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PHOTODYNAMIC THERAPY FOR BREAST CANCER AND THE TRANSLATIONAL POTENTIAL OF *QUANTUM DOTS*

TERAPIA FOTODINÂMICA NO CÂNCER DE MAMA E POTENCIAL TRANSLACIONAL DOS *QUANTUM DOTS*

TERAPIA FOTODINÁMICA EN EL CÁNCER DE MAMA Y EL POTENCIAL TRASLACIONAL DE LOS *PUNTOS CUÁNTICOS*

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Abstract

Breast cancer remains one of the leading causes of female mortality worldwide, requiring more selective and less invasive therapeutic approaches. This study aimed to analyze the clinical landscape of Photodynamic Therapy (PDT) in breast cancer and discuss the translational potential of Quantum Dots (QDs) as photosensitive platforms. The methodology consisted of a documentary and exploratory analysis of secondary data from five interventional human studies registered on ClinicalTrials.gov, focusing on phases I and II, complemented by public SISCAN/DATASUS records for 2020–2025 and a narrative review of recent preclinical literature on QDs and PDT. The clinical records indicate initial evidence of feasibility, tolerability, and local antitumor activity in selected breast cancer settings, particularly with verteporfin; however, the studies were early-phase, small, and heterogeneous. No human clinical protocol directly combining QDs and PDT was identified. A phase I QD study (NCT04138342) was identified as an independent QD clinical protocol, but no results were posted in the registry. SISCAN records fluctuated during 2020–2025, with a peak in 2022; the 2025 value should be interpreted cautiously because the database was not fully consolidated at the time of extraction. Overall, QDs show translational potential for bioimaging, targeted delivery, and photosensitization, but clinical integration with PDT remains predominantly preclinical and requires further evaluation of toxicity, biodistribution, stability, pharmacokinetics, optical dosimetry, and safety.

Keywords: Breast Cancer; Photodynamic Therapy; Quantum Dots; Nanomedicine; Nanotechnology.

Resumo

O câncer de mama permanece como uma das principais causas de mortalidade feminina mundial, exigindo abordagens terapêuticas mais seletivas e menos invasivas. Este estudo teve como objetivo analisar o panorama clínico da Terapia Fotodinâmica (PDT) no câncer de mama e discutir o potencial translacional dos Quantum Dots (QDs) como plataformas fotossensíveis. A metodologia consistiu em uma análise documental e exploratória de dados secundários provenientes de cinco estudos intervencionais em humanos registrados na plataforma ClinicalTrials.gov, com foco nas fases I e II, complementada por registros públicos do SISCAN/DATASUS referentes ao período de 2020 a 2025 e por revisão narrativa de literatura pré-clínica recente sobre QDs e PDT. Os registros clínicos indicam evidências iniciais de viabilidade, tolerabilidade e atividade antitumoral local em contextos selecionados de câncer de mama, especialmente com verteporfina; entretanto, os estudos são precoces, pequenos e heterogêneos. Não foi identificado protocolo clínico humano que associasse diretamente QDs e PDT. O estudo de fase I NCT04138342 foi identificado como protocolo clínico independente envolvendo QDs, porém sem resultados publicados no registro. Os registros do SISCAN apresentaram oscilações entre 2020 e 2025, com pico em 2022; o valor de 2025 deve ser interpretado com cautela, devido à consolidação incompleta da base no momento da extração. De

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modo geral, os QDs apresentam potencial translacional para bioimagem, entrega direcionada e fotossensibilização, mas sua integração clínica à PDT permanece predominantemente pré-clínica e requer avaliação adicional de toxicidade, biodistribuição, estabilidade, farmacocinética, dosimetria óptica e segurança.

Palavras-chave: Câncer de Mama; Terapia Fotodinâmica; Quantum Dots; Nanomedicina; Nanotecnologia.

Resumen

El cáncer de mama sigue siendo una de las principales causas de mortalidad femenina a nivel mundial, lo que exige enfoques terapéuticos más selectivos y menos invasivos. Este estudio tuvo como objetivo analizar el panorama clínico de la Terapia Fotodinámica (PDT) en el cáncer de mama y discutir el potencial traslacional de los Quantum Dots (QDs) como plataformas fotosensibles. La metodología consistió en un análisis documental y exploratorio de datos secundarios provenientes de cinco estudios intervencionistas en humanos registrados en ClinicalTrials.gov, centrados en las fases I y II, complementado con registros públicos del SISCAN/DATASUS correspondientes al período 2020–2025 y con una revisión narrativa de literatura preclínica reciente sobre QDs y PDT. Los registros clínicos indican evidencia inicial de viabilidad, tolerabilidad y actividad antitumoral local en contextos seleccionados de cáncer de mama, especialmente con verteporfina; sin embargo, los estudios son tempranos, pequeños y heterogéneos. No se identificó ningún protocolo clínico humano que combinara directamente QDs y PDT. El estudio de fase I NCT04138342 fue identificado como un protocolo clínico independiente con QDs, pero no presentaba resultados publicados en el registro. Los registros del SISCAN mostraron fluctuaciones entre 2020 y 2025, con un pico en 2022; el valor correspondiente a 2025 debe interpretarse con cautela debido a la consolidación incompleta de la base en el momento de la extracción. En conjunto, los QDs presentan potencial traslacional para bioimagen, administración dirigida y fotosensibilización, pero su integración clínica con la PDT permanece predominantemente en fase preclínica y requiere una evaluación adicional de toxicidad, biodistribución, estabilidad, farmacocinética, dosimetría óptica y seguridad.

Palabras clave: Cáncer de Mama; Terapia Fotodinámica; Quantum Dots; Nanomedicina; Nanotecnología.

1. Introdução

Breast cancer represents one of the most prevalent malignant neoplasms among women worldwide and is one of the leading causes of female mortality in both developed and developing countries. According to Uprety et al. (2022), malignant neoplasms were responsible for approximately 9–10 million deaths in 2020, reflecting the substantial global burden of cancer. The high incidence and mortality associated with breast cancer also reflect the biological complexity of the disease, which is characterized by tumor heterogeneity and the ability to metastasize to organs such as the bones, lungs, and liver (Bourang et al., 2024).

Over the past decades, advances in breast cancer research have focused on understanding the mechanisms underlying cellular growth, angiogenesis, and drug

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resistance, with the aim of improving existing therapeutic modalities. Current treatments include surgery, chemotherapy, radiotherapy, endocrine therapy, targeted therapies, and immunotherapy according to tumor subtype and clinical indication. Nevertheless, these approaches may be associated with systemic toxicity, treatment resistance, and adverse effects that limit their therapeutic window (Ji et al., 2022). Therefore, there is continued interest in alternative or adjuvant strategies capable of combining antitumor activity with greater spatial selectivity and reduced tissue damage.

Among the promising approaches, Photodynamic Therapy (PDT) stands out as a minimally invasive technique that combines light, molecular oxygen, and a photosensitizer (PS) to induce localized photochemical damage. The activation of the PS in the presence of oxygen generates reactive oxygen species (ROS), including singlet oxygen, which can promote apoptosis, necrosis, vascular damage, and other forms of tumor cell death (Gunaydin et al., 2021; Niculescu and Grumezescu, 2021). Although PDT has an established role in selected localized diseases, its application to breast cancer remains investigational, particularly because light delivery and treatment depth are critical determinants of efficacy.

The clinical application of PDT to breast cancer is constrained by factors such as limited light penetration, photosensitizer distribution, tumor geometry, and the availability of molecular oxygen. In this context, nanostructured systems such as Quantum Dots (QDs) have attracted attention because of their tunable optical properties and potential roles in bioimaging, targeted delivery, energy transfer, and photosensitization (Uprety and Abrahamse, 2022; Kolarikova et al., 2023). QDs are nanoscale materials that can be broadly classified into inorganic semiconductor QDs, such as CdSe, CdTe, and CdS/ZnS systems, and carbon-based materials, including carbon dots (CDs) and graphene quantum dots (GQDs). These classes should not be considered interchangeable because their composition, surface chemistry, photophysical behavior, toxicity, biodistribution, and clearance can differ substantially.

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In PDT, QDs may function as carriers or photoactive components and can be engineered to interact with photosensitizers through mechanisms such as energy or electron transfer. Preclinical studies have reported enhanced photodynamic responses in QD-containing systems, including carbon-based and graphene-based nanostructures, in cancer models (Jovanović et al., 2023; Anjusha et al., 2023; Li et al., 2022; Magaela et al., 2022). However, these findings should be interpreted as preclinical evidence rather than clinical proof of efficacy. The potential advantage of QDs does not imply that they intrinsically increase tissue light penetration; rather, their contribution may depend on absorption and emission characteristics, excitation wavelength, energy transfer, surface functionalization, tumor targeting, and the method used to deliver light. Ultimately, tissue penetration is also governed by wavelength, absorption, scattering, tumor geometry, and light-delivery configuration.

Therefore, this study aimed to analyze the early clinical landscape of PDT in breast cancer and discuss the translational potential of QDs as photosensitive platforms, emphasizing the current level of clinical evidence, technological limitations, safety requirements, and the gap between preclinical QD-PDT research and future human clinical translation.

2. Methodology

The study was conducted as a documentary and exploratory analysis of secondary data, combining clinical trial records, public health records, and complementary narrative literature. The methodology comprised four components: (i) identification and selection of interventional human studies involving PDT or QDs in the context of breast cancer; (ii) extraction and organization of clinical information from phases I and II; (iii) descriptive contextualization of breast cytology records from SISCAN/DATASUS in Brazil; and (iv) narrative supplementation with recent preclinical literature addressing QD-based photodynamic mechanisms, ROS generation, and nanomaterial-related translational barriers. The interpretation prioritized translational maturity and explicitly distinguished registered protocols from published clinical outcomes.

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2.1. Clinical trial identification and selection

The clinical trial search was conducted between August and October 2025 in ClinicalTrials.gov, maintained by the U.S. National Library of Medicine, using the descriptors “Photodynamic therapy AND breast cancer”, “Quantum dots AND breast cancer”, and “nanoparticle phototherapy AND breast”. Eligible studies were interventional human studies in phases I or II, registered between 2000 and 2025, with relevance to breast cancer and/or QD-based photonic approaches. Studies were excluded when they were exclusively in vitro, reviews, non-interventional studies, or unrelated to PDT or QD-based approaches. Five records met the inclusion criteria: NCT00862901, NCT02872064, NCT02939274, NCT00028405, and NCT04138342.

For each record, the extracted variables included study phase, population and clinical context, intervention, photosensitizer or nanomaterial, route of administration, light-delivery parameters when applicable, enrollment, registry status, availability of posted results, and reported safety or tumor-response information. Protocol objectives were kept separate from outcomes actually reported in publications or in the registry. In particular, NCT04138342 was treated as a phase I QD protocol independent of PDT, whereas the verteporfin studies were analyzed as PDT investigations. NCT00028405 was classified as indirect evidence because it included refractory solid tumors of different origins rather than being specific to breast cancer.

2.2. Contextualization of SISCAN/DATASUS records

To contextualize the Brazilian healthcare scenario, public SISCAN/DATASUS records were collected for the number of female patients undergoing breast cytology between 2020 and 2025. The indicator analyzed was “Cito de mama por pacientes (feminino) Brasil”. These records were treated as an assistential/contextual indicator and not as a measure of breast cancer incidence, because the number of examinations or patients recorded does not correspond directly to the number of new cancer cases.

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Annual values were analyzed descriptively, including the mean, sample standard deviation, and year-to-year percentage variation. The temporal distribution was represented by a column chart generated in Python/Matplotlib (version 3.9), using a linear scale. A permutation test (n = 50,000) was retained as an exploratory complementary analysis of linear trend, with $p < 0.05$ adopted as the statistical threshold. Because the period is short and the 2025 record was not fully consolidated at the time of extraction, inferential interpretation was deliberately limited.

2.3. Ethical consideration

The present study did not involve direct experimentation with humans, animals, or biological samples and was based exclusively on publicly available secondary data obtained from ClinicalTrials.gov and SISCAN/DATASUS. Therefore, no submission to a Research Ethics Committee (CEP/CONEP) was required for the use of public, non-identifiable data without direct intervention, in accordance with the ethical framework applicable to this type of research.

3. Results and Discussion

3.1. Contextualization of SISCAN/DATASUS breast cytology records in Brazil (2020–2025)

The SISCAN records for female patients undergoing breast cytology between 2020 and 2025 showed substantial annual fluctuations. The corrected cumulative total for the period was 59,565 records, based on 9,869 in 2020, 10,298 in 2021, 11,808 in 2022, 10,381 in 2023, 10,535 in 2024, and 6,674 in 2025. The series increased from 2020 to 2022, reaching a maximum of 11,808 records, followed by lower values in 2023 and 2024 and a marked reduction in 2025. Year-to-year variation was +4.3% in 2021, +14.7% in 2022, −12.1% in 2023, +1.5% in 2024, and −36.7% in 2025. The annual mean was 9,928 ± 1,723 records. The linear correlation coefficient was negative and moderate ($r = -0.518$), while the permutation test did not indicate a statistically significant linear trend ($p \approx 0.307$). Thus, the observed

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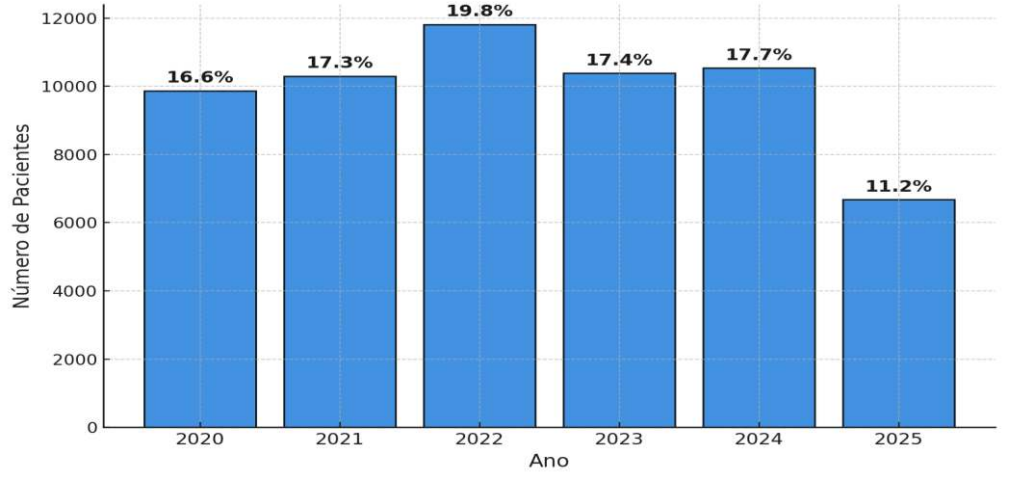
fluctuations should not be interpreted as evidence of a consistent temporal increase or decrease (Table 1).

Table 1. SISCAN (breast cytology, female, Brazil), 2020–2025: patients/year, variations, mean and SD

Year	Patients	Absolute variation vs. previous year	Variation (%) vs. previous year
2020	9,869	—	—
2021	10,298	+429	+4.3%
2022	11,808	+1,510	+14.7%
2023	10,381	−1,427	−12.1%
2024	10,535	+154	+1.5%
2025*	6,674	−3,861	−36.7%
Mean ± SD	**9,928 ± 1,723**	—	—

Source: SISCAN, DATASUS, Ministry of Health (2025).

Figure 1. Annual distribution of female patients with breast cytology records in Brazil (2020–2025)



Source: SISCAN, DATASUS, Ministry of Health (2025).

The temporal pattern should be interpreted as an assistential context rather than as a direct epidemiological measure of breast cancer. The increase in records observed through 2022 occurred during a period of broader recovery of health services after the most critical phases of the COVID-19 pandemic; however, the descriptive design does not allow a causal relationship to be established between the

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pandemic, service recovery, and the observed variation. The lower number recorded in 2025 should be interpreted cautiously because the database was not fully consolidated at the time of extraction. The absence of a statistically significant linear trend further supports a cautious interpretation of the series.

SISCAN records represent the volume of patients or examinations registered in the information system and do not constitute a direct estimate of breast cancer incidence. They therefore should not be used interchangeably with the number of new cases. Their main contribution in the present study is contextual, helping to describe the assistential environment in which new diagnostic and therapeutic technologies may eventually be incorporated. National cancer estimates from INCA remain a separate epidemiological source and should be interpreted independently from the SISCAN cytology indicator.

3.2. Clinical Trials.gov analysis

The ClinicalTrials.gov analysis identified five eligible records and revealed distinct levels of translational maturity between PDT and QD-based approaches. Importantly, the existence of a registered protocol does not necessarily demonstrate clinical efficacy. Registry entries describe planned interventions and outcomes, whereas published results or posted registry results provide evidence of what was actually observed. This distinction is particularly relevant for the present dataset because several records did not have results posted in the registry.

Table 1. Summary of the five clinical trial records included in the analysis.

Registry	Phase	Population / context	Intervention	PDT / QD	Results status / interpretation
NCT00862901	I	Breast cancer with chest-wall progression	CLIPT; Photofrin + fiber-optic light delivery	PDT	No results posted; safety/feasibility protocol
NCT02872064	I/IIa	Primary breast cancer	IV verteporfin + interstitial 690-nm light	PDT	Published derived results; early proof of concept

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NCT02939274	II	Cutaneous metastases of breast cancer	Continuous low-irradiance verteporfin-PDT	PDT	No results posted; efficacy/safety protocol
NCT00028405	I	Refractory solid tumors, including breast cancer	LS11 + intratumoral light delivery	PDT	No breast-specific efficacy result; indirect evidence
NCT04138342	I	Breast cancer	CdS/ZnS QDs conjugated with veldoreotide	QD, not PDT	No results posted; independent QD clinical protocol

Source: Clinical Trials.gov analysis (2025).

NCT00862901 is a phase I study of continuous low-irradiance photodynamic therapy (CLIPT) for patients with chest-wall progression of breast cancer after previous radiotherapy. The registry describes a safety- and feasibility-oriented dose-escalation design using Photofrin and a fiber-optic light-delivery patch. No study results were posted in ClinicalTrials.gov. Therefore, the record should be interpreted as evidence of clinical investigation and feasibility assessment rather than as proof of efficacy.

NCT02872064 is a completed phase I/IIa study of verteporfin-based PDT in primary breast cancer. The protocol involved a single intravenous dose of verteporfin followed by interstitial 690-nm laser irradiation before planned surgery. Published reports derived from this study describe measurable tumor necrosis in most treated patients and support the interpretation of the study as an important early proof of concept for image-guided, interstitial PDT. Nevertheless, the small sample and early-phase design do not establish PDT as a standard neoadjuvant treatment; the appropriate interpretation is experimental neoadjuvant investigation and proof of concept.

NCT02939274 is a phase II study of continuous low-irradiance PDT using verteporfin for cutaneous metastases of breast cancer. The registry describes evaluation of safety and efficacy in superficial metastatic lesions, with continuous low-irradiance illumination and repeated treatment parameters. No study results were posted in the registry at the time of the record available for this analysis.

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Consequently, the protocol demonstrates continued clinical investigation of verteporfin-PDT but does not, by itself, establish treatment efficacy.

NCT00028405 is a phase I study of a photodynamic therapy system for refractory or unresponsive solid tumors. The study included several tumor types, including breast cancer, but was not designed specifically for breast cancer. It therefore provides indirect clinical evidence for PDT technology rather than breast-cancer-specific efficacy evidence. Its inclusion also illustrates the exploratory nature of early PDT development across different solid tumors.

Taken together, the five records illustrate three distinct translational stages. Stage 1 comprises PDT, for which early clinical evidence is available, especially for verteporfin-based approaches in selected superficial or interstitial breast lesions. Stage 2 comprises QDs investigated independently of PDT, represented in this corpus by the phase I NCT04138342 protocol, which remains without posted clinical results. Stage 3 comprises QD-PDT, for which no human clinical protocol directly combining the two technologies was identified in the analyzed corpus and the evidence therefore remains predominantly preclinical. This distinction is central to interpreting the translational maturity of the technologies.

The QD-PDT gap is scientifically relevant rather than merely a limitation of the literature. Preclinical studies of carbon dots, graphene quantum dots, semiconductor QDs, and hybrid nanostructures suggest that these materials can contribute to photosensitization, energy transfer, ROS generation, imaging, and targeted delivery. However, these materials are not a homogeneous category. Semiconductor QDs may present concerns related to metal composition, surface stability, ion release, biodistribution, organ retention, and long-term toxicity, whereas carbon-based QDs may exhibit different physicochemical and biological profiles depending on synthesis and functionalization. Consequently, claims of “ideal biocompatibility” are not justified across the entire QD class. A more appropriate translational perspective is that some carbon-based systems may display favorable optical properties and potentially more suitable biocompatibility profiles in selected preclinical models, but safety remains material- and formulation-dependent.

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Another relevant limitation is tumor hypoxia. Because PDT depends on molecular oxygen to generate phototoxic ROS, low oxygen availability and local oxygen consumption during irradiation may reduce treatment efficiency in hypoxic tumor regions. The optical challenge should also be described precisely: QDs do not automatically increase tissue penetration of light. Potential benefits may arise from tunable absorption and emission, excitation at favorable wavelengths, energy transfer, surface functionalization, targeting, and integration with light-delivery systems, while actual penetration remains dependent on wavelength, tissue absorption, scattering, tumor geometry, and the method of light delivery. These considerations support a staged translational pathway in which toxicological characterization, pharmacokinetics, biodistribution, optical dosimetry, and safety are established before comparative efficacy studies in humans.

4. Conclusion

Photodynamic therapy presents initial clinical evidence of feasibility, tolerability, and local antitumor activity in selected approaches for breast cancer, particularly in early studies involving verteporfin. However, the available clinical literature remains limited by small sample sizes, early stages of development, and heterogeneity among treatment protocols, preventing PDT from being considered an established therapy for breast cancer. In the field of nanotechnology, quantum dots exhibit photophysical properties that support their potential as platforms for bioimaging, drug delivery, and photosensitization; however, their clinical translation remains contingent upon addressing issues related to toxicity, biodistribution, stability, and safety. The absence of human clinical trials directly combining QDs with PDT represents the main gap identified and indicates that this association remains predominantly at the preclinical stage. Therefore, future phase I and II studies should prioritize toxicological characterization, optical dosimetry, pharmacokinetics, and safety assessment before proceeding to comparative evaluations of clinical efficacy.

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