

Rate of Diagnostic Change in Surgical Pathology Reports after Mandatory Intradepartmental Peer Review in a Tertiary Hospital in the Philippines: A Retrospective Study

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ABSTRACT

Objective. There is a mandatory intradepartmental peer review algorithm in the University of the Philippines - Philippine General Hospital (UP-PGH) Department of Laboratories wherein specific cases are required to be reviewed by another pathologist before the release of results. The main objective of this study was to determine the rate of diagnostic change in surgical pathology reports after undergoing the said review.

Methods. All surgical pathology cases which underwent the review from 2015 to 2018 were retrieved from the records of the Section of Surgical Pathology. The cases were classified as concordant or discordant. A case was considered concordant if the reviewing pathologist had agreed with the primary pathologist's diagnosis. A case was considered discordant if the reviewing pathologist had disagreed with the primary pathologist's diagnosis.

Results. Out of 5,377 cases included in this study, there were 5,209 concordant cases and 168 discordant cases, with the rate of discordance computed to be 3.1%. Out of the 168 discordant cases, 107 were revised for diagnostic change. Rate of diagnostic change was computed to be 2.0% (107 out of 5,377 cases for review). The most common criterion satisfied for meriting a mandatory review is being under the category of biopsies or cytology cases with malignant or borderline diagnoses (49.4%). The most common category of diagnostic change is change in immunohistochemistry recommendations (24.3%). Most of the discordant cases and cases revised for diagnostic change fall under the categories of gastrointestinal, gynecology, and head & neck pathology.

Conclusion. The low rate of diagnostic change in our institution might be attributed to good diagnostic accuracy. However, it is also possible that reviewing pathologists tended to agree with the diagnosis made by their colleagues because of the element of peer pressure. Data from the study may imply that special courses/lectures or institutional standard practice guidelines on interpreting biopsy and cytology cases as well as on the utility of immunohistochemistry studies, especially those focused on gastrointestinal, gynecology, and head & neck pathology are needed by the pathologists and the doctors training to become pathologists in our institution.

Keywords: diagnostic change, review, surgical pathology



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INTRODUCTION

Background of the Study

A surgical pathology report is a final written product of a surgical pathology laboratory which contains a diagnosis on a specimen that was delivered to the laboratory from an operation or a patient visit to a clinician.¹ It is very important that surgical pathology reports contain correct and complete diagnosis. Since such reports are a basis for the management of clinicians for their patients, diagnostic errors may inflict harm. To ensure diagnostic accuracy, a review of cases by another pathologist might be crucial.

There is an existing mandatory intradepartmental peer review algorithm in the University of the Philippines - Philippine General Hospital (UP-PGH) Department of Laboratories wherein 1) biopsies and cytology cases with malignant or borderline diagnoses, 2) cases with diagnoses incompatible with the clinical impression or presentation, 3) rare cases, and 4) cases with unusual or atypical morphology are required to be reviewed by another pathologist in the department before the release of results. The need for peer review is flagged by the primary pathologist and/or the pathology resident-in-charge of the cases. If the second pathologist agrees with the primary pathologist's diagnosis, he/she signs the report as the second pathologist signatory, and the result is then released. On the other hand, if the second pathologist disagrees with the primary pathologist's diagnosis, he/she does not sign the report, and the report is returned to the resident-in-charge who will then communicate with the primary pathologist the reason why the pathologist reviewer disagrees. There is no strict rule on the selection of pathologists who will be consulted for such cases to be passed around; it depends on the choice of the primary pathologist or resident-in-charge. The number of pathologists consulted for a case depends on the primary pathologist, whether he/she is already satisfied with the number of opinions gathered and with the degree of concurrence reached. The initial diagnosis of the primary pathologist as well as the opinions of the other pathologists are documented in an intradepartmental consultation report which is also known as the pass around form. This pass around form and the Surgical Pathology request form are attached to the final Surgical Pathology report and are kept on record in the Section of Surgical Pathology.

The mandatory intradepartmental peer review applies to service (charity), pay, and outpatient cases. This review algorithm is commonly referred to in the department as the "second sig" or "second signature" process.

Definition of Terms

Amendment – It is a change in a surgical pathology report after it has been released already that is not purely addition of information, i.e., in contrast to an addendum which purely adds information.

Concordance – The existing mandatory intradepartmental peer review algorithm in the UP-PGH Department

of Laboratories requires one pathologist to review a case falling under the categories listed above. If the reviewing pathologist agrees with the primary pathologist, that is considered a concordance.

Discordance – If the reviewing pathologist for the mandatory intradepartmental peer review disagrees with the primary pathologist's diagnosis, that is considered a discordance, in which case the primary pathologist has the choice to let more pathologists see the case.

Error – In this study, an error is defined as an incorrect diagnosis which might have been corrected if it had been reviewed by other pathologists.

Intradepartmental review – The primary pathologist and the pathologist doing the review are both from the UP-PGH Department of Laboratories.

Mandatory review – There is an existing algorithm in the UP-PGH Department of Laboratories wherein 1) biopsies and cytology cases with malignant or borderline diagnoses, 2) cases with diagnoses incompatible with the clinical impression or presentation, 3) rare cases, and 4) cases with unusual or atypical morphology are required to be reviewed by another pathologist.

Peer review – The cases are reviewed by another pathologist who at least passed the diplomate examination for Anatomic Pathology.

Prospective review – The review is done before release of results, as opposed to retrospective in which the review is done after the results are released already.

Rate of diagnostic change – It is the percentage of reports revised for change in diagnosis after mandatory prospective intradepartmental peer review.

Sign-out – It is the process in which a pathologist together with a pathology resident finalizes a surgical pathology report.

Review of Related Literature

The College of American Pathologists (CAP) Pathology and Laboratory Quality Center in cooperation with the Association of Directors of Anatomic and Surgical Pathology (ADASP) drafted recommendations to address the question, "What are the most effective ways to reduce interpretive diagnostic errors in Anatomic Pathology?" and two of the recommendations drafted are the following: 1) Anatomic pathologists should develop procedures for the review of selected pathology cases to detect disagreements and potential interpretive errors in order to improve quality of patient care; and 2) If pathology case reviews show poor agreement within a defined case type, anatomic pathologists should take steps to improve agreement.²

The "second signature" process of the UP-PGH Department of Laboratories permits review of cases before sign-out. The advantage of a prospective review or review of cases before sign-out is that errors are caught before the report is released, as can be implied from the results of studies by Lind and colleagues published in 1995, by Nakhleh and Zarbo published in 1998, and by Owens and

colleagues published in 2010.³⁻⁵ This potentially reduces the amount of rework necessary to amend reports. On the other hand, review of too many cases before sign-out adds to the burden of initial work and may impact turn-around time.⁶ Suitably, the "second signature" process in the UP-PGH Department of Laboratories is a targeted type of review, i.e., a review of specific types of cases only.

A study by Renshaw and Gould published in 2006 compared the diagnostic disagreement and amendment rates of cases seen by one and by more pathologists based on results of a blinded review. A lower disagreement rate and a lower amended report rate were correlated with reports seen by more than one pathologist prior to release of results.⁷

In a cancer center in Taiwan, all pathologic diagnoses of patients done outside are reviewed before rendering therapy to the patients. Tsung did a one-year retrospective study published in 2004, wherein the frequency of discordant diagnoses was assessed and cases were classified into four basic categories: 1) no diagnostic disagreement; 2) no diagnostic disagreement but pertinent information not included, such as tumor size, lymphovascular invasion, perineural invasion, histologic grading, margin status, extracapsular spread in metastatic lymph nodes; and 3) major disagreement, which was defined as follows: a) change from benign to malignant, b) change from malignant to benign, c) a different type of neoplasm, and d) change in N and M classification in TNM staging framework. Of the 715 cases included in the study, 42 cases (6%) showed discordance in which 27 cases have major disagreement.⁸

In a study by Middleton and colleagues published in 2014, all 2,718 pathology cases of patients in a tertiary care hospital in Texas, USA in September 2011 which had been interpreted outside were reviewed by a pathologist with subspecialty expertise. There was discordance in 25% of the cases. When categorized into subspecialties, head & neck cases had the highest discordance at 46%, soft tissue cases at 40%, gastrointestinal cases at 33%, dermatologic cases at 30%, and genitourinary cases at 30%.⁹

Significance of the Study

The results of the study may be used as a quality metric for diagnostic accuracy, as review by other pathologists, given there are acceptable ways to adjudicate disagreements, has already become the gold standard to judge diagnostic "correctness" in surgical pathology. This is because long-term follow-up and response to therapy, although the only true gold standard for diagnosis, is impractical.¹⁰

Moreover, the study might be used as future reference for further refinement of the existing mandatory prospective intradepartmental peer review algorithm and possible revision of other existing and creation of new algorithms in the UP-PGH Department of Laboratories. It may also become a basis for future studies in Surgical Pathology. For example, if report discordances are repeatedly identified in a particular tissue or organ system, then steps should be taken

to understand the source of discordance and underlying deficiency in the existing system.⁶

OBJECTIVES

The main objective of the study was to determine the rate of diagnostic change in surgical pathology reports after mandatory prospective intradepartmental peer review in UP-PGH from the start of implementation of the review algorithm in 2015 until December 31, 2018.

The following were the specific objectives:

1. To categorize discordant cases according to the specific criterion satisfied why they merited a mandatory review;
2. To classify the discordant cases according to the diagnostic changes made;
3. To classify the discordant cases according to tissue or organ system involved;
4. To compute the proportion of the number of cases revised for diagnostic change to the number of discordant cases in general and for each tissue or organ system category; and
5. To compute the percentage of cases revised for diagnostic change by tissue or organ system category.

METHODS

This is a descriptive study done in the UP-PGH Department of Laboratories, which was from where Surgical Pathology reports, Surgical Pathology request forms, and pass around forms were retrieved. All Surgical Pathology cases which underwent mandatory prospective intradepartmental peer review from the start of implementation of the review algorithm in 2015 until December 31, 2018 were considered for the study. These cases include service (charity), pay, and outpatient cases. However, cases with no proper documentation of the primary pathologist's initial diagnosis were excluded.

Data Collection

Concordances and discordances were counted. Concordances were identified by searching for a second pathologist signature in the Surgical Pathology reports. Discordances were identified by looking at the second pathologist's opinion written in the Surgical Pathology request forms or pass around forms. Codes were assigned to cases included in the study to protect identity of patients. The initial diagnosis of the primary pathologist and the diagnosis in the final Surgical Pathology report were noted and compared.

Data Processing and Analysis

Rate of discordance was computed using equation [1].

Rate of diagnostic change was computed using equation [2].

Note that the rate of discordance and the rate of diagnostic change have the same denominators, hence the difference of values between the two parameters would be attributable

$$[1] \quad \text{Rate of discordance} = \frac{\text{number of discordant cases within the study period}}{\text{number of cases for prospective intradepartmental review within the study period}}$$

$$[2] \quad \text{Rate of diagnostic change} = \frac{\text{number of reports revised for diagnostic change within the study period}}{\text{number of cases for prospective intradepartmental review within the study period}}$$

to different numerators. Difference in the numerators would be because not all initial diagnoses of discordant cases are eventually revised by the primary pathologist.

The discordant cases were categorized according to the specific criterion satisfied why they merited a mandatory review. The following are the categories:

- Biopsies and cytology cases with malignant or borderline diagnoses
- Cases with diagnoses incompatible with the clinical impression or presentation
- Rare cases
- Cases with unusual or atypical morphology

The percentage or proportion of each specific criterion to the total number of discordant cases were computed.

Diagnostic changes were classified using the following categories as modified from the methodology used in a study by Tsung in 2004:⁸

- Diagnosis changed from benign to malignant
- Diagnosis changed from malignant to benign
- Diagnosis changed from benign entity to another benign entity
- Diagnosis changed from malignant entity to another malignant entity
- Diagnosis changed from benign to suspicious for malignancy
- Diagnosis changed from malignant to suspicious for malignancy
- Diagnosis changed from suspicious for malignancy to benign
- Diagnosis changed from suspicious for malignancy to malignant
- Diagnosis changed from benign entity to a recommendation for rebiopsy
- Diagnosis changed from malignant entity to a recommendation for rebiopsy
- Diagnosis changed from suspicious for malignancy to a recommendation for rebiopsy
- Change in TNM staging
- Change in margin status
- Presence or absence of lymphovascular, perineural, or capsular invasion
- Change in histologic grade
- Change in recommendations on immunohistochemistry studies, molecular studies, or other special tests
- No diagnostic disagreement but pertinent information is added to the report, such as tumor size and histologic grading

Cases with borderline diagnoses were considered “suspicious for malignancy”. The percentage or proportion of each specific change to the total number of cases revised for diagnostic change was computed.

Cases revised for diagnostic change after review were classified by tissue or organ system using the following categories as modified from the methodology used in a study by Middleton and colleagues published in 2014:⁹

- Thyroid cytology
- Non-thyroid cytology
- Bone
- Breast
- Endocrine
- Eye
- Gastrointestinal
- Genitourinary
- Gynecology
- Head and neck
- Hematopathology / lymph node / bone marrow
- Neurology / central nervous system / peripheral nervous system
- Soft tissue
- Skin
- Thoracic
- Others

The proportion of the number of cases revised for diagnostic change to the number of discordant cases was determined. This was done for the totality and for each tissue or organ system category.

The percentage of cases revised for diagnostic change by tissue or organ system category was computed.

Data collected were encoded in a password-protected Microsoft Excel spreadsheet for ease in computation.

Ethical Considerations

The protocol for this study was submitted for review by the University of the Philippines Manila Research Ethics Board (UPMREB) and was carried out after approval.

No additional costs were incurred by the patients. All results were de-identified during data collection. Patient demographics were not collected since only the diagnoses in the surgical pathology reports were needed. Only the investigators were allowed to analyze the data. This study does not in any way violate the Data Privacy Act of 2012.

RESULTS AND DISCUSSION

There were 5,377 cases included in the study, out of 5,396 cases for mandatory review from the start of implementation of the review in 2015 until December 31, 2018. Cases with no proper documentation of the primary pathologist's initial diagnosis were excluded (19 cases). There were 5,209 concordant cases and 168 discordant cases, with the rate of discordance computed to be 3.1%. This is lower compared to the results of the study by Tsung (2004) in a cancer center in Taiwan wherein there was 6% discordance from 715 cases included in the study, and the results of the study by Middleton and colleagues (2014) in a tertiary care hospital in Texas, USA wherein there was 25% discordance from 2,718 cases included in the study.^{8,9} However, the studies by Tsung and by Middleton and colleagues involved cases from outside of their respective institutions, i.e., the review involved in their studies were not intradepartmental, which might render the computed discordance from those studies not directly comparable to that from this study.

Out of the 168 discordant cases, 61 cases were not revised despite the discordance because most if not all other pathologists agreed with the original diagnosis. These cases were signed-out with the original diagnosis but with the note that the cases were signed-out in consultation with other pathologists. Out of the 168 discordant cases, 107 were revised for diagnostic change. Rate of diagnostic change was computed to be 2.0% (107 out of 5,377 cases for review). The low rate of diagnostic change might mean that there is good diagnostic accuracy in our institution, as review by other pathologists, given there are acceptable ways to adjudicate disagreements, has already become the gold standard to judge diagnostic "correctness" in surgical pathology as stated by Nakhleh and colleagues in 2006.¹⁰ However, it is also possible that since reviewing pathologists were not blinded to the identity and diagnosis of the respective primary pathologists, they tended to agree with the diagnosis made by their colleagues because of the element of peer pressure.

Figure 1 shows that the most common criterion satisfied for meriting a mandatory review is being under the category of biopsies or cytology cases with malignant or borderline diagnoses

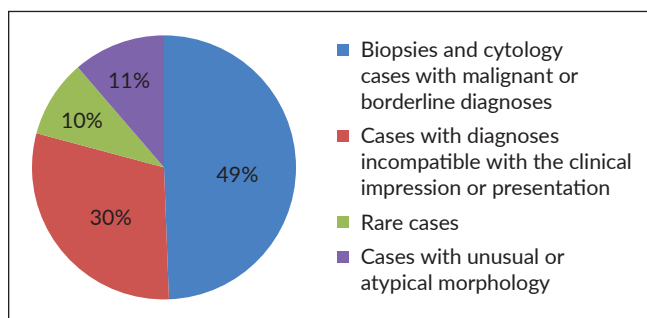


Figure 1. Discordant cases classified according to criteria satisfied for meriting a mandatory review.

diagnoses (49.4%). The second most common criterion is incompatibility with clinical impression or presentation (29.8%). Cases with unusual or atypical morphology (11.3%) and rare cases (9.5%) have almost the same frequency.

Figure 2 shows the diagnostic change categories by frequency. The most common category is change in immunohistochemistry recommendations (26 out of 107; 24.3%), followed by change from a benign entity to another benign entity (23 out of 107; 21.5%), and followed by change from a malignant entity to another malignant entity (10 out of 107; 18.7%). Therefore, assuming that the initial diagnosis is incorrect, the majority of the incorrect diagnoses by the pathologists in our institution have relatively low therapeutic implications compared to diagnostic errors with worse therapeutic implications, for example, a benign pathology being misdiagnosed as malignant and vice versa.

Cases revised from benign to malignant were typically biopsy cases in which dysplasia was evident to all pathologists who saw the cases but absence or presence of invasion seemed equivocal. An example of a case revised from benign to malignant is a sigmoid colon biopsy case initially diagnosed as "few severely dysplastic glands in a background of necrosis" by the primary pathologist and diagnosed as "adenocarcinoma" by the reviewer pathologist. After showing the case to other pathologists, the primary pathologist and pathology resident-in-charge eventually signed out the case as "adenocarcinoma, well-differentiated". Another case is a rectal biopsy case initially diagnosed as "tubulovillous adenoma with severe dysplasia" by the primary pathologist and diagnosed as "intramucosal carcinoma" by the reviewer pathologist. After letting other pathologists see the case, the case was eventually signed out as "adenocarcinoma". It seems that the limited amount of tissue material in biopsy cases makes absence or presence of invasion difficult to interpret.

Similarly, cases revised from malignant to benign were typically biopsy cases in which dysplasia was evident to all pathologists who saw the cases but absence or presence of invasion seemed equivocal. An example of a case revised from malignant to benign is an anal verge biopsy case initially diagnosed as "adenocarcinoma" by the primary pathologist and diagnosed as "villous adenoma" by the reviewer pathologist. After showing the case to other pathologists, the case was eventually signed out as "villous adenoma". Another case is a rectal biopsy case initially diagnosed as "adenocarcinoma, well-differentiated" by the primary pathologist and diagnosed as "clusters of severely dysplastic glands" by the reviewer pathologist. After letting other pathologists see the case, the case was eventually signed out as "fragments of rectal tissue with detached high-grade dysplastic epithelium". Again, it seems that the limited amount of tissue material in biopsy cases makes absence or presence of invasion difficult to interpret.

No discordant case had change in recommendations on molecular studies or special tests other than immunohistochemistry studies. There were also no cases which had

change in TNM staging, margin status, and absence/presence of lymphovascular space invasion or perineural invasion. There were also no cases changed from a benign entity to a recommendation for repeat biopsy. Therefore, these are not included in Figure 2.

Figure 3 shows the number of discordant cases according to tissue or organ system involved. The blue bars represent cases with no change in diagnosis despite being discordant, while the red bars represent the cases revised for diagnostic change. The green bars represent all discordant cases, equivalent to the sum of the blue and red bars.

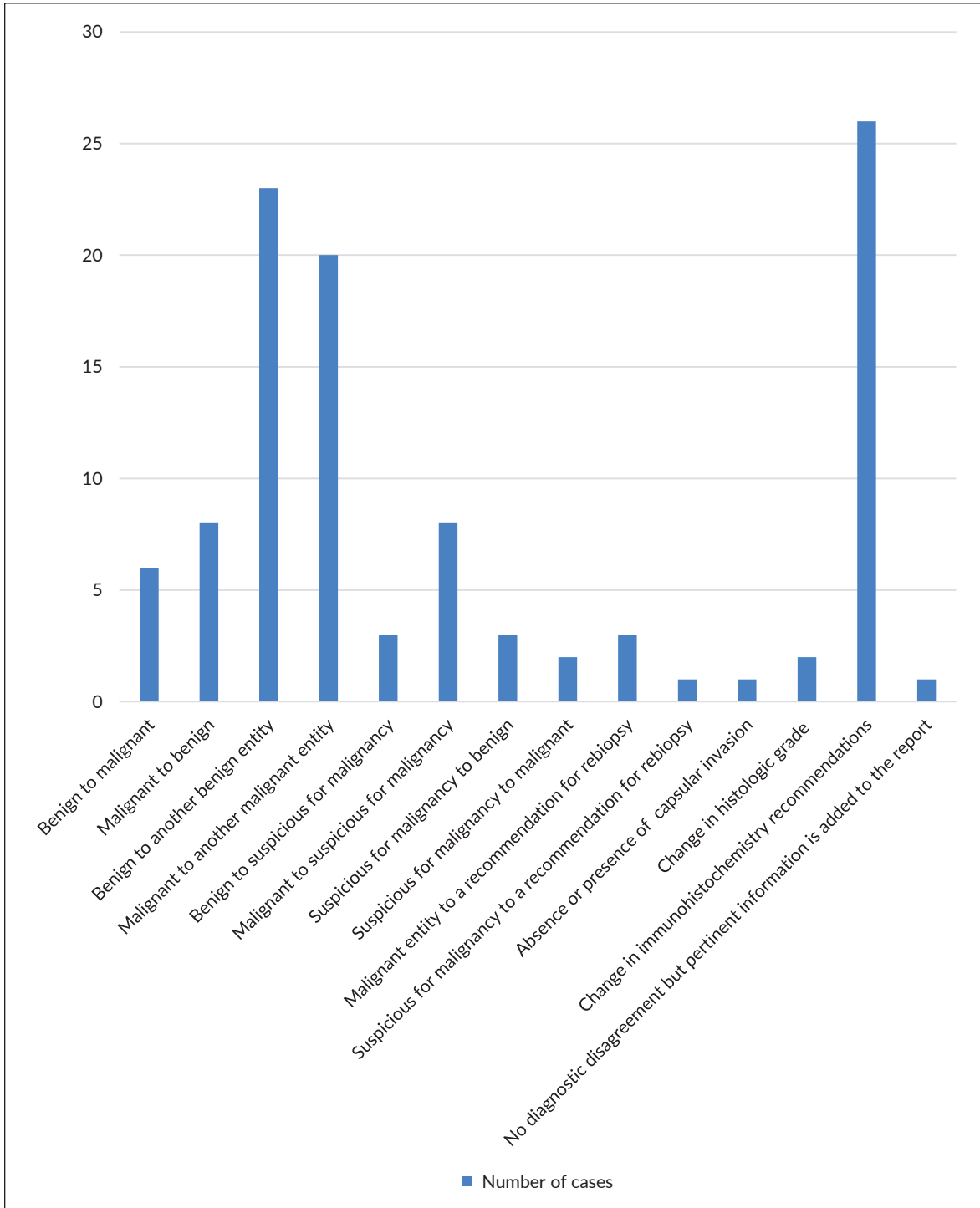


Figure 2. Number of cases revised for diagnostic change by category.

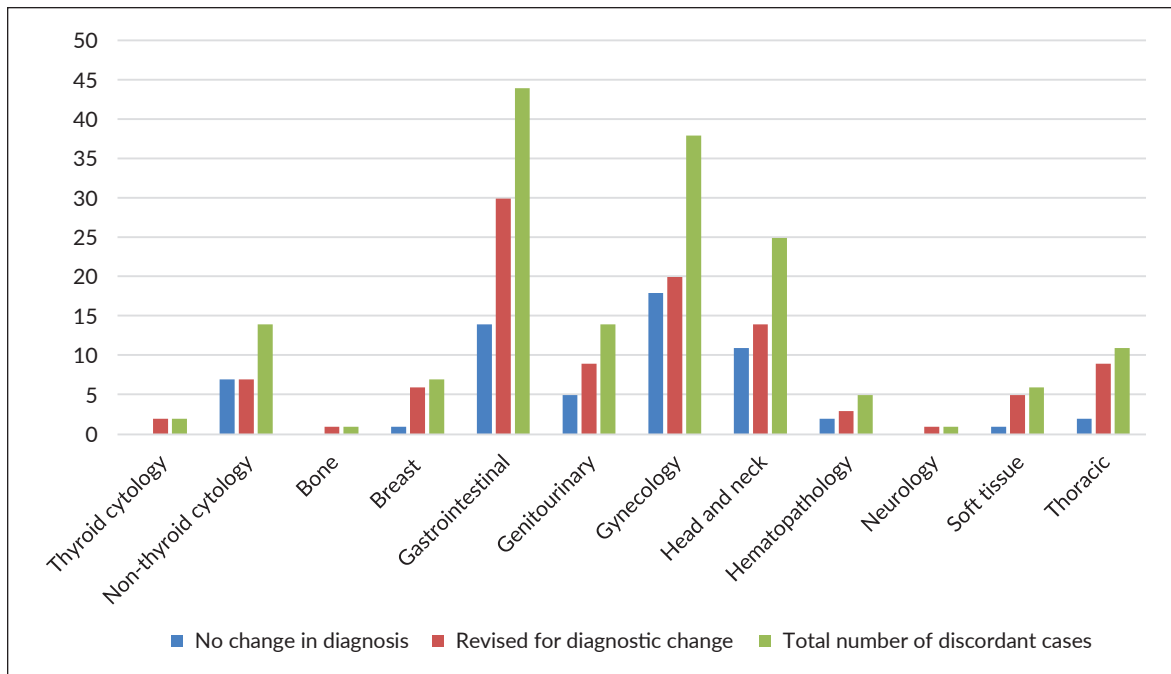


Figure 3. Number of cases with no change in diagnosis, number of cases revised for diagnostic change, and total number of discordant cases according to tissue or organ system category.

Most of the discordant cases (green bars) fall under the category of gastrointestinal (44 out of 168 discordant cases), followed by gynecology (38 out of 168 discordant cases), and head & neck pathology (25 out of 168 discordant cases).

Out of the 168 discordant cases, only 107 cases eventually had change in diagnosis and 61 had the diagnosis retained by the primary pathologist. The number of cases revised for diagnostic change have almost the same trend (red bars) as the number of discordant cases (green bars), with the most number of cases under the category of gastrointestinal (30 out of 107 cases; 28.0%); followed by gynecology (20 out of 107 cases; 18.7%); and head & neck pathology (14 out of 107 cases; 13.1%).

Majority of the revised discordant cases under the gastrointestinal category were changed from a benign entity to another benign entity (e.g., from one type of polyp to another, addition or removal of dysplasia/atypia in the diagnosis, addition or removal of acute/active component of inflammation in the diagnosis). These data show that there might be a need to standardize interpretation of gastrointestinal polyps (e.g., features to look for in the different polyps) and to standardize thresholds for dysplasia/atypia and for the presence of acute/active component of inflammation.

Majority of the revised discordant cases under the gynecologic category were changed from a malignant entity to another malignant entity, most of which are cervical biopsy cases revised for keratinization/differentiation of squamous cell carcinoma. This shows that there might be a need to standardize thresholds for the interpretation of

keratinization/differentiation of squamous cell carcinoma of the uterine cervix.

Majority of the revised discordant cases under the head & neck category were changed from a malignant entity to another malignant entity or revised for additional immunohistochemistry recommendations. Cases changed from a malignant entity to another malignant entity were total thyroidectomy specimens (e.g., from “hurthle cell carcinoma” to “papillary thyroid carcinoma, oncocytic and follicular variants”; from “papillary thyroid carcinoma, columnar variant” to “malignant neoplasm” with considerations of papillary thyroid carcinoma, columnar variant and follicular carcinoma). Cases revised for addition of immunohistochemistry recommendations include addition of CK, CD34, and HMB45 for a malignant scalp mass, addition of CK19 and HBME-1 for a thyroid lesion, and addition of CK, LCA, CD3, and CD20 for a nasopharyngeal biopsy specimen. These data show that there might be a need for pathologists to undergo lectures or training by a head & neck specialist in interpreting thyroid malignancies and in recommending IHC studies for head & neck lesions.

Figure 3 also reflects the proportion of cases revised for diagnostic change (red bars) to the total number of discordant cases (green bars).

There were no discordant cases under the categories of endocrine, eye, and skin. Therefore, these are not included in Figure 3. In this study, thyroid gland cases were included under the category of head & neck instead of under the category of endocrine pathology.

CONCLUSION AND RECOMMENDATIONS

Out of 5,377 cases included in this study, there were 5,209 concordant cases and 168 discordant cases, with the rate of discordance computed to be 3.1%.

Out of the 168 discordant cases in this study, 107 were revised for diagnostic change. Rate of diagnostic change was computed to be 2.0% (107 out of 5,377 cases for review). The low rate of diagnostic change might be attributed to a good diagnostic accuracy in our institution. However, it is also possible that reviewing pathologists tended to agree with the diagnosis made by their colleagues because of the element of peer pressure.

The most common criterion satisfied for meriting a mandatory review is being under the category of biopsies or cytology cases with malignant or borderline diagnoses. The most common category of diagnostic change is change in immunohistochemistry recommendations. Most of the discordant cases and cases revised for diagnostic change fall under the categories of gastrointestinal, gynecology, and head & neck pathology. These data may imply that special courses/lectures or institutional standard practice guidelines on interpreting biopsy and cytology cases as well as on utility of immunohistochemistry studies, especially those focused on gastrointestinal, gynecology, and head & neck pathology are needed by the pathologists and the doctors training to become pathologists in our institution.

Statement of Authorship

Both authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

Both authors declared no conflicts of interest.

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