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Original Research Article

An audit of reporting of prostatic biopsy at a teaching hospital, a journey in quality improvement

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Abstract

Background: The College of American Pathologists (CAP) guidelines provide the latest evidence-based practices to maintain quality and proficiency among the entire pathology team. Audits are a quality improvement process that measures current patient care and outcomes against established standards, involving repeated cycles of planning, implementation, assessment, and action. Our aim was to compare prostatic biopsy reporting against the CAP dataset protocol.
Materials and Methods: An audit of prostate core biopsy reporting was conducted, including an initial audit of 22 cases and a re-audit of 10 new cases, assessed against CAP guidelines.
Results: The number and length of cores, specimen location, and histologic type were documented in all 22 cases (100%). Histologic grade and overall grade were reported in 18 cases (81.81%). Tumour microfocus and intraductal carcinoma were not assessed in any of the 22 cases (0%). The percentage of patterns 4 and 5 was applicable in 12 cases but was not reported in any (0%). The cribriform gland pattern was assessed and reported in 7 cases (38.88%). Tumour quantification was mentioned in 20 cases (90.90%). The length of prostatic tissue involved by the tumour was reported in 8 cases (36.36%). Periprostatic fat invasion was noted in 1 case. Seminal vesicle invasion and ejaculatory duct invasion were absent in all cases. Lymphovascular invasion was reported in 5 cases (22.72%). Perineural invasion was documented in 17 cases (77.27%).
Re-audit Findings: Ten prostate core biopsy specimens were reviewed. Macroscopic details were provided in all cases (100%). Essential microscopic information was available in 9 cases (90%). In one case (10%), intraductal carcinoma components and the cribriform pattern were not assessed.
Conclusion: Audit and PDCA cycle significantly improve reporting according to CAP dataset.

Keywords: College of American pathologists, Quality, Plan-do-check-act (PDCA) Cycle.

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1. Introduction

The pathology report is a critical component of the diagnostic process. The primary doctor uses this report, along with other relevant test results, to make a final diagnosis and develop a treatment strategy. Laboratories across the country and around the world rely on the College of American Pathologists (CAP) to stay current with the latest evidence-based practices and to maintain quality and proficiency within the entire pathology team.

This clinical audit was conducted to assess the histopathology reporting of prostatic biopsies and its adherence to standard reporting practices according to CAP, as part of a quality improvement initiative for better patient care. Audits are a quality improvement process that measures current patient care and outcomes against established best-practice standards and involves repeated cycles of planning, implementation, assessment, and action.

Our aim was to compare our prostatic biopsy reporting against the College of American Pathologists (CAP) protocol.[1]

2. Materials and Methods

2.1. Study design

A retrospective cases (audit cases) as well as prospective (reaudit cases) descriptive study.

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2.2. Study area

Histopathology Laboratory, Shree Krishna Hospital, Karamsad, Gujarat.

2.3. Study population

A total of 22 cases of prostatic biopsy reported as adenocarcinoma were audited.

This study includes an audit (conducted from January 2019 to May 2022) and a re-audit (conducted in January 2023) of prostate core biopsy reporting at the Histopathology Laboratory, Shree Krishna Hospital, Karamsad, Gujarat.

A list of all prostate biopsy specimens was obtained from the Laboratory Information System (LIS) for the period from January 2019 to May 2022 **(Table 1)**. All consecutive reports were reviewed, and only old slides of prostatic core biopsies that were histologically confirmed as prostate adenocarcinoma were included in the study.

A total of 22 prostate core biopsy specimens were identified. Prostate biopsies in our histopathology department were reported by three pathologists based on consensus. The histopathology reports were compared with the parameters outlined in the College of American Pathologists (CAP) dataset for prostatic biopsy reporting. The updated CAP protocol for prostate biopsy reporting was published in November 2021.

A re-audit was conducted in January 2023 for 10 new cases of prostate core biopsies, which were histologically confirmed as prostate cancer. These cases were obtained from the LIS for the period from July 2022 to December 2022.

Data was collected, verified, and entered into a Microsoft Excel worksheet. The worksheet was then imported into SPSS version 2.0 for statistical analysis. Results were presented as frequencies and percentages in tables.

3. Results

This audit of prostatic biopsy was done between January 2019 and May 2022. A total 22 cases were analysed. **Table 1** illustrates the distribution of the cases per year.

Table 1: Distribution of cases studied per year

Year	Cases	Percentage (%)
2019	10	45.4%
2020	03	13.6%
2021	06	27.3%
2022 (January to May)	03	13.6%
Total	**22**	**100%**

Data for patient name, age, hospital number, date of specimen receiving, clinical history, type of procedure were provided in all cases.

The comparison of parameters of audit and re-audit with the CAP guideline dataset yielded the results shown in **Table 2**.

Table 2: Comparison of audit and re-audit parameters with the CAP guideline dataset

Pre audit CAP parameters	CAP requirement	Parameters reported in Audit	Parameters reported in Reaudit
Macroscopic Data			
Number and length of cores	Core data	22 (100%)	10 (100%)
Microscopic Data			
1. Positive Specimen Location	Core data	22 (100%)	10 (100%)
2. Histologic Type	Core data	22 (100%)	10 100%)
3. Histologic Grade	Core data	18 (81.8%)	10 (100%)
4. Overall Grade	Core data	18 (81.8%)	10 (100%)
5. Tumour Microfocus	Core data	00 (00%)	10 (100%)
6. Percentage of Pattern 4 (applicable for Gleason Score 8 and above)	Non-core data	Not reported in all 12 cases (00%)	10 (100%)
7. Percentage of Pattern 5 (applicable for Gleason Score 8 and above)	Non-core data	Not reported in all 12 cases (00%)	10 (100%)
8. Intraductal carcinoma grade	Core data	00 (00%)	09 90%)
9. Cribriform gland (applicable to Gleason Score 7 or 8 cancer only	Core data	07 (38.9)	09 (90%)
10. Tumour quantification	Core data	20 (90.90%)	10 (100%)
a. Total Number of Cores			
b. Number of Positive Cores	Core data	20 (90.90%)	10 (100%)
c. Percentage of Prostatic Tissue Involved by Tumour	Core data	20 (90.90%)	10 (100%)
d. Length of Prostatic Tissue Involved by Tumour	Non-core data	08 (36.4%)	10 (100%)

Table 2 Continued…			
11. Periprostatic Fat Invasion	Core data Report if identified in specimen	01 (4.5%)	10 (100%)
12. Seminal Vesicle Invasion / Ejaculatory Duct Invasion	Core data Report if identified in specimen	00	10 (100%)
13. Lymphovascular Invasion	Non-core data	05 (22.7%)	10 (100%)
14. Perineural Invasion	Non-core data	17 (77.3%)	10 (100%)
15. Atypical intraductal proliferation (AIP)	Non-core data	00	10 (100%)
16. High-grade prostatic intraepithelial neoplasia (PIN) Atypical small acinar proliferation / small focus of atypical glands (ASAP / ATYP):	Non-core data	01 (4.5%)	10 (100%)
17. Inflammation (specify type):	Non-core data	04 (18.2%)	10 (100%)
Table: 2 CAP parameters			

Table 3: Microscopic core data elements reporting in audit

	Total Number of Cores	**Number of Positive Cores**	**Percentage of Prostatic Tissue Involved by Tumour**	**Length of Prostatic Tissue Involved by Tumour**
Provided	20 (90.90%)	20 (90.90%)	20 ((90.90%)	08 (36.36%)
Not provided	02 (09.90%)	02 (09.90%)	02 (09.90%)	14 (63.63%)
Total	**22**	**22**	**22**	**22**

In all cases (100%) both the macroscopic core data features (number of cores and length of cores) were given.

This protocol applies to invasive adenocarcinomas and other carcinomas of the prostate gland. Carcinomas other than adenocarcinoma are exceptionally rare, accounting for less than 1% of prostatic tumours. Tumours such as neuroendocrine and squamous cell carcinomas may occur in pure form or as a component mixed with adenocarcinoma. This protocol does not apply to urothelial carcinoma.

Some adenocarcinoma subtypes and unusual patterns have percentage cut-offs for diagnosis. Since examination of the entire tumour is not feasible in a biopsy, a descriptive approach should also be considered (e.g., adenocarcinoma with mucinous features, adenocarcinoma with signet ring-like cell features).

Microscopic core data features (**Table 3**) including the total number of cores, number of positive cores, and the percentage of prostatic tissue involved by the tumour, were mentioned in 20 cases (90.90%). Non-core data, such as the length of prostatic tissue involved by the tumour, were reported in 8 cases (36.36%). According to the College of American Pathologists (CAP) dataset, these four core microscopic data elements should be provided in all cases. For needle core biopsy specimens, the number of positive cores out of the total number of cores should always be reported, except in cases where fragmentation precludes accurate counting. Additionally, the estimated percentage of prostatic tissue involved by the tumour and/or the linear millimeters of the tumour should be documented.[7]

Tumour microfocus and intraductal carcinoma were not assessed or mentioned in any of the 22 cases (0%). A tumour microfocus refers to the presence of a limited number of carcinoma cells within a few glands from a specimen site that is too small to confidently assign a grade. To avoid providing a potentially inaccurate grade that could influence patient management, it is recommended not to assign a grade to such a small focus. The presence of intraductal carcinoma (IDC) is important to record in biopsy specimens, as it has independent prognostic significance.[2-5] IDC is uncommon in needle biopsies and, when present, is usually found within invasive tumours. It is strongly associated with a high Gleason score, high tumour volume in radical prostatectomies, and metastatic disease. Both the International Society of Urological Pathology (ISUP) and the Genitourinary Pathology Society (GUPS) recommend that Gleason scores or grade groups should not be assigned to pure IDC.[6-8] However, there is ongoing controversy regarding the grading of invasive cancer with concomitant IDC. ISUP recommends incorporating IDC in determining the grade, whereas GUPS advises against including IDC in the grading process.[7] It is recommended to specify which of these two grading approaches is applied when grading invasive cancer with concomitant IDC.

Table 4: Findings on lymphovascular embolism, perineural invasion and extra prostatic extension reporting in audit

	Lymphovascular embolism		Perineural invasion		Extra prostatic Extension	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Provided	05	22.72%	17	77.27%	01	04.54%
Not provided	17	77.27%	05	22.72%	21	95.45%
Total	22	100	22	100	22	100

Table 4 shows that lymphovascular invasion status was not recorded in 77.27% of cases.

Extra-prostatic extension (EPE) or the presence of a tumour in fat is difficult to assess in core biopsy specimens, as it depends on whether the core biopsy contains any fatty tissue. Additionally, small groups of adipose cells are rarely seen within the prostate. Despite these limitations, according to the College of American Pathologists (CAP) dataset, extra-prostatic extension should be commented on if a tumour is found in fat. This observation is significant because it indicates that the tumour is at least pT3a in the TNM staging system. EPE detected on biopsy correlates well with EPE found in radical prostatectomy specimens and is usually associated with high-grade and high-stage disease.[9,10] In this audit, extra-prostatic extension was not commented on in any of the 22 cases (0%).

For staging purposes, seminal vesicle involvement is defined as the presence of a tumour in the muscular wall of the extraprostatic portion of the seminal vesicle.[11,12] In a biopsy directed at the extraprostatic seminal vesicle, carcinoma involvement indicates at least pT3b disease. Seminal vesicle involvement should be mentioned if the seminal vesicle is included in the biopsy.

Perineural invasion (PNI) was not reported in 5 cases (22.72%). PNI in needle core biopsies has been associated with extra-prostatic extension (EPE) in some correlative radical prostatectomy studies. However, its significance as a predictor of tumour stage and clinical outcome remains uncertain in multivariate analysis. A recent study on targeted biopsies found PNI to be an independent predictor of EPE.[13] Studies on active surveillance (AS) cohorts have shown conflicting results regarding the ability of PNI to predict adverse pathological findings and clinical outcomes.[14,15]

Atypical intraductal proliferation (AIP) is characterized by loose cribriform intraductal growth of neoplastic cells that lack significant nuclear atypia or the intraluminal necrosis required for the diagnosis of intraductal carcinoma (IDC). The presence of AIP in a needle core biopsy may indicate an unsampled intraductal carcinoma and has been shown to be associated with adverse pathological features in radical prostatectomy.[16]

The term prostatic intraepithelial neoplasia (PIN), unless otherwise specified, refers to high-grade PIN. Low-grade PIN is not reported. The presence of isolated PIN (PIN without carcinoma) should be documented in biopsy specimens, especially if more than one site is involved. The reporting of PIN in biopsies that also contain carcinoma is considered optional.

High-grade PIN in a biopsy without evidence of carcinoma was previously considered a risk factor for carcinoma detection in subsequent biopsies. However, recent studies suggest that this risk has diminished, and in some cases, high-grade PIN is no longer regarded as a significant predictor of carcinoma.[17,18] Some studies indicate that the presence of high-grade PIN in two or more sites may increase the likelihood of detecting carcinoma in subsequent biopsies.[19,20]

3.1. Missing information in reporting noted in the audit

1. Total number of cores, number of positive cores, percentage of prostatic tissue Involved by Tumour – Core data
2. Length of prostatic tissue involved by tumour – Non-core data
3. Tumour microfocus and intraductal carcinoma – Core data
4. Cribriform pattern – Core data
5. Percentage of pattern 4 & 5 – Non-core data
6. Lymphovascular invasion status – Non-core data
7. Perineural invasion – Non-core data
8. Extra-prostatic extension reporting – Non-core data
9. High-grade prostatic intraepithelial neoplasia (PIN) – Non-core data

3.2. Reason for missing information in reports

In our department, three groups of pathologist's report biopsies on a rotational basis. We use simplified templates that do not include all elements from the College of American Pathologists (CAP) dataset. Among our nine consultants, only a few are aware of and follow some CAP parameters for reporting. The majority of consultants are unfamiliar with the CAP checklist and instead use free-text narrative reports rather than the structured CAP checklist.

Thus, the main reasons for missing information include:

1. Lack of awareness and training
2. Time-consuming report format
3. Non-availability of a standardized CAP checklist

To ensure uniformity in reporting, inclusion of essential data elements, and optimal patient care, we have decided to implement the PDCA (Plan-Do-Check-Act) cycle (**Figure 1**) for continuous quality improvement.

The first step in the PDCA cycle is "Plan." This includes:

1. Defining problems and collecting all relevant data.
2. Identifying issues and conducting a root cause analysis using the Ishikawa diagram.
3. Recognizing key barriers, such as lack of training, time-consuming report formats, and the absence of a checklist, to develop an effective action plan.

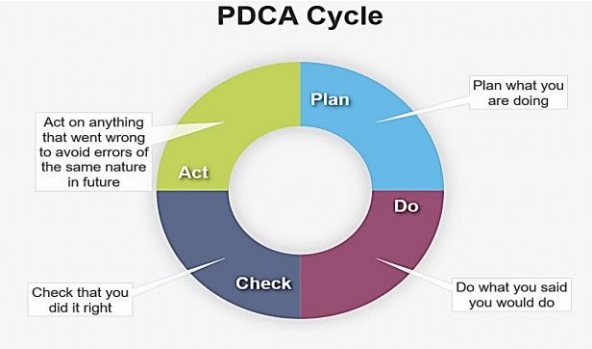

Figure 1: PDCA cycle

3.3. Action plan

This audit was presented at a departmental meeting of the pathology department at PSMC. A discussion on the CAP guidelines for reporting prostatic cancer biopsies was conducted with the concerned pathologists in June 2022.

A checklist for synoptic reporting of prostatic biopsies was prepared for our department according to CAP guidelines. This was developed by me in consultation with other consultants and was discussed among all reporting pathologists for implementation. Synoptic reporting ensures standardization, improved clinical communication, enhanced data collection, and reduced errors. The Histopathology Department officially implemented synoptic reporting for prostate core biopsies in July 2022. This system is designed to incorporate all CAP dataset parameters, with the expectation that all core parameters would be recorded according to CAP standards.

3.3.1. Re-audit (January 2023)

A LIS-generated list of all prostate biopsy specimens was obtained for the period from July 1, 2022, to December 31, 2022. A total of 10 new prostate core biopsy specimens were identified.

1. Macroscopic details were provided in all 10 cases (100%).
2. All essential microscopic information was recorded in 9 cases (90%).
3. In one case (10%), intraductal carcinoma components and the cribriform pattern were not assessed or mentioned.

Challenges in synoptic reporting:

1. Synoptic reports require more time and pose interpretation challenges, particularly for intraductal carcinoma components and the cribriform pattern.
2. Pathologists tend to focus on major elements, sometimes leading to the omission of certain parameters.
3. One-time CAP training may not be sufficient.

To ensure continuous improvement, we require regular audits and consistent feedback for reporting pathologists.

4. Discussion

In this study, we audited prostatic biopsy reports against the CAP protocol. A total of 22 request forms with their histopathology reports were selected, and corresponding slides were obtained for analysis. Clinical and demographic information, as well as macroscopic features, was adequately recorded in all cases.

There was a complete assessment of histologic type in all 22 cases (100%), with all diagnoses being prostate adenocarcinoma, not otherwise specified (NOS). This finding is consistent with a study by Idowu et al., in which there was 100% inclusion of histologic type in prostate cancer specimens.[21] Histologic type plays a crucial role in determining tumour grade and in patient prognostication. Other histologic types, apart from acinar adenocarcinoma, are associated with a poor prognosis, the severity of which depends on the specific subtype.

The Gleason grade is essential for guiding treatment decisions and risk stratification. In 18 cases (81.08%), grading was complete, with the primary, secondary, and final Gleason scores reported. However, two cases (9.1%) had incomplete grading, where only the final score was provided without specifying the primary and secondary patterns. This contrasts with the study by Siddiqui et al., where the Gleason grade was reported in 100% of cases.[22]

4.1. Inconsistencies in reporting prognostic and predictive factors

Certain prognostic and predictive factors for prostate cancer were inconsistently reported, including:

1. Tumour quantity
2. Lymphovascular invasion
3. Perineural invasion
4. Extraprostatic extension

In the study by Idowu et al., the missing elements included extent of invasion, tumour volume, and lymphovascular invasion.[20] Similarly, a study by Aumann et al. found that extraprostatic extension, seminal vesicle invasion, perineural invasion, and lymphovascular invasion were inconsistently reported in descriptive reports.[23]

Tumour quantitation, an important prognostic indicator linked to pathologic and clinical outcomes, was recorded in 90.90% of cases, while it was not assessable in two cases. The following elements were frequently omitted:

1. Lymphovascular invasion status (not recorded in 70.7% of cases)
2. Perineural invasion (missing in 62.9% of cases)
3. Extraprostatic extension (missing in 89.8% of cases)

In contrast, Siddiqui et al. reported 100% completeness for these elements, which was attributed to the use of a standardized reporting protocol.

4.2. Impact of synoptic reporting on reporting accuracy

Macroscopic features were sufficiently reported in all cases. However, incomplete reporting of various microscopic tumour features was observed, mainly due to the limitations of descriptive reporting. The use of a standardized reporting protocol ensures the comprehensive capture of all essential diagnostic, management, and prognostic parameters in prostate cancer.

5. Conclusion

A significant improvement in reporting patterns was observed in the re-audit of prostatic biopsies, largely due to the introduction of the synoptic reporting system and training for consultants involved in reporting prostatic core biopsies. This improvement followed the implementation of the PDCA cycle, ensuring continuous quality enhancement in pathology reporting.

6. Ethical Approval

This study approved by Ethical committee of the institute with ref. no. IEC/BU/2023/Ex.32/162/2023.

7. Source of Funding

None.

8. Conflict of Interest

None.

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