

A Randomized Controlled Trial of EBUS under General Anesthesia versus Moderate Sedation

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Background: Data about the influence of anesthesia type on yield, complications, and tolerance of EBUS-TBNA is mostly based on retrospective studies and it is largely inconsistent. These are preliminary results from our prospective randomized trial.

Methods: Adults with an indication for EBUS-TBNA of mediastinal or hilar lymph nodes were randomized (1:1) to undergo the procedure under general anesthesia (GA) versus moderate sedation (MS). Cytologists were blinded to randomization arm. The main objectives were diagnostic yield and sensitivity. The study was self-funded.

Results: A total of 57 patients were performed under GA and 52 under MS. The median age was 65 years (range 46 to 77) and 66 years (range 43 to 84) in the GA and MS group, respectively. There were no significant differences in baseline comorbidities and ASA score. There were no differences in the indications for EBUS-TBNA: diagnosis (GA 32%, MS 31%), staging (GA 26%, MS 25%), both diagnosis and staging (GA 33%, MS 34%), or re-staging (GA 9%, MS 10%). Per patient, an average of 3.03 +/- 1.8 lymph nodes (LN) were sampled in the GA group vs. 2.55 +/- 1.6 in the MS group (p=NS). The average LN size was 11mm +/- 6mm (standard deviation) in the GA group, vs. 12 +/- 7mm in the MS group (p=NS). Procedure time (first scope in/last scope out) was 25 +/- 15 min in the GA group and 21 +/- 9 min in the MS group. In the MS group, the average doses of Midazolam was 4 mg, and the average dose of Fentanyl was 100 mcg. Samples were adequate in 100% of LN in the GA group vs. 99.8% of LN in the MS group. A specific diagnosis was found in 72% of patients in the GA group vs. 67% in the MS group (p=NS). Sensitivity was 98% in the GA group and 94% in the MS group (p=NS). Malignancy was found in 61% of GA group and 51% of MS group. There were no EBUS-related complications in either group. Sedation/anesthesia related complications were only minor, and more common in the MS group (25% vs. 7%) (p<0.05). Patients' tolerance was assessed post-procedure with a Likert scale questionnaire, showing no significant difference.

Conclusions: Anesthesia type seems to have no influence on EBUS-TBNA diagnostic yield, but a greater rate of minor sedation-related complications was detected in the MS group. Final results will be available at the meeting.