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RESEARCH ARTICLE

AUDIT IN SURGICAL HISTOPATHOLOGY: STUDY OF PREANALYTICAL AND ANALYTICAL PHASES

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ABSTRACT: An audit provides information about the conformance to required standards, assesses their implementation, and provides corrective actions to improve quality. Surgical histopathology includes biopsy, small and large organ resections. Audit of a surgical histopathology laboratory allows improving the overall performance and better patient care. **Aims**: To evaluate preanalytic and analytic phases of surgical histopathology. **Materials and methods**: Biopsy, small resections and large organ resections received in histopathology were categorized as I, II and III, respectively. A manual audit was done for the preanalytic phase (patient details, adequacy of clinical information, specimen and grossing adequacy) and analytic phase (tissue section quality, special stains, immunohistochemistry and turnaround time (TAT). **Results**: Among 540 total cases, category I, II and III had 56.8%, 29.8% and 13.3% cases, respectively. Category I had maximum number of cases with inadequate clinical details and specimen inadequacy, however shortest TAT was seen in most of these cases. Category II had maximum cases with inadequate grossing followed by category III. Longest TAT was observed in category III. **Conclusions:** The present study was a manual audit and most of the quality indicators were achieved in accordance with the international standards. Corrective actions were suggested to further improve the quality and better patient care.

KEYWORDS: Audit, quality, surgical histopathology, turnaround time

INTRODUCTION:

Surgical histopathology is the gross and microscopic analysis of tissues to help diagnose a disease and further determine a treatment plan. An internal audit plays an important role in the quality management system including pre-examination, examination, and post-examination.

Audit conforms to the requirements of standard criteria and guides actions for improvement. [1-4]

AIMS AND OBJECTIVES

1. To audit the preanalytical and analytical phases of surgical histopathology.
2. To evaluate turnaround time (TAT) for formalin fixed tissues

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MATERIALS AND METHODS:

An observational retrospective study was conducted in the surgical histopathology laboratory in the department of pathology at a tertiary care hospital over a period of two months (January to February 2020). An internal audit was done and data was collected manually from the archived histopathology forms. The preanalytical data was analysed and the specimens received were further categorized as Category I (biopsies), Category II (small specimens) and Category III (organ resections). The following information was collected:

Preanalytical phase

1. Patient details: name, registration number, age, gender
2. Clinical history and laboratory investigations
3. Specimen adequacy: labelling of containers, volume of formalin
4. Grossing adequacy: description of the grossed specimen, relevant diagrams

Analytical phase

I. Technical performance: quality of sections and slides

II. Turnaround time (TAT): calculated from tissue receipt to final reporting, including delay due to tissue fixation and/or decalcification. It also included the time required for special stains and immunohistochemistry in some cases.

In our institution, all cases are screened by the histopathology reporting consultant.

All data was compiled in MS Excel sheet and analyzed by PSPP version 0.8.5 and simple frequencies were calculated.

RESULTS:

Total 540 samples were analysed and categorized as category I, II and III. Category I had 307 (56.8%), 161 (29.8%) were in category II and 72 (13.3%) cases were in category III. Maximum cases in Category I belonged to female genital system, mainly endometrial biopsies. Gastrointestinal system and female genital system contributed to maximum number of cases of Category II and category III. Preanalytical evaluation is shown in Table 1.

TABLE 1. PRE-ANALYTICAL EVALUATION OF CASES

CATEGORY	INADEQUATE PATIENT DETAILS	INADEQUATE CLINICAL DETAILS AND INVESTIGATIONS	SPECIMEN INADEQUACY	INADEQUATE GROSSING
I	02	112	25	00
II	01	43	04	12
III	00	09	00	09
TOTAL	03	164	29	21

TABLE 2. ANALYTICAL EVALUATION OF CASES

CATEGORY	INADEQUATE SECTION QUALITY	ADDITIONAL SECTIONS AND RECUTS	DECAL	SPECIAL STAINS	IHC*	TAT (M± SD) Days
I	01	11	06	16	06	7.0± 2.7
II	05	07	03	06	04	7.1± 2.9
III	03	04	01	02	08	7.4± 3.6
TOTAL	09	22	10	24	18	7.3± 3.4

*IHC = Immunohistochemistry

TABLE 3- TURNAROUND TIME (TAT) OF CASES

CATEGORY	TAT (IN DAYS)								
	3	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11-15**
I	17	07	170	76	23	08	02	01	03
II	07	10	58	50	20	09	01	01	05
III	00	06	06	21	13	07	03	09	07
TOTAL (%)	24 (4.4)	23 (4.2)	234 (43.3)	147(27.2)	56(10.3)	24(4.4)	06(1)	11(2)	15 (2.7)

TABLE 4- QUALITY INDICATORS IN PREANALYTICAL AND POSTANALYTICAL PHASES: COMPARISON WITH OTHER STUDIES

Quality indicators	Present study (%)	Zuk et al[3] (%)	Shinde et al[4] (%)	Nwafor et al[5] (%)	Priyadarshini et al[6] (%)	Bhattacharya et al[7] (%)	Malami et al[11] (%)	Akinfenwa et al[12] (%)
Category I,II,III	56.8, 29.8, 13.3	55, 0, 31.3	49, 34.6. 10.8	62.5, 0, 20.5	NA	NA	NA	NA
IA patient details	0.5	15.1	2.2	NA	38.5	NA	NA	25.0
IA clinical details &	30.4	NA	3.8 & 3.7	NA	35.5 & 30.7	NA	NA	50.0 & 53.0
IA Specimen	5.4	78	0.6	NA	10.2	NA	NA	20.0
IA Grossing	3.8	29	2.1	NA	NA	0.01	NA	NA
IA Section quality	1.7	3	17.8	NA	NA	0.03	18	NA
TAT (Days)	7.0, 7.1, 7.4	1.5, 2.1, 1.3	3.3, 3.4, 5	8.1	NA	NA	6.2	NA

Category I-biopsy, Category II- small specimen, Category III- Large organ resection, IA-Inadequate, NA-Not available, TAT-Turnaround time

Inadequate patient details were seen only in 3 cases. Inadequate specimen adequacy was observed in 25 cases belonging to category I. Inadequate grossing was found in 21 (3.9%) cases, manifested by incomplete description (4), no representative diagram (16), and specimen not properly oriented (1).

Analytical phase was studied and further evaluated as described in Table 2 and Table 3 showed the TAT.

Out of 540 cases, only 9 cases showed inadequate section quality, the reasons were poor Haematoxylin-Eosin stain (5), thick section (2) and improperly embedded tissue (2). The maximum numbers of additional sections were taken in 9 cases belonging to category II and 3 cases of category III. The main reason for additional sections were for observing more representative areas to rule out invasiveness in cases of tumour. Recuts of blocks were required for better cut (3), complete cut (2) and serial sections (4). Special stains were done for only 24 (4.4%) cases and control slides were put with all these cases.
Immunohistochemistry was required in 18 cases: 6 of category I, 4 of category II and 8 cases of category III. Positive control slides were provided for all these cases.
Turnaround time (TAT) of 3 days was observed in 24 cases, most of these cases were of category I (17 cases). TAT of 5 days accounted for maximum number of cases (118 cases). The maximum TAT was of 15 days, observed in 14 cases. TAT was maximum for bony tissue, the reason being the time required for decalcification. The other cases requiring immunohistochemistry and regrossing also showed delayed TAT.

DISCUSSION:

A total of 540 histopathology specimens received during the study period were audited. The maximum number of cases was contributed by category I which included biopsies. Similar findings were observed by Zuk et al [3] and Shinde et al [5] - 55% and 49% of cases respectively. 62.5% biopsy cases were noted in the study by Nwafor et al [6] [Table 4].

The maximum number of cases in the present study belonged to female genital system and gastrointestinal system. Shinde et al reported that gastrointestinal system contributed more in their study. [5]

In our study, the requisition forms with complete patient details were found in 537 (99.5%) cases. Priyadharisini et al found 98.3% requisition forms with complete patient details. However, information related to clinical history and investigations were complete in 35% and 30.7%, respectively.[7] Complete clinical details and investigations were observed in 376 (69.6%) cases in our study. Most requisition forms with incomplete details of symptoms and relevant laboratory investigations belonged to category I (112 cases), followed by category II (43 cases) and 9 cases belonging to category III. Providing proper clinical history along with relevant laboratory investigations saves the time rendered in collecting these details. Minimising the errors in the requisition forms and providing important clinical information improves patient care.[8] Hence, this corrective action plays an important role in improving TAT in cases where diagnosis is delayed because of lack of information.

Priyadarshini et al also noted in their study that 89.8% specimens were received in formalin and 85% specimens were in appropriate containers.[7] Akinfenwa et al observed inadequate amount of fixative in the specimen containers in 23.5% of specimens and inappropriate containers in 16.5% and incomplete labelling in 32.5%.[9] In our study, all the specimens received were in formalin fixative in appropriate containers. The date of specimen collection was present in all the requisition forms; however the time was not mentioned. Adequate tissue fixation plays an important role for special studies such as immunohistochemistry. Smaller tissues like trucut biopsies require proper fixation so that further immunohistochemistry if required can be put and results are not affected due to fixation issues. Also, specimens received in inappropriate containers may get distorted and important findings during grossing can be missed.

In the present study, specimen inadequacy was observed in 29 (5.4%) cases. Out of 29, 25 cases belonged to category I, mainly endometrial biopsies. These cases showed blood and blood elements and no endometrial tissues. The result can be improved by taking biopsies from more representative area.

Zuk et al observed an average score of 71% for grossing description.[3] Shinde et al reported 16.4% cases belonging to category III with inadequate grossing.[5] In the present study, inadequate grossing was noted in 21 (3.8%) cases. Grossing is done by senior residents following standard textbook guidelines. A standard operating procedure (SOP) manual will further improve grossing techniques and prevent regrossing which delays reporting.

Analytical phase. In the present study, 9 (1.7%) cases showed inadequate section quality. Zuk et al reported poor section quality in 3% cases [3], almost similar to our study. Shinde et al found inadequate section quality in 16.8% category I cases, 14.9% category II cases and 28.1% category III cases.[5] 5 (0.9%) category II cases had inadequate section quality in our study. 0.03% cases with inadequate staining quality was noted by Bhattacharya et al.[10] Inadequate grossing, requirement for more representative areas and reembedding of tissues led to additional sections and recuts in the present study.

In the present study, control slides were provided with all the cases requiring special stains and immunohistochemistry. Association of Directors of Anatomic and Surgical Pathology (ADASP) recommends control slides to be put with all the cases for better quality assurance.[11] Shinde et al found control slides were not provided in 50.3% cases requiring special stains.[5]

CAP recommends TAT of 2 days for biopsies excluding cases requiring decalcification, intradepartmental and extra departmental consultations.[12] TAT of 2.72 days was reported by Volmar et al. in an American Q-Probes study involving 56 institutions with reports on 2763 large or complex histology cases.[13] Zuk et al noted TAT of 1.5 and 2.1 days, respectively, for biopsies and resection specimens.[3] Malami and Iliyasu observed TAT ranging from 2 to 16 days in their study.[14] In

the present study, we found highest TAT for bony tissue. Soft tissue specimens needed more immunohistochemistry which further increased the reporting time in 2 cases. Also, regrossing for more representative areas also increased TAT in 4 cases.

CONCLUSIONS:

The present study involved the preanalytic and analytic phases and it was conducted manually. It was observed that most of the quality indicators were achieved in accordance with recommended standards. Properly filled requisition forms along with detailed clinical history and investigations can save the time spent in retrieving the required information. Detailed SOPs can improvise the grossing technique. Daily documentation of reasons for inadequate section quality should be noted and proper corrective actions should be taken on regular basis to further improve the quality. More improvement can be achieved by faster processing of tissues to reduce TAT. Sample size in the present study was smaller and post analytical phase was not evaluated. Conducting an audit on larger number of cases will contribute more towards deciphering the inadequacy and will allow for more corrective actions to improve the quality and hence better patient care.

REFERENCES:

[1]. Omorodion NT, Achukwu PU, Ebo N. Review on laboratory auditing in histopathology laboratory. Sokoto J Med Lab Sci 2017; 2:124-8.
[2]. Iyengar JN. Quality control in the histopathology laboratory: An overview with stress on the need for a structured national external quality assessment scheme. Indian J Pathol Microbiol 2009; 52:1-5.
[3]. Zuk JA, Kenyon WE, Myskow MW. Audit in histopathology- Description of internal quality assessment scheme with analysis of results. J Clin Pathol 1991; 44:10-6.
[4]. Karki S. Errors: Detection and minimization in histopathology laboratories. J Pathol Nepal 2015;5: 859-64.
[5]. Shinde SV, Dhanve MJ. Audit in surgical histopathology at a tertiary healthcare center: Study of preanalytical andanalytical phase. Indian J Pathol Microbiol 2021; 64: 136-9.
[6]. Nwafor CC, Ekpo MD. Timeliness of surgical pathology results: A departmental audit of histopathological services. Sub-Saharan Afr J Med 2019; 6:96-100.
[7]. Priyadharisini, Porko S, Barman PP. Audit of histopathology request forms submitted in laboratory of a tertiary care hospital. J Med Sci Clin Res 2019; 7:1085-9.
[8]. Sirota RL. Error and error reduction in pathology. Arch Pathol Lab Med 2005;129: 1228–3.
[9]. Akinfenwa TA, Raphael S. Role of surgeons in determining outcome of histopathology specimens. Niger J Surg 2013; 19: 68-72.
[10]. Bhattacharya AB, Bohara S, Das R, Sharma P, Vidyadhar S. An audit of diagnostic surgical pathology: A tool forquality assurance. Original study in a rural teaching hospital in Eastern Uttar Pradesh, India. J Dent Med Sci 2015; 14:32-3.
[11]. Nakhleh R, Coffin C, Cooper K. Association of Directors of Anatomic and Surgical Pathology. Recommendations for quality assurance and improvement in surgical and autopsy pathology. Am J Surg Pathol 2006; 126:334-7..
[12]. CAP QCDR MEASURES ID/CMS QCDR ID-22. Measure title: Turnaround time biopsies
[13]. Volmar KE, Idowu MO, Souers RJ, Karcher DS, Nakhleh RE. Turnaround time for large or complex specimens insurgical pathology. A college of American pathologists Q-Probes study of 56 institutions. Arch Pathol Lab Med. 2015; 139:171-7.
[14]. Malami SA, Iliyasu Y. Local audit of diagnostic surgical pathology as a tool for quality assurance. Niger J Med2008; 17: 186-90.

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