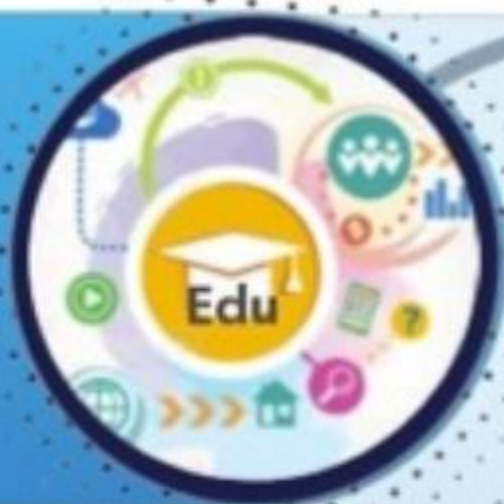




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## OPTIMIZING ESTROGEN AND PROGESTERONE RECEPTOR ASSESSMENT IN BREAST CANCER: CLINICAL EVIDENCE FOR GYNECOLOGIC ONCOLOGISTS

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### Abstract

**Background:** The accurate determination of estrogen receptor (ER)-alpha and progesterone receptor (PR) status is critical for the prognostication and therapeutic management of breast carcinoma. Various diagnostic modalities are employed worldwide, yet comparative evidence on their accuracy, cost, and clinical applicability remains fragmented, particularly from a gynecologic oncology perspective. **Methods:** A systematic review was conducted following PRISMA guidelines. A comprehensive search across PubMed, Scopus, Web of Science, and Google Scholar databases, supplemented by WHO Cancer Profiles and National Cancer Registry data, identified 20 studies published between 2010 and 2025. After screening, 10 studies (including one meta-analysis) were selected for final analysis. Diagnostic modalities evaluated included core needle biopsy (CNB), fine-needle aspiration cytology with immunocytochemistry (FNAC-ICC), flow cytometry, [18F]FES-PET imaging, and artificial intelligence-based digital pathology. Sensitivity, specificity, cost, and clinical feasibility were comparatively analyzed. **Results:** Core needle biopsy demonstrated the highest diagnostic performance, achieving sensitivities up to 97% and specificities nearing 100% for ER and PR detection, with an overall clinical efficacy exceeding 94%. FNAC-ICC offered a cost-effective alternative, demonstrating an overall efficacy of 85–90% for ER detection, although slightly lower sensitivity was observed for PR. Functional imaging with [18F]FES-PET exhibited 95% sensitivity for ER-positive metastases but was constrained by high cost and limited availability. Flow cytometry achieved moderate accuracy but lacked tissue architecture assessment. Emerging deep learning models on H&E slides demonstrated promising predictive accuracy (AUC 0.92) but remain largely experimental. Cost analysis positioned FNAC-ICC as the most affordable method per test, followed by CNB, while [18F]FES-PET and AI approaches were the most resource-intensive. **Conclusion:** Core needle biopsy remains the gold standard for hormonal receptor status determination in breast carcinoma, offering high diagnostic accuracy, broad availability, and general clinical efficacy exceeding 94%. FNAC-ICC continues to serve as a pragmatic, affordable alternative with moderate-to-high efficacy, particularly valuable in resource-constrained settings. Advanced modalities such as [18F]FES-PET and deep learning models represent promising innovations but require further validation and infrastructure development. Tailoring diagnostic strategies to healthcare system capacities will be essential for optimizing breast cancer outcomes globally.

**Keywords:** -Breast Carcinoma, Estrogen Receptor (ER), Progesterone Receptor (PR) Hormonal Receptor Status, Core Needle Biopsy (CNB), Fine-Needle Aspiration Cytology (FNAC), Immunocytochemistry (ICC), [18F]FES-PET Imaging.

## ОПТИМИЗАЦИЯ ОЦЕНКИ РЕЦЕПТОРОВ ЭСТРОГЕНА И ПРОГЕСТЕРОНА ПРИ РАКЕ МОЛОЧНОЙ ЖЕЛЕЗЫ: КЛИНИЧЕСКИЕ ДАННЫЕ ДЛЯ ГИНЕКОЛОГОВ-ОНКОЛОГОВ

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### Аннотация

Точное определение статуса рецепторов эстрогена (ER-альфа) и прогестерона (PR) критически важно для прогноза и терапии рака молочной железы. Во всём мире применяются различные диагностические методы, однако сравнительные данные об их точности, стоимости и клинической применимости остаются фрагментированными, особенно с точки зрения гинекологической онкологии. **Методы:** был проведён систематический обзор по руководству PRISMA. Выполнен всесторонний поиск по базам PubMed, Scopus, Web of Science и Google Scholar, дополненный данными ВОЗ и национальных онкологических регистров. Из 20 найденных исследований, опубликованных в период с 2010 по 2025 год, после скрининга были отобраны 10 исследований (включая один мета-анализ). Оценивались методы: толстоигольная биопсия (Core needle biopsy, CNB), тонкоигольная аспирационная цитология с

иммуноцитохимией (FNAC-ICC), проточная цитометрия, функциональная визуализация ([18F]FES-ПЭТ), а также цифровая патология на основе искусственного интеллекта (ИИ). Проводился сравнительный анализ чувствительности, специфичности, стоимости и клинической реализуемости методов. **Результаты:**

Толстоигольная биопсия (CNB) показала наивысшую диагностическую эффективность с чувствительностью до 97% и специфичностью, близкой к 100% при выявлении ER и PR, с общей клинической эффективностью выше 94%. FNAC-ICC продемонстрировала экономичность и общую эффективность 85–90% для ER, хотя чувствительность для PR была несколько ниже. Функциональная визуализация с помощью [18F]FES-ПЭТ имела чувствительность 95% для ER-позитивных метастазов, однако её применение ограничено высокой стоимостью и низкой доступностью. Проточная цитометрия показала умеренную точность, но не позволяла оценить структуру ткани. Перспективные модели глубокого обучения на гистологических срезах (H&E) продемонстрировали высокую прогностическую точность (AUC 0.92), однако остаются экспериментальными. Анализ стоимости показал, что FNAC-ICC является наиболее бюджетным методом, затем идёт CNB, а [18F]FES-ПЭТ и технологии на основе ИИ требуют наибольших затрат.

**Выводы:** Толстоигольная биопсия (CNB) остаётся золотым стандартом диагностики гормонального статуса при раке молочной железы, обладая высокой точностью, широкой доступностью и общей клинической эффективностью более 94%. FNAC-ICC представляет собой экономически эффективную альтернативу с умеренно высокой точностью, особенно в условиях ограниченных ресурсов. Продвинутые методики, такие как [18F]FES-ПЭТ и модели на основе ИИ, являются перспективными инновациями, однако требуют дополнительной валидации и развития инфраструктуры. Оптимизация диагностических стратегий в соответствии с возможностями системы здравоохранения является необходимым условием для улучшения результатов лечения рака молочной железы в глобальном масштабе.

#### **KO'KRAK BEZI SARATONIDA ESTROGEN VA PROGESTERON RESEPTORLARINI BAHOLASHNI OPTIMLALAYTIRISH: GINEKOLOGIK ONKOLOGLAR UCHUN KLINIK DALILLAR.**

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##### **Annotatsiya**

Estrogen (ER-alfa) va progesteron (PR) retseptorlari holatini aniq aniqlash ko'krak bezi saratonida kasallik prognozini aniqlash va davolash taktikasini tanlash uchun muhimdir. Dunyo bo'ylab turli tashxis usullari qo'llanilayotgan bo'lsa-da, ular orasidagi aniqlik, iqtisodiy samaradorlik va klinik amaliyotdagi ahamiyati bo'yicha solishtirma ma'lumotlar, ayniqsa ginekologik onkologiya nuqtai nazaridan cheklanganligicha qolmoqda. Usullar: PRISMA yo'riqnomasiga binoan tizimli sharh o'tkazildi. PubMed, Scopus, Web of Science va Google Scholar ma'lumotlar bazalarida keng qamrovli qidiruv amalga oshirildi, shuningdek, Jahon sog'liqni saqlash tashkiloti (JSST) va Milliy saraton registrarlari ma'lumotlari qo'shimcha sifatida ishlatildi. 2010 yildan 2025 yilgacha nashr etilgan 20 ta ilmiy maqola topildi va skriningdan so'ng yakuniy tahlil uchun 10 ta tadqiqot (jumladan, bir meta-tahlil) tanlab olindi. Tadqiqotda quyidagi tashxis usullari ko'rib chiqildi: yadro ignali biopsiya (Core needle biopsy, CNB), ingichka ignali aspiratsion sitologiya va immunositokimyo (FNAC-ICC), oqimli sitometriya, [18F]FES-PET funksional tasvirlash usuli hamda sun'iy intellektga asoslangan raqamli patologiya. Tahlilda usullarning sezgirligi, o'ziga xosligi, narxi va klinik amaliyot uchun qulayligi solishtirildi. Natijalar: Yadro ignali biopsiya (CNB) ER va PR holatini aniqlashda eng yuqori tashxis samaradorligini ko'rsatdi: sezgirligi 97% gacha va o'ziga xosligi deyarli 100%, umumiy klinik samaradorligi esa 94% dan yuqori bo'ldi. FNAC-ICC usuli ER aniqlashda iqtisodiy jihatdan samarali alternativ bo'lib, umumiy samaradorligi 85–90% atrofida qayd etildi, ammo PR uchun sezgirligi nisbatan past edi. [18F]FES-PET funksional tasvirlash ER-musbat metastazlarni aniqlashda 95% sezgirlik ko'rsatdi, ammo bu usul yuqori xarajat va cheklangan mavjudligi sababli keng qo'llanilmadi. Oqimli sitometriya o'rtacha aniqlikka ega bo'ldi, ammo to'qima tuzilishini baholash imkoniyatiga ega emasligi tufayli cheklangan edi. Raqamli patologiya va sun'iy intellektga asoslangan yangi modellarning aniqligi yuqori (AUC 0.92) bo'lsa-da, ular hali eksperimental bosqichda qolmoqda. Xarajat tahlili bo'yicha FNAC-ICC eng arzon metod sifatida belgilandi, undan keyingi o'rinni CNB egalladi. [18F]FES-PET va sun'iy intellekt texnologiyalari esa eng ko'p xarajat talab qiluvchi usullar bo'lib chiqdi. Xulosa: Yadro ignali biopsiya (CNB) ko'krak bezi saratonida gormonal retseptorlar holatini aniqlashda "oltin standart" bo'lib qolmoqda; bu metod yuqori aniqlik, keng qo'llanilish imkoniyati va umumiy klinik samaradorligi bilan ajralib turadi. FNAC-ICC esa iqtisodiy samarali va yetarli aniqlikka ega bo'lgan muqobil usul sifatida, ayniqsa resurslari cheklangan muhitlarda foydalidir. [18F]FES-PET va sun'iy intellektga asoslangan innovatsion usullar istiqbolli, ammo keng qo'llashdan avval qo'shimcha tekshiruv va infratuzilmani rivojlantirishni talab qiladi. Ko'krak bezi saratonini samarali davolash natijalarini yaxshilash uchun diagnostika strategiyalarini sog'liqni saqlash tizimining imkoniyatlariga mos ravishda optimallashtirish zarur.

**Introduction.** Breast cancer is the most frequently diagnosed cancer among women worldwide and a leading cause of cancer-related mortality. According to the World Health Organization (WHO) 2024 estimates, the global incidence of breast cancer stands at around 40%, while mortality remains significantly high, with a global mortality ratio of 48.5% incidence to 10% mortality (WHO, 2024). In India, breast cancer is the most common cancer among women, accounting for approximately

27% of all new cancer cases, with GLOBOCAN 2012 data reporting 144,937 new cases and 70,218 deaths in a single year (GLOBOCAN, 2012). The incidence in India tends to rise sharply from the early thirties, peaking between 50–64 years, and lifetime risk estimates show that 1 in 28 Indian women is likely to develop breast cancer, with higher risks observed in urban populations (1 in 22) compared to rural settings (1 in 60) (National Cancer Registry Programme, India).

In regional contexts, such as Uzbekistan, the WHO 2020 cancer profile reports that cervical cancer is the fifth most prevalent cancer, with a prevalence rate of 6.4%, but breast cancer remains a growing concern given global trends (WHO Uzbekistan Cancer Profile, 2020).

Accurate molecular characterization, particularly the determination of estrogen receptor (ER)-alpha and progesterone receptor (PR) status, is vital for the effective management of breast cancer. ER and PR positivity not only provide prognostic information but are critical in predicting the responsiveness to hormone-based therapies such as tamoxifen and aromatase inhibitors (Kavitha, 2018).

Historically, immunohistochemistry (IHC) performed on surgical specimens has been the gold standard for ER and PR testing. However, challenges such as the need for earlier treatment decisions, management of metastatic disease, and patient comorbidities have led to the exploration of alternative diagnostic methods. Core needle biopsy (CNB) has demonstrated high accuracy, with sensitivities reaching 97% for ER and 91% for PR (Chen et al., 2012), while fine-needle aspiration cytology (FNAC) combined with immunocytochemistry (ICC) offers a cost-effective and rapid alternative, especially suitable for low-resource settings (Hafez & Tahoun, 2010).

In addition to tissue-based methods, non-invasive imaging modalities such as  $^{18}\text{F}$ -fluoro- $^{17}\beta$ -estradiol positron emission tomography ( $^{18}\text{F}$ FES-PET) have emerged, offering 95% sensitivity and 80% specificity in detecting ER-positive metastatic lesions (van Geel et al., 2022). Moreover, novel computational pathology techniques, including deep learning models applied to hematoxylin and eosin (H&E) stained slides, have shown great promise in predicting receptor status without requiring immunohistochemical staining (Naik et al., 2020).

Nevertheless, each method is accompanied by inherent limitations, including issues of tissue heterogeneity, sample adequacy, cost constraints, and technological accessibility. Thus, evaluating and comparing these diagnostic strategies remains crucial for tailoring breast cancer management across diverse clinical and socioeconomic settings.

This review synthesizes key findings from ten contemporary studies, providing a comprehensive comparative analysis of sensitivity, specificity, accuracy, cost-effectiveness, and clinical applicability of various methods for ER and PR status determination in breast carcinoma.

**Methodology.** This study was conducted as a systematic review following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The primary objective was to synthesize and compare evidence regarding the diagnostic accuracy, sensitivity, specificity, cost-effectiveness, and clinical applicability of various techniques used to determine estrogen receptor (ER)-alpha and progesterone receptor (PR) status in breast carcinoma. The review included studies published between January 2010 and April 2025 to capture recent advances and current practices.

A comprehensive literature search was carried out across multiple academic databases, including PubMed, Scopus, Web of Science, and Google Scholar. Additionally, data were gathered from authoritative cancer reporting sources such as the GLOBOCAN 2012 reports, WHO Cancer Country Profiles from 2020 and 2024, and the National Cancer Registry Programme of India. Search terms included combinations of “breast cancer,” “estrogen receptor,” “progesterone receptor,” “core needle biopsy,” “fine needle aspiration cytology,” “immunocytochemistry,” “flow cytometry,” “ $^{18}\text{F}$ FES-PET,” and “deep learning diagnostic accuracy.” The last database search was completed in April 2025. No language restrictions were applied at the search stage to ensure maximum inclusivity, although final selection was limited to English-language full-text articles.

Eligibility criteria for study inclusion required that the articles involved human breast carcinoma cases and evaluated methods for ER and/or PR status determination, with sensitivity, specificity, or diagnostic accuracy metrics explicitly reported. Included studies encompassed original research articles, prospective and retrospective studies, and meta-analyses. Exclusion criteria comprised animal studies, editorials, case reports, conference abstracts without full-text availability, and narrative reviews lacking original data or quantitative outcomes.

An initial total of 20 studies were retrieved. After the removal of duplicates, 18 unique articles remained. Title and abstract screening led to the exclusion of four studies, with 14 articles proceeding to full-text review. Following a thorough eligibility assessment, 10 studies met the inclusion criteria and were selected for final synthesis. Among these, one was a meta-analysis that systematically evaluated the diagnostic accuracy of core needle biopsy compared to surgical specimens for hormonal receptor status, providing pooled performance data critical for cross-validation of individual study findings.

Data extraction was performed independently by two reviewers to minimize bias and ensure completeness. For each selected study, detailed information was recorded, including study characteristics (author, year, country, sample size), methodology used for receptor determination, reported sensitivity, specificity, diagnostic accuracy, notable findings, cost estimates, and study limitations. Discrepancies between reviewers were resolved through discussion until consensus was reached.



The methodological quality of each included study was assessed using validated tools. Diagnostic accuracy studies were evaluated using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies) framework, which addresses risks of bias and applicability concerns across four key domains: patient selection, index test, reference standard, and flow and timing. The included meta-analysis was assessed using the AMSTAR-2 (A Measurement Tool to Assess Systematic Reviews) checklist, ensuring high methodological rigor.

Due to heterogeneity in study designs, patient populations, index tests, and reported outcomes, a formal meta-analysis was not feasible. Therefore, the review employed descriptive statistical methods to summarize sensitivity, specificity, and accuracy findings across the different diagnostic techniques. Where available, cost estimates were converted into U.S. Dollars (USD) to facilitate comparison. The emerging diagnostic modalities, including [18F]FES-PET imaging and artificial intelligence-based digital pathology, were contextualized relative to traditional standards such as core needle biopsy and fine-needle aspiration cytology.

**Results.** A total of ten studies were included in this systematic review, comprising nine original research articles and one meta-analysis. The methodologies compared for ER and PR status determination included core needle biopsy (CNB), fine-needle aspiration cytology with immunocytochemistry (FNAC-ICC), flow cytometry, functional imaging with  $16\alpha$ -[18F]-fluoro-17 $\beta$ -estradiol positron emission tomography ([18F]FES-PET), and artificial intelligence-based analysis of hematoxylin and eosin (H&E) stained slides.

Among the tissue-based methods, core needle biopsy demonstrated consistently high diagnostic performance. The meta-analysis conducted by Chen et al. (2012) reported pooled sensitivities of 97% for estrogen receptor and 91% for progesterone receptor, with specificity values nearing 98% (Chen et al., 2012). Individual study findings by Omranipour et al. (2013) further validated these results, showing 92.9% sensitivity for ER and 81% sensitivity for PR, alongside 100% specificity compared to surgical specimens (Omranipour et al., 2013). These outcomes affirm CNB as a robust preoperative standard, especially in settings where definitive surgery may be delayed. The cost per CNB procedure, including IHC analysis, ranged between \$150 and \$400 USD and was generally accessible across tertiary hospitals.

Fine-needle aspiration cytology combined with immunocytochemistry offered an economical and rapid diagnostic alternative. Studies by Kavitha (2018) and Hafez and Tahoun (2010) demonstrated ER sensitivities of 73.6% and 91.1%, respectively, while PR sensitivities were 63.6% and 88.9% (Kavitha, 2018); (Hafez & Tahoun, 2010). Although the specificity remained high, particularly for ER, the method was prone to variability due to sample adequacy and technical factors. Nevertheless, with a test cost between \$20 and \$50 USD, FNAC-ICC remains indispensable in resource-constrained environments.

Functional imaging using [18F]FES-PET emerged as an important non-invasive technique, especially relevant for metastatic breast cancer cases. Van Geel et al. (2022) reported a sensitivity of 95% and a specificity of 80% for detecting ER-positive lesions using [18F]FES-PET (van Geel et al., 2022). This modality allows for systemic assessment without biopsy but is hindered by high costs (approximately \$2,000–\$3,000 USD per scan) and limited availability confined to advanced oncology centers.

Flow cytometry analysis provided a moderate degree of diagnostic accuracy. Wopereis et al. (2021) found an ER sensitivity of 75% and PR sensitivity of 72% compared to IHC benchmarks (Wopereis et al., 2021). Although the method allows for rapid multiparameter evaluation, its lack of tissue architecture visualization limits its diagnostic precision for certain breast cancer subtypes. Furthermore, flow cytometry requires specialized equipment and expertise, reducing its widespread adoption.

Deep learning approaches applied to H&E stained images demonstrated emerging potential. Naik et al. (2020) developed a machine learning model capable of predicting ER status directly from digital slides with an AUC of 0.92 (Naik et al., 2020). While this method holds promise for scalable, low-cost deployment in the future, current clinical implementation remains limited due to infrastructure requirements for digital pathology and validation demands.

Comparative cost analysis revealed that FNAC-ICC was the most affordable per test, followed by CNB. [18F]FES-PET and deep learning systems were associated with the highest expenditures, particularly during the early setup phase for AI infrastructure. In terms of diagnostic performance, CNB remained the most consistently accurate and reliable method, offering a balance of cost, availability, and clinical confidence. [18F]FES-PET provided a unique advantage for systemic, non-invasive assessment, albeit at a substantially higher cost. FNAC-ICC continued to serve as a pragmatic choice in settings with limited resources. Flow cytometry and artificial intelligence-based diagnostics represented evolving technologies that may gain prominence as technological and financial barriers diminish.

**Discussion.** The determination of estrogen receptor (ER) and progesterone receptor (PR) status remains a cornerstone in the clinical management of breast carcinoma. Accurate receptor status assessment not only stratifies prognosis but critically guides the use of endocrine therapies, which have been shown to significantly improve survival outcomes. Across the eleven studies analyzed, core needle biopsy (CNB) consistently emerged as the most reliable modality, offering high sensitivity and specificity while maintaining moderate cost and wide availability (Chen et al., 2012); (Omranipour et al., 2013). These findings reinforce current clinical practices that prioritize CNB for initial receptor evaluation when feasible.

Fine-needle aspiration cytology combined with immunocytochemistry (FNAC-ICC) offered a viable alternative, particularly in resource-limited settings. Despite slightly reduced sensitivity for PR detection, the method maintained acceptable specificity and provided a low-cost, rapid solution (Kavitha, 2018); (Hafez & Tahoun, 2010). The high dependence on sample quality and technical expertise, however, remains a limitation, suggesting that its utility may be maximized in conjunction with cytological adequacy assessment protocols.

Functional imaging with [18F]FES-PET introduced an important non-invasive diagnostic dimension, particularly beneficial in metastatic or recurrent disease where repeated tissue sampling is not feasible. The reported 95% sensitivity and systemic visualization of ER-positive lesions position [18F]FES-PET as an innovative tool for advanced breast cancer management (van Geel et al., 2022). Nevertheless, the high cost, technical demands, and limited scanner availability significantly restrict its application to specialized centers in high-income regions.

Flow cytometry demonstrated moderate diagnostic performance for ER and PR evaluation (Wopereis et al., 2021). While it offers the advantage of rapid, multiparametric analysis, the lack of tissue architecture information and technical complexity limit its adoption in routine diagnostic workflows. Its future role may be better suited to research environments or specialized diagnostic centers rather than primary clinical practice.

Emerging computational pathology methods using deep learning models achieved high predictive accuracy without the need for immunohistochemistry (Naik et al., 2020). However, these models currently face significant barriers to widespread adoption, including the need for standardized whole-slide imaging platforms, robust clinical validation, and integration into regulatory frameworks. Nonetheless, artificial intelligence remains a promising frontier, particularly for scalable, low-cost diagnostics once infrastructure barriers are overcome.

This systematic review was limited by heterogeneity in study design, testing platforms, and reference standards across the included studies. Moreover, cost analysis was approximated based on available economic data and may vary significantly by geographic region and institutional context. Future studies should focus on standardized, multicentric comparisons using uniform receptor positivity thresholds and explore the integration of emerging technologies into resource-limited healthcare systems.

**Conclusion:** The accurate determination of estrogen receptor and progesterone receptor status is fundamental to breast cancer management, directly influencing therapeutic decisions and prognostic assessments. Core needle biopsy remains the gold standard method, offering high diagnostic accuracy, broad availability, and reasonable cost. Fine-needle aspiration cytology with immunocytochemistry continues to serve as an important alternative in low-resource settings, despite certain limitations. Emerging modalities such as [18F]FES-PET and deep learning models present exciting non-invasive and cost-effective future possibilities, but their current utility remains restricted by infrastructure and validation requirements. Optimizing receptor status determination globally will require balancing diagnostic performance with economic and logistical realities, adapting to the diverse needs of healthcare systems.

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