

Safety and feasibility of a sheath cryoprobe for bronchoscopic transbronchial biopsy: The FROSTBITE trial

Thiboutot J.a · Illei P.B.b · Maldonado F.c · Kapp C.M.a · DeMaio A.a · Lee H.J.a · Feller-Kopman D.d · Lentz R.J.c · Sathyanarayan P.a · Rahman N.M.e · Silvestri G.A.f · Yarmus L.a · on behalf of the Interventional Pulmonary Outcomes Group; *Respiration* 2022;101:1131–1138; <https://doi.org/10.1159/000526876>

Background

Traditional transbronchial cryobiopsy is performed using a 1.7 mm, 1.9 mm, or 2.4 mm cryoprobe. Compared to forceps biopsy, cryobiopsy offers the potential for larger specimens with less crush artifacts and a modality that can provide 360 degree tissue acquisition. Thus, cryobiopsy may overcome the limited diagnostic capabilities of forceps biopsies.

However, traditional cryoprobes require en bloc removal of the bronchoscope, probe, and specimen from the airway, which leaves the patient vulnerable to bleeding complications and there remains a significant concern over the safety profile given reported increased rates of bleeding and pneumothorax.

Current IPF guidelines therefore suggest performing traditional cryobiopsy through a rigid bronchoscope or an endotracheal tube with a balloon blocker under fluoroscopic guidance. These recommendations have limited the widespread adoption of cryobiopsy as the expertise for these measurements is restricted to fewer centers.

Challenges and goals

Recently, a small 1.1 mm cryoprobe with an overshath has been developed. The device permits retrieval of the specimen through the working channel of the bronchoscope utilizing the same procedural approach as forceps biopsy. The bronchoscope remains in the airway throughout the procedure, thus permitting rapid assessment and management of any potential bleeding.

The FROSTBITE trial prospectively addressed the safety profile of these new 1.1 mm single use cryoprobes in patients with diffuse lung disease, lung transplant allograft evaluation, and pulmonary parenchymal lesions.

Method

FROSTBITE was a prospective, single-arm study evaluating the safety profile of a novel 1.1 mm cryoprobe with overshath for transbronchial biopsy in 50 patients. To ensure initial safety, the first 10 cases were performed using rigid bronchoscopy enabling rapid management of bleeding should it occur. After initial safety was confirmed, the procedures were moved from the OR to the bronchoscopy suite and flexible bronchoscopy was performed.

During the procedure the overshath, and subsequently the 1.1 mm cryoprobe, were inserted into the working channel of the bronchoscope. After freezing, the cryoprobe along with the biopsy specimen was extracted through the overshath while the bronchoscope remained in the airway.

Primary safety outcome of the study was the combined rate of specific severe complications: severe bleeding (bleeding requiring inflation of a bronchial blocker or stronger), symptomatic pneumothorax (requiring intervention), and device-related respiratory failure.

Results and key findings

No device related severe complications (severe bleeding, symptomatic pneumothorax, or respiratory failure) occurred. Minor complications observed were 2 pneumothoraces (4%), neither of which required aspiration or chest tube placement, and mild bleeding in 25 (50%) of cases.

Implications and recommendations

The FROSTBITE study demonstrates, that transbronchial cryobiopsy using a 1.1 mm cryoprobe with oversheath:

- Can be performed safely under standard flexible bronchoscopic practice in a routine bronchoscopy suite.
- Allows extraction of cryoprobe and biopsy sample through the oversheath while leaving the bronchoscope in place.
- Can minimize safety concerns (occurrence of pneumothorax and bleeding) across multiple disease entities.
- Has a comparable complication profile to forceps biopsy.

The FROSTBITE trial was aimed to address questions about safety of the 1.1 mm cryoprobe. Transbronchial cryobiopsy using a 1.1 mm cryoprobe is feasible with an acceptable safety profile comparable to conventional forceps. Thus, it was not powered to assess the diagnostic yield, yet, early data suggests promising results on diagnostic yield. This will be further evaluated in an upcoming randomized controlled trial.

Products

For FROSTBITE the flexible single-use 1.1 mm cryoprobe with oversheath was used in combination with the ERBECRYO® 2.



*Flexible cryoprobe for single use, 1.1 mm
(20402-401)*

Reference

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