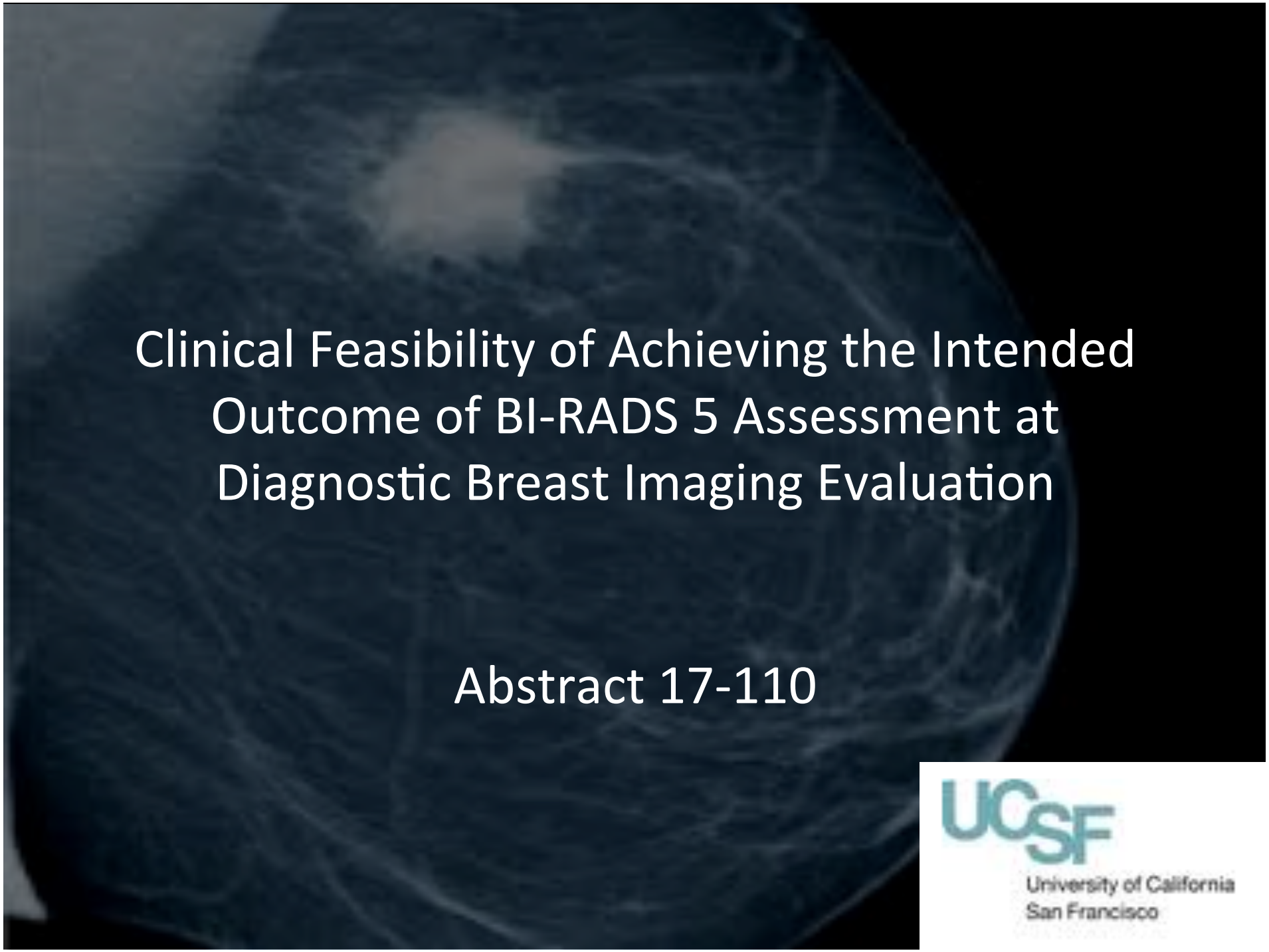

Clinical Feasibility of Achieving the Intended Outcome of BI-RADS 5 Assessment at Diagnostic Breast Imaging Evaluation

Abstract 17-110

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Authors and Disclosures

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Purpose: Understanding BI-RADS 5

- Highly suggestive of malignancy
  - PPV needs to be ≥ 95% per ACR BI-RADS Atlas
- However, no literature to support such a PPV in clinical practice
  - Literature suggests overuse of BI-RADS 5 to include lesions whose likelihood of malignancy is less than 95% [3,4]
- Study aims:
  - Assess PPV of BI-RADS 5 given at diagnostic mammography and/or ultrasound at our institution
  - Identify the specific imaging features needed to reach PPV ≥ 95%
    - Prior reports suggest that multiple suspicious features are needed to reach this threshold [3,6,7]

Materials and Methods

- Retrospective review of 22,564 patients who underwent diagnostic breast imaging evaluation, January 2010-September 2015.
  - 238 patients (1.1%) were given BI-RADS 5 assessment (237 women, 1 man)
  - Imaging descriptors extracted for each BI-RADS 5 patient:
    - Mass shape and margin
    - Calcifications and distribution
    - Asymmetry
    - Distortion
    - Secondary features: Skin thickening/retraction, nipple retraction, lymphadenopathy
  - All patients went on to percutaneous biopsy or surgical excisional biopsy (pathology gold standard)

Results: Demographics of BI-RADS 5 patients

Table 2. Distribution of Age and Breast Density in BI-RADS Category 5 Patients.

*Age (years)	Number of patients (%)
< 40	20 (8.4)
40 - 49	43 (18.1)
50 - 59	60 (25.2)
60 - 69	50 (21.0)
70+	65 (27.3)
Breast density	**Number of patients (%)**
A	36 (15.1)
B	100 (42.0)
C	79 (33.2)
D	12(5.1)

Total number of patients = 238. 10 patients did not have reported breast density because they did not undergo diagnostic mammogram.

Note: * mean age is 62.5 years; range: 29-96 years; one male patient: 83 years old.

Results: Exam Indications for BI-RADS 5 patients

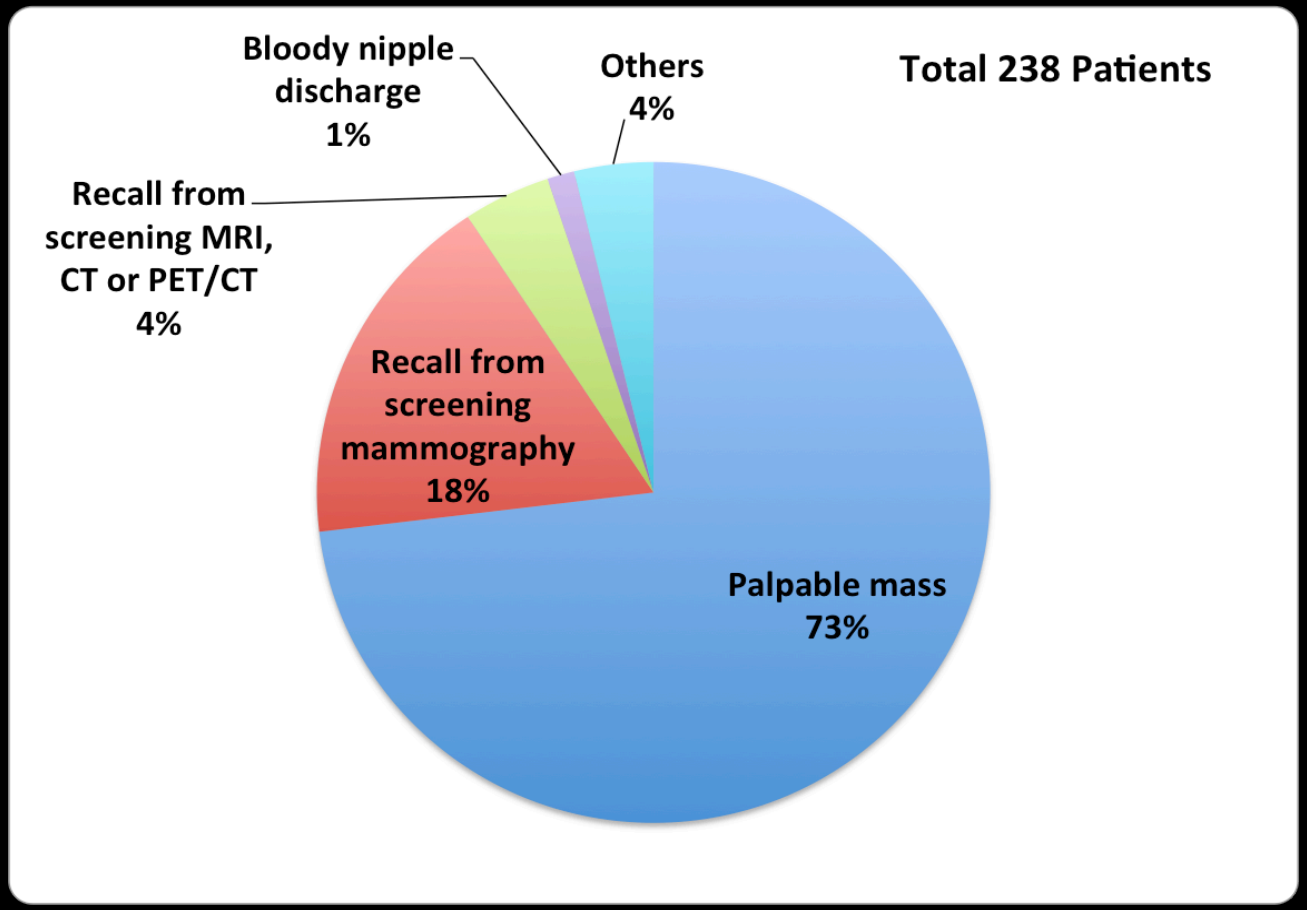

Figure 1: Distribution of exam indications for diagnostic breast imaging evaluation. Others include nipple retraction (0.8%), breast contour change (0.4%), palpable axillary lymph nodes (1.7%), bone metastasis with unknown primary (0.8%)

Results: Pathologic Diagnoses

Table 3. Pathologic Diagnoses of BI-RADS Category 5 Lesions.

Pathologic diagnosis	Number of lesions (%)
IDC only	51 (21.4)
ILC only	21 (8.8)
DCIS only	10 (4.2)
IDC + DCIS	104 (43.7)
ILC + DCIS	5 (2.1)
IDC + ILC	8 (3.4)
IDC + ILC + DCIS	10 (4.2)
Adenocarcinoma (FNA only)	18 (7.6)
[1]Benign	5 (2.5)
[2]Others	6 (2.1)

Notes: IDC = invasive ductal carcinoma ILC = invasive lobular carcinoma;

DCIS = ductal carcinoma in situ; FNA = fine needle aspiration.

1. Benign lesions include: fat necrosis and fibrocystic change (n=1), intra-ductal papilloma with calcifications (n=1), fibromatosis (n=1), and low-grade phyllodes (n=2).

2. Others include: papillary carcinoma (n=2), metastatic breast cancer (n=2), malignant lymphoma (n=1), metaplastic carcinoma and grade II tumor (n=1).

- 233/239 malignant (true positive) = 0.977 PPV (0.952-0.993 95% CI)

Results: Lesion Descriptors

Vast majority of patients (92%) underwent both diagnostic mammography and ultrasound

- Mass as a primary or secondary finding:
  - 170 patients (71.4%)
- Calcifications as a primary or secondary finding:
  - 115 patients (48.3%)
  - Most common morphology: fine pleomorphic (30.5%)
  - Most common distribution: regional (24.4%)
- Architectural distortion as a primary or secondary finding:
  - 46 patients (20.7%)
- Mammographic asymmetry/focal asymmetry/developing asymmetry as a primary or secondary finding:
  - 30 patients (13.5%)

Almost all patients exhibit 4 or more suspicious descriptors when undergoing both diagnostic MG/US

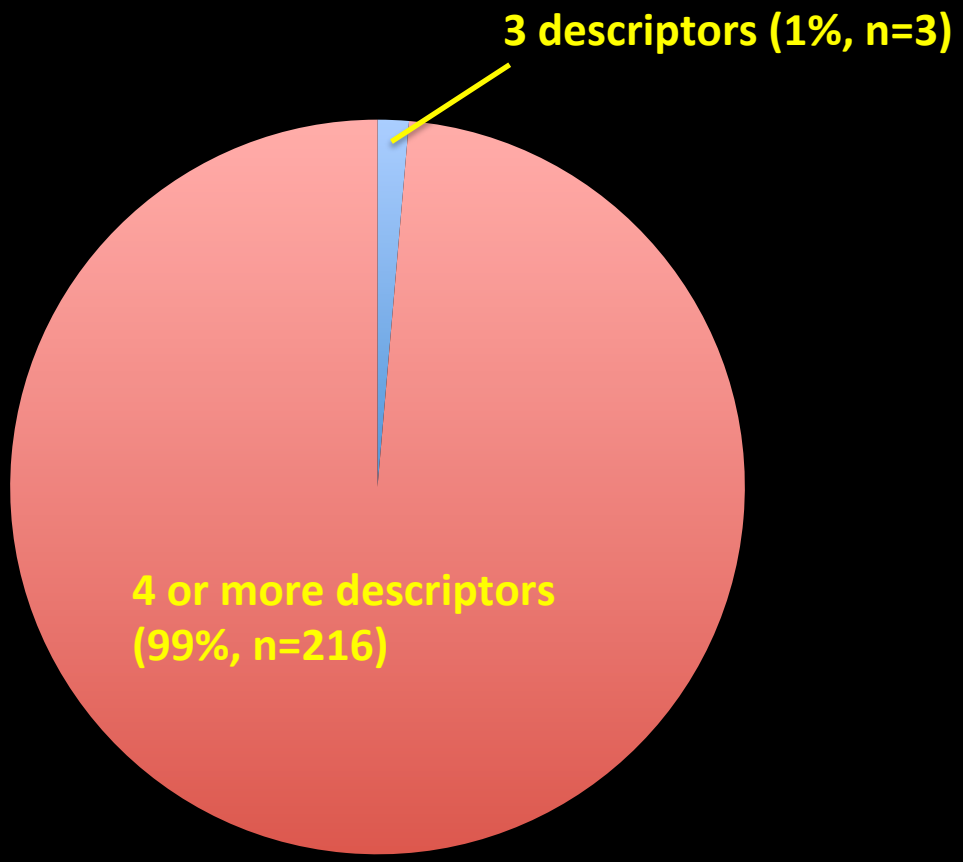

Figure 3: Number of suspicious descriptors for BI-RADS 5 patients who underwent both diagnostic mammography and ultrasound (n=219)

Most patients who only underwent diagnostic US still exhibit 3-4 suspicious descriptors

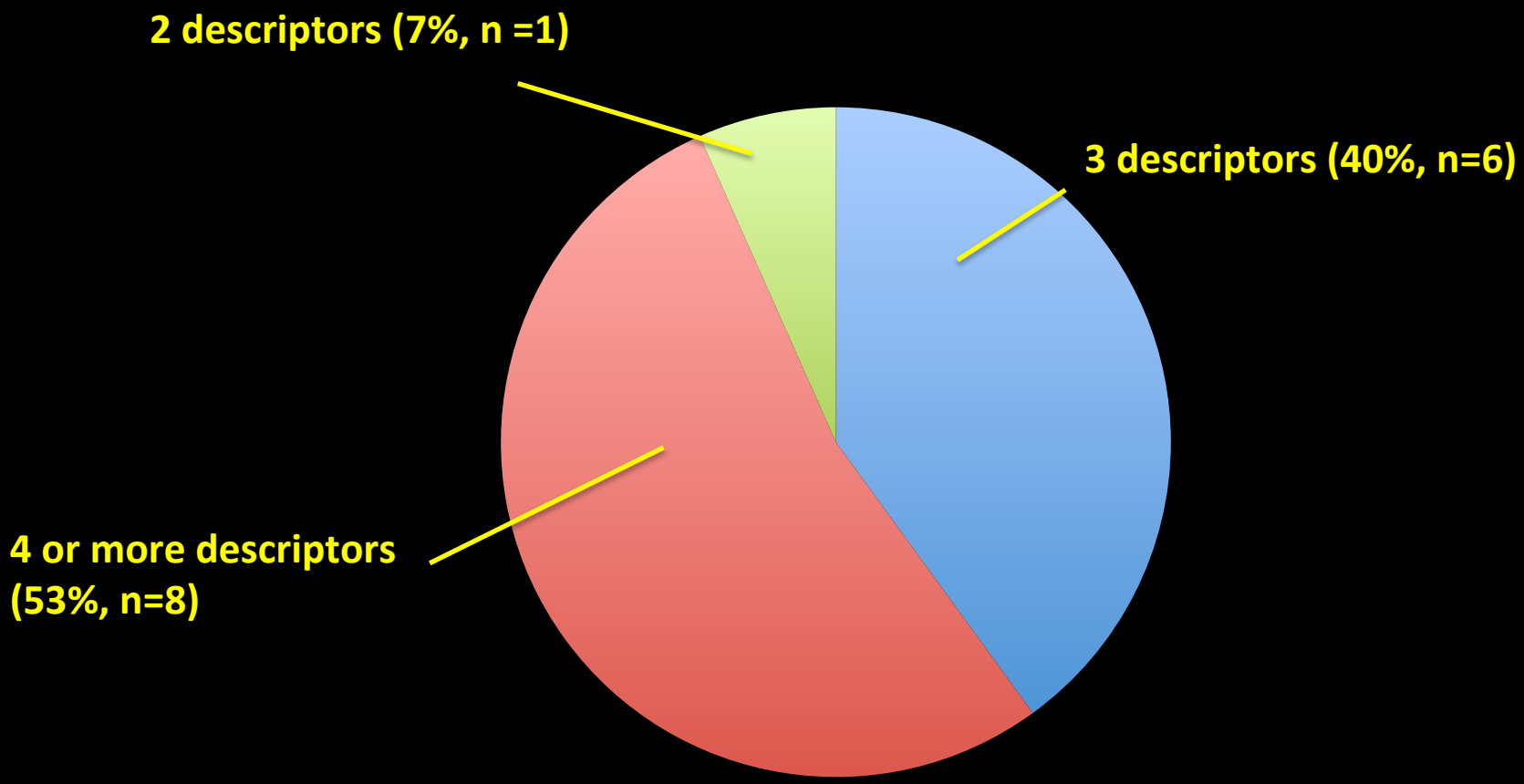

Figure 4: Number of suspicious descriptors for BI-RADS 5 patients who underwent diagnostic ultrasound only (n=15)

Patients undergoing only diagnostic MG exhibit at least 2 suspicious descriptors

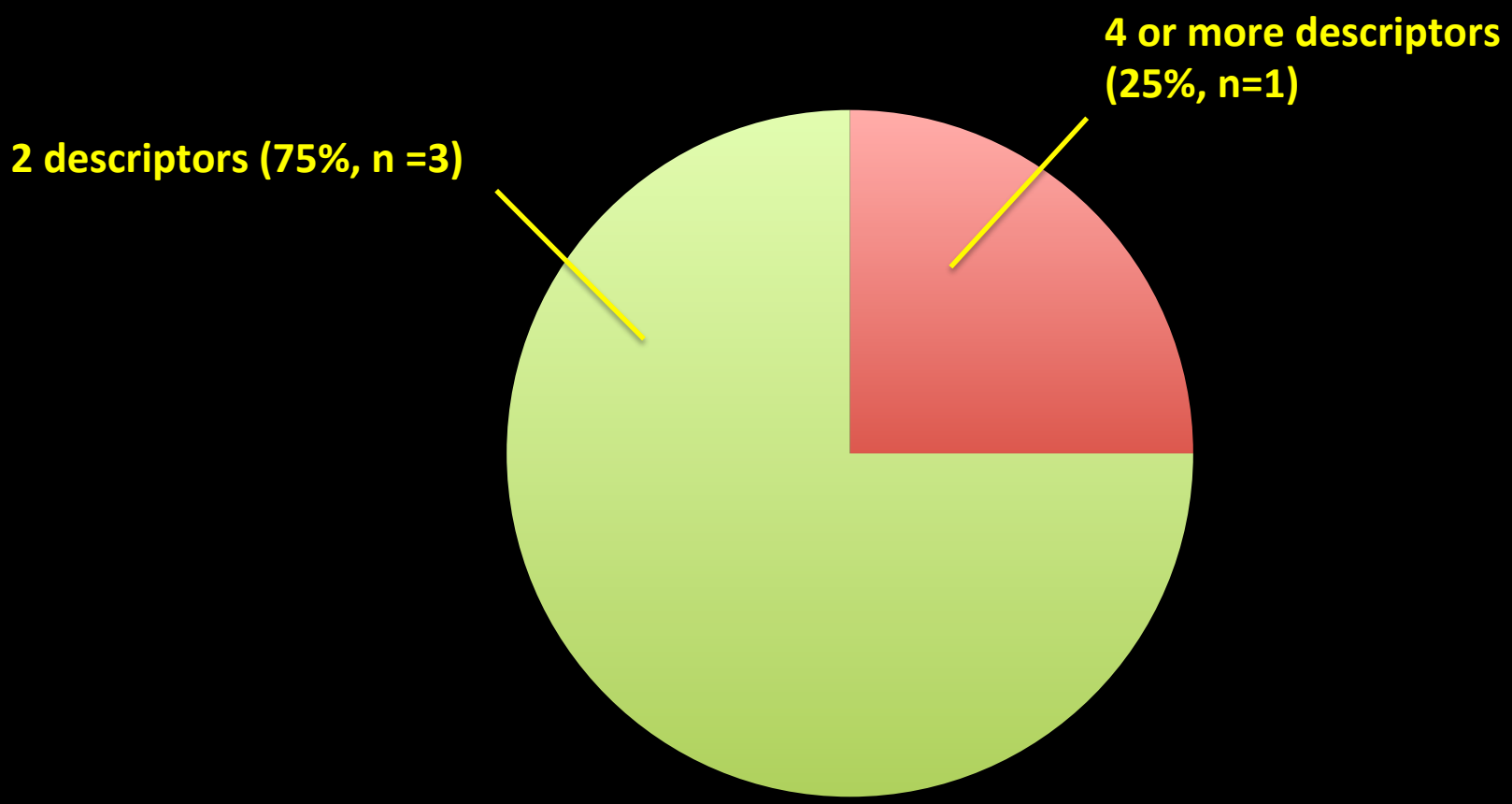

Figure 5: Number of suspicious descriptors for BI-RADS 5 patients who underwent diagnostic mammogram only (n=4)

Conclusions

- PPV of BI-RADS 5 lesions in our study was 97.9%, which meets the ACR guidance of PPV ≥ 95% (95% CI = 95.2-99.3%)
- BI-RADS 5 rarely used, only accounting for 1.1% of overall diagnostic imaging evaluations (place exact numbers)
- Most common presenting symptom was a palpable mass, as expected (73%)
    - Bloody nipple discharge only 1.3%, lower than previously reported rates of 3-12% [9,10]
    - Fewer than 5% reported skin thickening, lymphadenopathy, nipple retraction

Conclusions

- Overall, majority of patients had 4 or more suspicious imaging descriptors, which is recommended to justify BI-RADS 5 assessment
  - 95% with 4 or more descriptors (225/238)
  - 4% with 3 descriptors (9/238)
  - <2% with 2 descriptors (4/238, imaged with single modality)

Study Limitations

- Retrospective study design can introduce retrospective bias
    - Descriptors were extracted from available radiology reports, and not all useful descriptors may have been reported in the data set
- Radiologists with varying levels of experience (1-30+ years)
    - However, all had fellowship training in breast imaging
- Given study design, inter- and intra-reader variation could not be addressed

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THANK YOU!

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