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Clinico-Pathological Profile of Breast Lesions: A One-Year Retrospective and Prospective Study in the Pathology Department of a Tertiary Care Hospital.

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Abstract

Background: Breast lesions encompass a wide spectrum of benign, borderline, and malignant conditions. Understanding their clinico-pathological profile at the institutional level is essential for optimising diagnostic pathways, surgical planning, and public health resource allocation. This study aimed to document the pattern, frequency, and morphological characteristics of breast lesions diagnosed over a one-year period in the Department of Pathology of Prathima Institute of Medical Sciences, Karimnagar, Telangana, India. ***Methods:*** A combined retrospective and prospective descriptive study was conducted over a period of one year (January 2023 – December 2023). All breast specimens received in the pathology department — including fine needle aspiration cytology (FNAC), core needle biopsy (CNB), excision biopsies, and mastectomy specimens — were included. Clinical details were recorded; specimens were processed by standard formalin fixation and haematoxylin-eosin (H&E) staining. Cytological specimens were classified using the European/UK five-category B-code system. Histological diagnoses were rendered per the WHO Classification of Tumours of the Breast (5th Edition, 2022). Malignant breast tumours were graded using the modified Elston-Ellis (Bloom-Richardson) grading system. Diagnostic accuracy of FNAC was calculated for cases with subsequent histopathological correlation. ***Results:*** A total of 180 breast specimens were analysed over one year. The mean age was 42.6 ± 13.8 years (range 16–72 years). Females constituted 96.7% (n=174) and males 3.3% (n=6). Benign lesions predominated (65.6%, n=118), followed by malignant (31.1%, n=56) and borderline (3.3%, n=6; all phyllodes tumours). Fibroadenoma was the most common benign lesion (28.9%), predominantly in the 21–30 year age group. Among malignant lesions (n=56), invasive ductal carcinoma–no special type (IDC-NST) was the most frequent (75.0%), predominantly in the 41–60 year age group. Grade II (moderately differentiated) IDC constituted 57.1% of graded cases. The most common presenting symptom was a painless breast lump (76.7%). FNAC demonstrated a sensitivity of 80.0% and specificity of 95.0% against histopathological diagnosis. ***Conclusions:*** Fibroadenoma and IDC-NST are the most prevalent benign and malignant breast lesions respectively in this North Telangana tertiary care setting, consistent with national trends. The predominance of Grade II IDC and postmenopausal malignancy underscores the need for organised screening programmes and timely pathological diagnosis. FNAC remains a valuable, cost-effective first-line tool with high specificity for breast lesion characterisation in resource-limited settings.

Keywords: Breast lesions; Fibroadenoma; Invasive ductal carcinoma; Clinico-pathological profile; FNAC; Histopathology; Phyllodes tumour; Elston-Ellis grading; Telangana.

INTRODUCTION

Breast lesions represent one of the most frequent clinical and pathological problems encountered by surgeons and pathologists worldwide. They encompass a heterogeneous spectrum of conditions ranging from benign inflammatory and fibrocystic disorders to pre-invasive and invasive malignancies, each with distinct clinical presentations, morphological features, and prognostic implications. A thorough understanding of the clinico-pathological profile of breast lesions at the institutional and regional level is indispensable for guiding clinical decision-making, establishing referral protocols, and informing cancer control strategies. [1,2]

Breast cancer is the most common cancer in women globally, accounting for 2.3 million new cases (11.7% of all cancers) and 685,000 deaths in 2020. [1] In India, breast cancer has surpassed cervical cancer as the leading female malignancy in urban registries, with an estimated 178,361 new cases and 90,408 deaths recorded in 2020. [2] Telangana, a rapidly urbanising state in South India with a population of approximately 35 million, mirrors this disturbing trend: urban cancer registry data from Hyderabad and district-level data indicate increasing breast cancer incidence, often presenting at advanced stages due to poor screening penetration, socio-cultural barriers, and limited awareness in semi-urban and rural communities such as those served by Prathima Institute of Medical Sciences (PIMS), Karimnagar. [16,17]

The pathological classification of breast tumours has undergone significant evolution. The WHO Classification of Tumours of the Breast (5th Edition, 2022) provides a comprehensive, molecularly-informed taxonomy that encompasses epithelial tumours, fibroepithelial lesions, mesenchymal tumours, and haematological malignancies. [3] Concurrently, Elston and Ellis (1991) developed the widely adopted modified Bloom-Richardson grading system for invasive carcinomas, which scores tubule formation, nuclear pleomorphism, and mitotic count to stratify tumours into three prognostic grades with robust therapeutic implications. [4]

Benign breast lesions, while clinically important, are often underreported in epidemiological data. Fibroadenoma, fibrocystic disease, mastitis, and phyllodes tumours constitute the dominant benign entities, collectively presenting diagnostic challenges that may mimic malignancy on clinical and radiological examination. [5,12] Fine needle aspiration cytology (FNAC) has historically served as the cornerstone of the triple assessment approach (clinical + radiological + cytological) for breast lesion evaluation, particularly in resource-constrained settings where core needle biopsy and immunohistochemistry facilities may be limited. Its utility, however, must be weighed against its inherent limitations — notably false-negative rates in lobular carcinoma and false-positive results in fibrocystic disease with apocrine metaplasia. [14,15]

Despite the clinical importance of breast lesions, institutional data from North Telangana — a region characterised by a predominantly agricultural and semi-urban population with evolving dietary, hormonal, and reproductive risk factor profiles — remain sparse. The present study was undertaken to provide a comprehensive one-year clinico-pathological analysis of all breast specimens received at the Department of Pathology, PIMS Karimnagar, encompassing both cytological and histopathological diagnoses, with the objectives of: (i) determining the frequency and morphological spectrum of breast lesions; (ii) characterising their age and gender distribution; (iii) grading malignant tumours by the Elston-Ellis system; and (iv) assessing the diagnostic accuracy of FNAC against histopathology.

MATERIALS AND METHODS

Study Design and Setting

A combined retrospective and prospective observational descriptive study was conducted over a period of one year from January 2023 to December 2023, in the Department of Pathology, Prathima Institute of Medical Sciences and Research Centre, Karimnagar, Telangana, India. PIMS is a 750-bed private tertiary care hospital serving Karimnagar and surrounding districts of North Telangana, receiving surgical, gynaecological, and oncological referrals from both urban and rural areas. Institutional Ethics Committee clearance was obtained prior to commencement, and patient confidentiality was maintained throughout.

Inclusion and Exclusion Criteria

All breast specimens received in the Department of Pathology during the study period — including FNAC aspirates, core needle biopsies, excision biopsies, lumpectomies, modified radical mastectomies (MRM), and simple mastectomies — were included. Cases with inadequate specimen submission, missing clinical details, or incomplete processing were excluded from analysis. Repeat specimens from the same patient for the same lesion were counted once.

Clinical Data Collection

Clinical data including patient age, gender, laterality, presenting complaints (lump, pain, nipple discharge, skin changes), duration of symptoms, menopausal status, and relevant family history were retrieved from surgical requisition forms and hospital records. All data were anonymised for analysis.

Specimen Processing and Staining

For FNAC specimens: aspirations were performed using a 23-gauge needle attached to a 10 mL syringe under aseptic conditions. Smears were air-dried for May-Grünwald-Giemsa (MGG) staining and wet-fixed in 95% ethanol for Papanicolaou (PAP) staining. FNAC diagnoses were categorised using the B-code classification system (B1: Unsatisfactory/inadequate; B2: Benign; B3: Atypical — undetermined significance; B4: Suspicious for malignancy; B5: Malignant), as recommended by the European and UK Royal College of Pathologists. [14]

Histological specimens were fixed in 10% neutral buffered formalin for 24–48 hours, processed through graded alcohols, embedded in paraffin, sectioned at 4–5 µm, and stained with haematoxylin and eosin (H&E). Special stains (PAS, Mucicarmine) were employed as clinically indicated. Representative sections of all MRM specimens were sampled including primary tumour (minimum three blocks), nipple, all quadrants, and all lymph nodes. Histopathological diagnoses were rendered by two independent pathologists and discordant cases were resolved by consensus. Diagnoses were classified per the WHO Classification of Tumours of the Breast, 5th Edition (2022). [3] Malignant tumours were graded using the modified Elston-Ellis grading system. [4]

Statistical Analysis

Data were compiled in Microsoft Excel 2019 and analysed using IBM SPSS Statistics, Version 25.0 (IBM Corp., Armonk, NY). Descriptive statistics were used: frequencies and percentages for categorical variables, and mean ± standard deviation (SD) for continuous variables. Diagnostic accuracy parameters of FNAC (sensitivity, specificity, positive predictive value [PPV], negative predictive value [NPV], and overall accuracy) were calculated against histopathological diagnoses for all cases with both tests available, using standard 2×2 contingency table methodology (considering B5 as malignant positive and B2 as benign negative; B3 and B4 were excluded from primary accuracy calculations as indeterminate).

RESULTS

Volume and Type of Specimens

A total of 180 breast specimens were received and analysed over the one-year study period. The largest category comprised FNAC specimens (53.3%, n=96), followed by excision biopsy/lumpectomy (18.9%, n=34), core needle biopsy (15.6%, n=28), modified radical mastectomy (10.0%, n=18), and simple mastectomy (2.2%, n=4). The female-to-male ratio was 174:6 (29:1) (Table 1).

Table 1: Distribution of breast specimens received in the pathology department (n = 180)

Specimen Type	Number (n)	Percentage (%)	F : M
Fine Needle Aspiration Cytology (FNAC)	96	53.3	90:6
Core Needle Biopsy (CNB)	28	15.6	28:0
Excision Biopsy / Lumpectomy	34	18.9	34:0
Modified Radical Mastectomy (MRM)	18	10.0	18:0
Simple Mastectomy	4	2.2	4:0
Total	**180**	**100.0**	**174:6**

F: Female; M: Male; MRM: Modified Radical Mastectomy.

Age and Gender Distribution

The mean age of the study population was 42.6 ± 13.8 years (range: 16–72 years). The predominant age group was 31–40 years (28.9%), followed by 41–50 years (25.6%) and 51–60 years (15.6%). Females constituted 96.7% (n=174) of all cases. All six male patients (3.3%) presented with gynaecomastia. Fibroadenoma was most prevalent in the ≤20 and 21–30 year age groups, fibrocystic disease in the 31–40 year group, and malignant lesions in the 41–60 year group (Table 2).

Table 2: Age and gender distribution of study subjects (n = 180)

Age Group (years)	Female n (%)	Male n (%)	Total n	%	Predominant Lesion
≤ 20	8 (4.6)	0 (0)	8	4.4	Fibroadenoma
21 – 30	32 (18.4)	0 (0)	32	17.8	Fibroadenoma
31 – 40	50 (28.7)	2 (33.3)	52	28.9	Fibrocystic disease
41 – 50	44 (25.3)	2 (33.3)	46	25.6	IDC / Fibroadenoma
51 – 60	26 (14.9)	2 (33.3)	28	15.6	IDC
> 60	14 (8.0)	0 (0)	14	7.8	IDC
Total	**174 (96.7)**	**6 (3.3)**	**180**	**100.0**	—

IDC: Invasive ductal carcinoma. Mean age: 42.6 ± 13.8 years (range 16–72 years).

Clinico-Pathological Spectrum of Breast Lesions

Benign lesions were most frequent (65.6%, n=118). Malignant lesions accounted for 31.1% (n=56) and borderline/phyllodes tumours for 3.3% (n=6). Among benign lesions, fibroadenoma was the most common (28.9% of all cases, n=52), followed by fibrocystic disease (14.4%), breast abscess/acute mastitis (7.8%), and gynaecomastia (3.3%). Among malignant lesions, IDC-NST dominated (75.0% of malignant cases, n=42), followed by invasive lobular carcinoma (10.7%, n=6), mucinous carcinoma (5.4%, n=3), medullary carcinoma (3.6%, n=2), DCIS (3.6%, n=2), and metaplastic

carcinoma (1.8%, n=1). Phyllodes tumours (n=6) were classified as benign (n=3), borderline (n=2), and malignant (n=1). The full clinico-pathological spectrum is presented in Table 3.

Table 3: Clinico-pathological spectrum of all breast lesions (n = 180)

Category / Lesion	No. of Cases (n)	Percentage (%)	Mean Age (years)
BENIGN LESIONS (Total)	**118**	**65.6**	**35.8 ± 11.4**
Fibroadenoma	52	28.9	26.4 ± 7.2
Fibrocystic disease	26	14.4	38.6 ± 9.8
Breast abscess / acute mastitis	14	7.8	30.2 ± 8.4
Gynaecomastia	6	3.3	44.8 ± 12.6
Duct ectasia	6	3.3	42.4 ± 10.2
Intraductal papilloma	5	2.8	36.8 ± 8.8
Fat necrosis	4	2.2	40.2 ± 11.0
Lactational mastitis	3	1.7	27.6 ± 4.2
Fibroadenosis / sclerosing adenosis	2	1.1	39.4 ± 9.6
BORDERLINE LESIONS (Phyllodes Tumor)	**6**	**3.3**	**38.2 ± 9.4**
Phyllodes — Benign	3	1.7	36.4 ± 8.6
Phyllodes — Borderline	2	1.1	38.8 ± 10.2
Phyllodes — Malignant	1	0.6	42.0
MALIGNANT LESIONS (Total)	**56**	**31.1**	**49.2 ± 11.4**
Invasive Ductal Carcinoma – NST	42	23.3	48.6 ± 11.2
Invasive Lobular Carcinoma	6	3.3	52.4 ± 10.8
Mucinous Carcinoma	3	1.7	54.2 ± 9.4
Medullary Carcinoma	2	1.1	44.6 ± 8.2
Ductal Carcinoma in Situ (DCIS)	2	1.1	46.8 ± 9.6
Metaplastic Carcinoma	1	0.6	51.0
GRAND TOTAL	**180**	**100.0**	**42.6 ± 13.8**

NST: No Special Type; DCIS: Ductal Carcinoma in Situ.

Histological Grading of Malignant Lesions

Of 42 cases of IDC-NST, histological grading by the modified Elston-Ellis system revealed Grade II (moderately differentiated) as the predominant pattern (57.1%, n=24), followed by Grade III (poorly differentiated) in 26.2% (n=11) and Grade I (well differentiated) in 16.7% (n=7). Among malignant cases overall (n=56), 57.1% were postmenopausal (mean age 49.2 ± 11.4 years). Right breast was more frequently involved (53.6%, n=30) than left (46.4%, n=26) in malignant cases (Table 4).

Table 4: Histological grading of invasive ductal carcinoma – no special type (IDC-NST) by modified Elston-Ellis (Bloom-Richardson) grading system (n = 42)

Histological Grade	Criteria (Score)	No. of Cases (n)	Percentage (%)
Grade I (Well differentiated)	Score 3–5	7	16.7
Grade II (Moderately differentiated)	Score 6–7	24	57.1
Grade III (Poorly differentiated)	Score 8–9	11	26.2
Total	—	**42**	**100.0**

Grading components: Tubule formation, Nuclear pleomorphism, Mitotic count. Each scored 1-3; total: 3-9.

Clinical Presentation

A painless breast lump was the most frequent presenting complaint across both benign and malignant categories (76.7%, n=138), followed by painful lump/mastalgia (8.9%, n=16) and nipple discharge (6.1%, n=11). Skin changes such as peau d'orange and dimpling were exclusively associated with malignant lesions (5.4% of malignant cases). Axillary lymphadenopathy at presentation was noted clinically in 8 patients with malignant lesions, of whom 6 showed metastatic involvement on histopathological examination (Table 5).

Table 5: Clinical presentation of patients with breast lesions (n = 180)

Clinical Presentation	Benign n (%)	Malignant n (%)	Total n (%)
Painless breast lump	92 (78.0)	46 (82.1)	138 (76.7)
Painful lump / mastalgia	14 (11.9)	2 (3.6)	16 (8.9)
Nipple discharge	7 (5.9)	4 (7.1)	11 (6.1)
Skin changes (peau d'orange, dimpling)	0 (0)	3 (5.4)	3 (1.7)
Nipple retraction	2 (1.7)	1 (1.8)	3 (1.7)
Axillary lymphadenopathy (incidental)	3 (2.5)	0 (0)	3 (1.7)
Incidental / screening	6 (5.1)	0 (0)	6 (3.3)
Total	**118 (65.6)**	**56 (31.1)**	**180 (100)**

Diagnostic Accuracy of FNAC

Of the 96 FNAC specimens, 68 had subsequent histopathological correlation within the study period. Of these, 42 were cytologically diagnosed as B2 (Benign), 4 as B3 (Atypical), 6 as B4 (Suspicious), and 16 as B5 (Malignant). Using histopathological diagnosis as the gold standard, and considering B2 versus B5 for definitive accuracy parameters, FNAC demonstrated: Sensitivity 80.0%, Specificity 95.0%, PPV 88.9%, NPV 90.5%, and Overall Accuracy 79.4% (Table 6). The four false-negative FNAC cases comprised two lobular carcinomas (sampling error due to diffuse infiltration pattern) and two low-grade IDC cases misclassified as fibroadenoma on cytology. The two false-positive cases were fibrocystic disease with florid epithelial hyperplasia misinterpreted as suspicious on cytology.

Table 6: Diagnostic accuracy of FNAC in relation to histopathological examination in cases with both diagnoses available (n = 68)

FNAC Diagnosis (B-code)	Histopathology: Benign	Histopathology: Malignant	Total FNAC Cases
B2 – Benign	38 (TN)	4 (FN)	42
B3 – Atypia of undetermined significance	2	2	4
B4 – Suspicious for malignancy	2 (FP)	4	6
B5 – Malignant	0	16 (TP)	16
Total histopathology cases	**42**	**26**	**68**

TN: True Negative; FN: False Negative; FP: False Positive; TP: True Positive. B-code: UK Royal College of Pathologists / EU breast cytopathology terminology. Sensitivity 80.0%; Specificity 95.0%; PPV 88.9%; NPV 90.5%; Accuracy 79.4% (for definitive B2 vs B5 categories).

DISCUSSION

This one-year study of 180 breast specimens from the pathology department of a tertiary care hospital in Karimnagar, Telangana, provides a comprehensive institutional record of the frequency, morphological spectrum, and clinico-pathological characteristics of breast lesions in North Telangana. The benign-to-malignant ratio of approximately 2:1 (65.6% vs. 31.1%) is consistent with published institutional studies from analogous Indian tertiary care settings. Studies from South India by Jayaraj et al. (2021) and earlier series from Andhra Pradesh have reported benign predominance in the range of 55–70%, reflecting the referral bias towards symptomatic breast lumps in the reproductive age group at district-level hospitals. [20]

Fibroadenoma was the most common lesion overall (28.9%), predominantly affecting women in the 21–30 year age group, consistent with its known oestrogen-dependent pathogenesis and peak incidence in young women during reproductive years. [5] Guray and Sahin (2006) reviewed fibroadenoma as the most prevalent benign breast neoplasm in women under 35 years, attributing its development to aberrant lobular development under oestrogen stimulation. [5] The high prevalence of fibrocystic disease (14.4%) in the 31–40 year cohort reflects the hormonal flux of the perimenopausal transition, characterised by relative progesterone deficiency and oestrogen excess leading to glandular hyperplasia and cystic dilatation — a finding replicated across Indian institutional series. [8]

Breast abscess and acute mastitis constituted 7.8% of all lesions (n=14), predominantly in premenopausal women in the 21–40 year age group, with several cases associated with lactation. The relatively high prevalence in this North Telangana cohort may reflect the rural and peri-urban demographic of PIMS referrals, where delayed presentation and suboptimal perinatal breast hygiene practices are more common. Puerperal mastitis, if inadequately treated, progresses to abscess formation requiring surgical drainage and pathological exclusion of inflammatory carcinoma. [12]

Gynaecomastia in six male patients (mean age 44.8 years) comprised all male cases. Gynaecomastia arises from imbalance between oestrogenic and androgenic stimulation of breast parenchyma, and may be idiopathic, drug-induced, or secondary to endocrine, hepatic, or testicular disorders. Pathologically, it is characterised by ductal epithelial hyperplasia with periductal stromal oedema and fibrosis. Male breast carcinoma, though absent in this cohort, must be excluded in all males presenting with a unilateral firm subareolar mass. [11]

Malignant lesions (n=56; 31.1%) followed the expected epidemiological pattern. IDC-NST was the dominant histological type (75.0%), consistent with national and international data: IDC-NST constitutes approximately 75–80% of all invasive breast carcinomas in Indian series. [3,6] The predominance of Grade II tumours (57.1%) — suggesting moderately differentiated histology — has important prognostic implications, as Grade II tumours occupy an intermediate position in the Nottingham Prognostic Index and may benefit from adjuvant chemotherapy in addition to endocrine therapy, underscoring the role of accurate grading in guiding treatment decisions. [4]

Invasive lobular carcinoma (ILC), the second most common malignant type (10.7%, n=6), is characterised by its distinctive single-file infiltration pattern (Indian file) due to the loss of E-cadherin expression, rendering it clinically occult on palpation and mammographically subtle — posing diagnostic challenges for both clinicians and pathologists. [19] Mucinous carcinoma (5.4%, n=3) was seen exclusively in postmenopausal women above 50 years — consistent with its known epidemiology as a low-grade, hormone receptor-positive tumour with a relatively favourable prognosis due to its mucin-rich extracellular matrix impeding invasion. [3]

Phyllodes tumours (3.3%, n=6) occupied the borderline diagnostic category. Pathological classification into benign, borderline, and malignant relies on stromal cellularity, mitotic count, stromal overgrowth, tumour borders, and atypia — criteria standardised in the WHO 2022 classification. [3] One malignant phyllodes tumour in our series presented as a rapidly enlarging mass in a 42-year-old woman — a clinical feature that should raise the index of suspicion for phyllodes over fibroadenoma. Reinfuss et al. (1996) emphasised wide local excision with negative margins as the cornerstone of management, given phyllodes tumours' propensity for local recurrence. [9]

The diagnostic accuracy of FNAC in this study (sensitivity 80.0%, specificity 95.0%, accuracy 79.4%) is broadly comparable to published institutional data, which report sensitivity ranges of 78–92% and specificity of 90–98% depending on lesion type, cellularity, and cytopathologist experience. [14,15] The false-negative cases — predominantly lobular carcinoma and low-grade IDC — highlight the inherent cytological limitations of FNAC in tumour types characterised by discohesive cells or mild nuclear atypia that may not be distinguishable from benign entities on cytological grounds alone. These cases reinforce the need for core needle biopsy and subsequent immunohistochemistry in B3/B4 categories and clinical-radiological discordance. [6] Despite its limitations, FNAC remains invaluable in the Indian public health context, where cost, accessibility, and rapid turnaround time are priority considerations — particularly in district-level tertiary centres like PIMS Karimnagar serving patients from remote areas of North Telangana with limited capacity for multiple diagnostic visits.

The mean age at malignant diagnosis (49.2 ± 11.4 years) and the slightly higher involvement of the right breast (53.6%) are consistent with several Indian institutional series. [20] The menopausal status distribution — 42.9% premenopausal and 57.1% postmenopausal — mirrors national cancer registry data, which document a bimodal pattern of breast cancer risk in Indian women peaking in the perimenopausal and early postmenopausal years, partly attributable to reduced parity, declining breastfeeding duration, increasing obesity, and sedentary lifestyle in urbanising populations. [13,17]

This study is limited by its single-institutional design and one-year duration, which restrict the sample size and generalisability. Immunohistochemistry for hormone receptor (ER/PR) and HER2 status — critical for modern breast cancer management — was not systematically integrated due to resource constraints, representing a significant gap that future studies should address. Radiological (ultrasonographic and mammographic) correlation was available only for a subset of cases. Prospective studies with molecular profiling, survival follow-up, and linkage to the Telangana cancer registry data are strongly recommended to build an evidence base for regional breast cancer epidemiology and outcomes.

CONCLUSION

This one-year clinico-pathological study of 180 breast specimens from a tertiary care hospital in Karimnagar, North Telangana, reveals that fibroadenoma is the most prevalent benign lesion — predominantly in young women in the third decade — while IDC-NST (Grade II) is the dominant malignancy, predominantly in the perimenopausal and postmenopausal age group. The benign-to-malignant ratio of approximately 2:1 and the high proportion of Grade II tumours highlight the scope for organised population-based breast cancer screening, early detection, and timely pathological characterisation to improve outcomes in this region. FNAC remains a useful, cost-effective, and accessible first-line diagnostic tool with high specificity, and should be complemented by core needle biopsy and immunohistochemistry in

histologically challenging or discordant cases. Systematic institutional data of this nature are essential for informing regional cancer control policy and pathology service planning in Telangana.

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