Hybridizing the "Hybrid" OR: A Case Report using Pulsed Electric Field Delivery in Early Stage, Non-Small Cell Lung Cancer, Treat and Resect Study "INCITE ES"

Marcelo Jimenez¹, Jose Fernandez², and William Krimsky³

¹University of Salamanca ²Instituto de Investigación Biomédica de Salamanca ³Galvanize Therapeutics

May 3, 2023

Hybridizing the "Hybrid" OR: A Case Report using Pulsed Electric Field Delivery in Early Stage, Non-Small Cell Lung Cancer, Treat and Resect Study "INCITE ES"

Marcelo Jimenez^{1,2,3}, MD, PhD, Jose M Fernandez¹, MD, and William Krimsky⁴, MD

Corresponding Authors' information:

1. Salamanca University Hospital, Paseo de San Vicente, 58-182, 37007 Salamanca

2. University of Salamanca, Paseo de San Vicente, 58-182, 37007 Salamanca

3. Instituto de Investigación Biomédica de Salamanca (IBSAL) Paseo de San Vicente, 58-182, 37007 Salamanca

4. Galvanize Therapeutics, Inc. 1531 Industrial Rd. San Carlos, CA 94070

Disclosure Statement: William Krimsky, MD is employed by Galvanize Therapeutics, Inc. Marcelo Jimenez and Jose Fernandez have not identified a conflict of interest.

ClinicalTrials.gov Identifier: NCT04732520

Funding Statement: Funding for the INCITE ES trial is provided to the Salamanca University Hospital by Galvanize Therapeutics, Inc.

EC Number and Date of Approval: C.E.I.M. reference 20/1615 (E.C.P.S.), approved January 22, 2021.

Informed Consent Statement: The patient was identified as an appropriate candidate and consented for study, standard of care procedures, and publication of the data for the Ethics Committee-approved INCITE ES trial (NCT04732520).

Corresponding Author Contact Information: William Krimsky, Galvanize Therapeutics, 1531 Industrial Rd, San Carlos, CA 94070

Article Word Count:750

Key Clinical Message: Hybrid ORs rarely support multiple specialties at once. We present a case where several specialties collaborated, mitigating non-diagnostic procedures when therapy relied on intraprocedural diagnosis.

Keywords: Lung Neoplasms, Carcinoma, Non-Small-Cell Lung, Thoracic Surgical Procedures, Operating Rooms.

Glossary of Abbreviations: OR (operating room), NSCLC (non-small cell lung cancer), CT (computed tomography), RUL (right upper lobe), PET (positron emission tomography), SUV (standardized uptake value), PEF (pulsed electric field), CBCT (cone-beam computed tomography), PACU (post anesthesia care unit).

INTRODUCTION:

The typical use of a hybrid operating room (OR) involves a variety of equipment to facilitate each individual clinician's ability to perform different procedures at different times, in the same space. The ideal state is one where different specialties share the same space so that patients benefit from an integrated procedural approach for diagnosis and treatment. This requires the collaboration of different care teams and proceduralists focused on developing an integrated care plan prior to the procedures.

Herein, we report an example in which the care plan was developed collaboratively for both diagnosis and potential treatment in a hybrid OR by two different clinical disciplines in one room during a single anesthetic event.

Clinical summary:

A 71-year-old man was referred to our thoracic surgery clinic for surgical assessment. He was a former smoker with a history of over 20 pack-years taking rivaroxaban for an atrial fibrillation and beta-blockers to treat hypertension. A computed tomography (CT) scan demonstrated a 1.2 cm spiculated nodule in the posterior segment of the right upper lobe (RUL) (Supplementary Figure 1). Positron emission tomography (PET)/CT showed a standardized uptake value (SUV) maximum of 5.9 in the nodule, and without lymph node or extra-thoracic involvement. His cranial CT was normal. The case was reviewed by our multidisciplinary lung tumor board, and the patient was deemed appropriate for surgery, with a planned RUL lobectomy and mediastinal lymphadenectomy.

The Institutional Review Board (IRB) of Salamanca University Hospital approved the study protocol and publication of data. The patient provided informed written consent for the publication of the study data. This is a treat-and-resect study evaluating the safety and feasibility of Aliya Pulsed Electric Fields (PEF) [Galvanize Therapeutics, Inc., Redwood City, CA] in patients with non-small cell lung cancer (NSCLC) tumors prior to surgical resection. The Aliya PEF system delivers a dose of non-thermal, high-voltage, and high-frequency electrical currents through a single monopolar electrode placed in the target tissue. The PEF energy destabilizes the cells, resulting in cell death, while preserving the stromal elements of tissue.

Sequential procedural access options were planned to limit the likelihood of a non-diagnostic biopsy result. In the hybrid OR, an initial bronchoscopic approach was taken by the thoracic surgeon to access the lesion. An alternate percutaneous cone-beam CT (CBCT)-guided approach by the interventional radiologist was planned in case the catheter was unable to be localized at or directly adjacent to the target using the bronchoscopic approach.

Appropriate navigation was unable to localize the catheter within the lesion and the closest position was roughly 4 mm lateral (Figure 1). Various attempts to improve the position were unsuccessful, therefore the bronchoscopic approach was abandoned and the patient was repositioned for a percutaneous approach.

The conversion to the percutaneous approach resulted in successful lesion access and biopsies were obtained. Intraprocedural diagnosis demonstrated malignancy, specifically NSCLC favoring adenocarcinoma. The percutaneous diagnostic instrument was withdrawn, and the PEF percutaneous needle and electrode were positioned within the lesion (Figure 2). PEF energy was delivered successfully. The PEF energy delivery apparatus was withdrawn, and the patient was moved to the post anesthesia care unit (PACU) without incident and discharged. The patient returned to undergo surgical resection 19 days later, which was performed via robotic assisted thoracic surgery. The surgical field was confirmed to be unaffected by the prior PEF energy delivery. The patient developed a non-continuous air leak in the immediate postoperative period and was discharged one week later following resolution.

Discussion:

Although increasingly popular, hybrid ORs are typically associated with single-specialty use. The ability to diagnose and deliver treatment in a single setting is of critical importance. Due to increasing specialization, multiple physician specialties are likely to be involved to achieve this goal.

Given the relatively deep location of the lesion within the RUL, a bronchoscopic approach was initially selected. However, there was a reasonable possibility that the catheter might not approximate the lesion. Therefore, interventional radiology was consulted in advance to provide an alternative approach. Percutaneous PEF energy was delivered successfully without impact on planned surgical resection. This case demonstrates a collaborative approach that establishes a plan of care utilizing different sub-specialties in advance of bringing the patient to the hybrid OR mitigated the likelihood of a non-diagnostic result. Thus, the need for a subsequent procedure and anesthetic was eliminated.

Legends:

Figure 1: Bronchoscopic catheter, 4 mm laterally from lesion.

Figure 2: Percutaneous needle and PEF electrode within the lesion to deliver PEF energy.

Supplementary Figure 1: Right Upper Lobe (RUL) lesion measuring 1.2 cm.

Video 1: Video abstract.

Authorship List:

Marcelo Jimenez: Conception and design, analysis and interpretation, writing, final approval, data collection, provision of materials, patients, or resources.

Jose M Fernandez: Conception and design, analysis and interpretation, final approval, data collection, provision of materials, patients, or resources.

William Krimsky: Conception and design, analysis and interpretation, writing, final approval, data collection, provision of materials, patients, or resources.





