurs during the operation. Generally, it is accepted that IOC is required at a rate of 5-15% in surgical operations performed (1, 2, 4-7). A total of 2.179 IOCs performed in our hospital over a five-year period were included in our study. Our cases corresponded to 3.05% of the total 71.430 surgical operations undertaken in our hospital between 2016 and 2020, and this rate is consistent with the literature data.

In the literature, it is stated that the agreement rate between the IOC and PS diagnoses varies between 89.1 and 98.4% in various series including all systems (1, 2, 4-7). It has been reported that 0.1% of the errors made cause a great change in treatment (1, 2) . In IOCs applied to surgical specimens, the accurate diagnosis rates are determined by the structure of the treated organ, type of tumor, size of lesion, number of samples, and most importantly clinic-pathological correlation (2). Many reasons such as limited sample size, freezing difficulty of fatty and necrotic tissues, poor quality of sections, freezing and folding artifacts, inadequate cellular details, presence of bleeding, mucus, inflammation, and insufficient clinical information and surgeon-pathologist communication are among the diagnostic difficulties that lead to errors. Other important causes of diagnostic error are interpretation and inexperience (1, 2, 4). In some studies, tissue sampling errors (45%), interpretation errors in microscopic examination (40%), technical reasons (18%) and insufficient clinical knowledge of the patient (14%) are stated to be the most common causes of errors in IOC (1, 2).

In our study, 57.4% of the cases were diagnosed as benign and 36.48% as malignant in IOC, and these diagnoses were confirmed by PS examination. Thus, the rate of PS confirmation of the IOC diagnoses was 93.89%. When we included 12 cases with a diagnostic disagreement between IOC and PS examination but an agreement in terms of malignant-benign differentiation in this evaluation, the accurate diagnosis rate of IOC increased to 94.81%. It is clear that this rate indicates a high accuracy value when compared with the literature data. It has been reported that the accuracy rate is reduced to 89.1% in various series (5-9). Kösem et al.(8) reported the accuracy rate as 92.7% and Arora et al. (9) as 98.48%.

The diagnosis of 3.6% of the cases in our series was deferred until PS examination, while this rate was reported to range from 0.2 to 7.56 % in different series (8-12). In a study by Hwang et al. including 4.434 cases, it was reported that 2.17% of the cases were deferred until PS examination (10) . This rate was determined as 4.7% by Wen et al (11). 6.6% by Kösem et al (8) and 7.56% by Alabalık et al.(12). It is generally stated that mostly the diagnoses of central nervous system and female genital system lesions are deferred until PS examination (8, 10-14). In our series, consistent with the literature, the most common tissue samples in which the definitive diagnosis was left to PS examination belonged to the central nervous system

lesions (n = 32) and female genital system lesions (n = 20).

In 54 (2.47%) cases in our study, there was a disagreement between the IOC and PS diagnoses. Eight of these cases were defined as false positive and 34 as false negative. Based on these values, the sensitivity of IOC was determined to be 95.8%, specificity 99.3%, positive predictive value 99.0%, and negative predictive value 97.3%. In various series, it has been reported that the sensitivity and specificity rates range from 86.9 to 100% (9) and 57.1 to 98.9% (13) respectively. In our 12 cases, the IOC and PS diagnoses were consistent in terms of benign/malignant differentiation but inconsistent in terms of histopathological type. Our sensitivity and specificity rates are in agreement with the literature (1, 10).

In the current study, central nervous system lesions constituted most of the false positive cases while female genital system lesions constitutes most of the false negative cases. There were three false positive and three false negative cases of brain and other nervous system lesions. Among the false positive cases, FS defined low-grade astrocytoma in one case and low-grade glial tumors in two, but these tissues indicated as gliosis, normal glial tissue, and abscess wall in PS examination. Many studies have demonstrated that abscesses of neuroglial tissue and gliosis areas can cause diagnostic problems and lead to errors (12, 15) . Among our false negative cases, one that was interpreted as benign in FS was reported as ependymoma in PS examination while the remaining two were defined as low-grade glial tumors in FS but diagnosed as gliosarcoma and oligodendroglioma in PS examination. In a study by Alabalık et al., it was stated that the highest disagreement between the FS and PS diagnoses was observed in central nervous system lesions (17.65%) (12). In another study evaluating intracranial tumors, Tofte et al. reported that the rate of disagreement between the IOC and PS diagnoses was 9.7% (15). Therefore, we consider our rate of 2.86% disagreement in nervous system cases to be in compliance with the literature. Especially in tumors of the central nervous system, insufficient sampling, freezing artifacts, and presence of gliosis, as well as inexperience and interpretation difficulties lead to erroneous evaluation.

We determined that one female genital system lesion was diagnosed to be positive for malignancy in the ovary without specifying the nature in FS but reported as a mucinous cyst in PS, and one case interpreted as an endometrial carcinoma focus (endometrial intraepithelial neoplasia) in the uterus in FS was tumor negative in PS examination. The 10 false-negative cases of the female genital system were generally related to benign-borderline tumors of the ovary and lesions evaluated as hyperplasia in the endometrium, which were reported to be carcinomas in PS examination. Problems arising from the nature of ovarian tumors and sampling inadequacy lead to significant FS errors. Especially borderline tumors constitute a common problem. There are studies indicating that the specificity of FS in borderline tumors can decrease to 31% (16). In a series of 792 cases including gynecological materials, Wang et al. reported the sensitivity of IOCs as 86.95% and specificity as 57.1% (17). In another study, Göl et al. stated that there were fewer false positive cases while a false negativity was more common (18). In a study by İlker et al. it was determined that the false-negative rate in ovarian tumors was 3.8% (19). In our study, the rate of disagreement between the IOC and PS diagnoses was 3.12%, which is compatible with the literature, and similar errors were determined as reasons for this disagreement.

In our study, sentinel lymph nodes represented another important group showing inconsistency between the FS and PS diagnoses, with two false positive and 10 false negative cases being observed in this group. In the evaluation of lymph nodes, in addition to interpretation errors concerning cells of many different structures, there are also freezing and sectioning difficulties. Many studies have been conducted on this subject, often reporting false negative results, varying between 10 and 60% (20-23). In a meta-analysis, the intraoperative FS sensitivity of breast cancers was investigated and the accurate detection rate was determined as 62-76% (24). The failure of FS in routine intraoperative evaluation can be attributed to this method not being able to detect micrometastatic disease (25) as in our cases.

Thyroid tissue is among the most problematic areas of IOCs. In our study, while parathyroid diagnosis was made in FS in one of the tissues sent for thyroid-parathyroid differentiation, this area disappeared in PS examination. Other false negative tissues occurred due to the inadequacy of sampling, as well as inappropriate freezing, especially for diagnoses based on nuclear properties. Studies suggest that in some lesions of the thyroid, it is not appropriate to perform FS examination due to its inability to detect lesions smaller than 1 cm or show signs of surrounding capsule invasion. It is emphasized that while FS is beneficial in 3% of the follicular lesions of the thyroid, it causes erroneous diagnoses in 5% of cases, and therefore it is not recommended to perform FS examination in follicular lesions of the thyroid (26, 27).

It has been reported that significant problems can be experienced in the detection of tumors and lymphoma/carcinoma differentiation in pulmonary, pleural and mediastinal lesions, differentiation of lepidic in situ, minimally invasive and invasive carcinomas, and differentiation of small cell carcinomas (28). In a study by Liu et al., the rate of FS/PS diagnosis agreement in early stage lung adenocarcinomas was found to be 84.4% (29). In our study, similar to the literature, three cases that were reported as lung, pleura and mediastinal tissues with benign lymphoid areas in FS were diagnosed as Hodgkin lymphoma (n=2) and epithelial tumor

metastasis to the lymph node (n=1) in PS. In another case, the result of the FS evaluation was the suspicion of insitu/minimally invasive carcinoma while it was diagnosed as invasive carcinoma in PS.

5. Conclusions

IOC is still a very important and valuable diagnostic method in terms of providing surgical guidance during the operation. A high rate of agreement between the IOC and PS diagnoses is an important quality indicator. This is even more important considering the possibility of irreversible procedures that can be performed on patients based on false positive diagnoses. Although false negative diagnoses and deferral lead to secondary operative interventions in patients, they seem to be rectifiable. On the other hand, it is inevitable that certain technical and interpretation errors will be experienced. The high rates of accurate diagnosis, sensitivity, specificity, positive predictive value and negative predictive value in our series are very important quality indicators for our clinic and consistent with the data reported in the literature.

Conflict of Interests

The authors declare that they have no affiliation with any private or legal entity that would result in conflict of interest.

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We do not have financial resources to declare.

Author Contributions

Arslan R, Ceylan O and Esin K.Ü originally conceived the idea and hypothesis. Arslan R designed the study. Arslan R made the research organization. Esin K.Ü collected the data. Ceylan O interpreted the results. Ceylan O and Arslan R drafted the manuscript. All authors reviewed and approved the manuscript.

Ethical Approval

This study was carried out in Atatürk University, Faculty of Medicine, Department of Pathology and was approved by the Ethics Committee of the same faculty with the decision numbere 07 and dated 29.11. 2018.

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