

Is Hypertonic Saline Nebulization Effective in Maintaining Central Airway Stents? A Pilot Randomized Controlled Trial

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The clinical question

Does the use of nebulized 3% hypertonic saline reduce the incidence of obstructive mucus plugging compared to normal saline following central airway stent placement?

Study Conclusions

Nebulized 3% saline is safe and may be more effective than normal saline in preventing obstructive mucus plugging after central airway stenting. This pilot RCT provides foundational data supporting the feasibility and potential benefit of hypertonic saline, warranting validation in a larger, multicenter trial.

Study Background

Airway stenting offers a minimally invasive approach to palliate central airway obstruction but complications of stents including mucus plugging are common.

Saline nebulization at different concentrations can be beneficial in conditions such as cystic fibrosis and bronchiectasis. To that end, studying its efficacy in maintaining airway stent patency is paramount.

Current guidelines recommend the use of pulmonary hygiene to avoid complications following tracheobronchial stenting but there is no data to guide this and there is significant variation in practice.

The prescribed regimens for maintaining airways stent patency varies significantly between centers and includes combinations of saline nebulization, bronchodilators, expectorants, mucolytics, and bronchopulmonary hygiene devices. There is no data to support this practice or consensus on the ideal regimen. When it comes to saline nebulization concentrations, it is generally thought that higher concentrations are more effective but lead to more irritation and side effects (e.g. bronchospasm).



Study Design

- **Design:** Single-center, unblinded, prospective, randomized pilot trial
- **Primary Outcome:** Incidence of obstructive mucus plugging requiring intervention
- **Secondary Outcomes:** Biofilm formation, granulation tissue requiring intervention, stent migration, adverse effects
- **Interventions:** 3 mL of nebulized 3% saline vs. 3 mL of normal saline, three times daily
- **Duration:** 4–6 weeks, ending with surveillance bronchoscopy

Population



Inclusion Criteria

- Adults (≥ 18 years) with central airway stent placement

Exclusion Criteria

- Lobar/segmental stents, tracheostomy, early stent removal, or inability to complete surveillance bronchoscopy

Baseline Characteristics

- **Patients analyzed:** 23 (13 in 3% saline group; 10 in normal saline group)
- **Age (mean):** 57 years (3%S) vs. 64 years (NS)
- **Gender:** Female majority in both groups (54% vs. 80%)
- **Smoking:** Mostly never or former smokers; 10% active smokers in NS group
- **Functional status:**
 - mMRC ≥ 2 in all; ECOG ≥ 2 in 85% (3%S) vs. 100% (NS)
- **Stent indication:**
 - Malignant: 31% (3%S) vs. 60% (NS)
 - Benign: 69% (3%S) vs. 40% (NS)
- **Stent type:**
 - Silicone: 85% (3%S) vs. 60% (NS)
 - SEMS: 15% (3%S) vs. 40% (NS)
- **Stent location:** Similar distribution between trachea and main bronchi



Outcomes

Primary outcomes:

- Obstructive mucus plug: 7.7% (1/13) 3% saline vs. 40% (4/10) normal saline

Secondary:

- Biofilm >25%: 0% (3% saline) vs. 30% (normal saline)
- Unscheduled bronchoscopy: 0% (3% saline) vs. 20% (normal saline)
- Granulation needing intervention: 7.7% (3% saline) vs. 10% (normal saline)
- Stent migration: None in either group

Adverse Events: None attributed to nebulized saline

Commentary

This pilot randomized controlled trial offers important preliminary insights into post-stenting airway hygiene. As the first RCT comparing 3% hypertonic saline to normal saline for central airway stent maintenance, the study addresses a relevant clinical gap. Notably, the trial demonstrates both the feasibility of enrollment and the potential clinical impact of hypertonic saline in reducing mucus plugging—an outcome with clear implications for patient safety and hospital utilization.

However, interpretation must be cautious due to several limitations:

- **Small sample size** and pilot nature limit statistical power and generalizability.
- **Lack of blinding** introduces potential bias in outcome assessment, particularly for subjective endpoints like mucus plugging or granulation tissue.
- **Short follow-up** (4–6 weeks) may not capture longer-term complications or tolerability issues.
- **Subjective assessments** (e.g., biofilm grading) were not validated or standardized, potentially affecting reproducibility.
- **Compliance** with the nebulization regimen was self-reported and not objectively verified.

Despite these caveats, the observed effect sizes are clinically meaningful and provide a strong rationale for a larger, multicenter, blinded trial. Additionally, this study highlights the **lack of standardized airway hygiene protocols** post-stenting—a practice area currently driven more by anecdote than evidence. As interventional pulmonology grows, establishing data-driven, reproducible care pathways for stent maintenance will become increasingly important.



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Suggested reading

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