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# Challenges in Observational Studies and Improving Preclinical Models for Better Clinical Trials

**Labard Baras***

*Department of Medicines, Iran National Standard Organization, Tehran, Iran*

## Abstract

Observational studies are research designs that involve observing and analyzing the outcomes of a group of individuals without any intervention or manipulation. These types of studies are useful in understanding the natural history of a disease or condition and identifying potential risk factors or associations. However, there are several challenges associated with observational studies, including in this manner, photosensitizers can prompt oxidative weight on a malignant growth cell or perform nearby hyperthermia. The expanded responsiveness of malignant growth cells to warming up to 41-47 °C underlies the viability of photo thermal treatment. To overcome these challenges, various strategies have been developed to improve the delivery and effectiveness of photosensitizers. Chemical modification, such as altering the molecular structure of the photosensitizer, can enhance its water solubility and stability. Another strategy is to use PE gelation, which involves the formation of a gel-like substance that can encapsulate the photosensitizer and improve its delivery to the target site. Additionally, photosensitizers can be encapsulated within nano carriers of various nature such as liposomes, nanoparticles, and dendrites.

**Keywords:** Cancer • Liposomes • Dendrimers

## Introduction

Photodynamic therapy (PDT) and photo thermal therapy (PTT) are promising approaches for cancer treatment due to their painlessness and spatial selectivity. However, one of the challenges in PDT and PTT is to find a photosensitizer that can efficiently enter and accumulate within cancer and stromal cells without causing harm in the dark. Unfortunately, many photosensitizers currently used in the clinic have poor water solubility, low bioavailability, and are unstable in physiological conditions. This can lead to adverse effects such as skin photosensitivity. Overall, these strategies hold great promise in overcoming the limitations of current photosensitizers used in PDT and PTT. With further research and development, these approaches may ultimately improve the specificity and effectiveness of cancer treatment while minimizing adverse effects [1-3].

## Literature Review

One of the challenges in the development of phototherapy and other cancer treatment techniques is the limited penetration of active substances deeper than 3-4 layers of cells in solid tumors of epithelial origin. This is due to the close intercellular contacts that restrict the diffusion of therapeutic agents. Cancer cells have a tendency to maintain the intercellular contacts that seal the boundaries of normal endothelial cells and intercellular spaces within the tumor, which makes conventional chemotherapies and targeted treatments ineffective. To address the limitations of current photo thermal sensitizers, biocompatible polymer nanocontainers loaded with magnesium phthalocyanine (Pht-Mg) were synthesized and characterized as effective photo thermal sensitizers. In 2D cell culture, these nanocontainers were effective in inducing specific destruction of cancer cells when exposed to near IR light. However, their efficacy decreased by more than ten times in the transition from 2D to 3D cell culture. To improve the quality of observational studies, researchers can use rigorous study designs, such as prospective cohort studies or randomized controlled trials, to minimize the impact of confounding, selection bias, and measurement bias. They can also use advanced statistical techniques, such as propensity score matching or instrumental variable analysis, to adjust for confounding and reduce bias [4].

### Therapeutic agents need to bypass the intercellular contacts

To effectively diffuse inside solid tumors and penetrate the cancer cells through physical barriers, therapeutic agents need to bypass the intercellular contacts. One promising approach to opening up cell contacts is through the use of junction opener (JO) proteins derived from human adenovirus serotype. The activation of MAP-kinases triggers transient trans-differentiation of epithelial cells, which reduces the expression of adhesion and blocking cell contact proteins, thereby enabling the diffusion of drugs inside the cancer cells. Overall, the development of JO proteins and other approaches to overcome the physical barriers of solid tumors holds great promise for improving the effectiveness of cancer treatments, including phototherapy. With further research and development, these strategies may ultimately improve the delivery and efficacy of cancer therapies, particularly for epithelial tumors that are resistant to conventional treatments [5,6].

## Discussion

The use of JO proteins to enhance drug delivery to tumors has been extensively demonstrated for antibodies and chemotherapy drugs, but their effect on nanostructure delivery is poorly understood. Studies have shown that JO significantly increases the mass tumor accumulation of 35 nm but not 120 nm gold nanoparticles, and significantly enhances the efficacy of liposomes loaded with doxorubicin. The treatment of strong growths of epithelial beginning having intercellular contacts is as yet a difficult issue. Significant endeavours are being made to upgrade the viability of nano agents of various beginnings, e.g., pointed toward expanding their circulatory system course or changing their bio distribution. By and by, close intercellular contacts regular for malignant growth cells make both conventional chemotherapies and treatment with monoclonal antibodies and supramolecular specialists insufficient. JO-1 and JO-4 proteins have been shown to induce a partial epithelial-mesenchymal transition (EMT), which increases the permeability of tumors to high molecular weight molecules and protein particles, including antibodies.

## Conclusion

The use of biocompatible polymer nanoparticles loaded with magnesium

***Address for Correspondence:** Labard Baras, Department of Medicines, Iran National Standard Organization, Tehran, Iran, E-mail: barbato@yahoo.com*

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phthalocyanine (PLGA/Pht-Mg) as photo thermal sensitizers has shown promise in non-invasive photo thermal treatment (PTT) for cancer. However, the limited penetration of sensitizers into solid tumours of epithelial origin with tight cellular connections has been a challenge for PTT. The combination of PLGA/Pht-Mg nanoparticles with an intersection opener protein JO-4 has been found to significantly enhance the efficiency of nanoparticle penetration into tumours and improve the efficacy of PTT in both 3D and 2D cell cultures. Further research in this area could lead to the development of more effective non-invasive cancer treatments.

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## Conflict of Interest

None.

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