Cadaveric Simulation of Otologic Procedures: An Analysis of Droplet Splatter Patterns During the COIVD-19 Pandemic

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Keywords: COVID-19, Droplets, Splatter, Myringotomy, Mastoidectomy, Otologic Surgery

Disclosure: The authors have no conflict of interests to disclose. This work has not been submitted for publication elsewhere.

Word Count: 1,744
ABSTRACT

Objective: The otolaryngology community has significant concerns regarding the spread of SARS-CoV-2 through droplet contamination and viral aerosolization during head and neck examinations and procedures. The objective of this study was to investigate the droplet and splatter contamination from common otologic procedures.

Study Design: Cadaver Simulation

Setting: Dedicated Surgical Laboratory

Subjects and Methods: Two cadaver heads were prepped via bilateral middle cranial fossa (MCF) approaches to the tegmen (n=4). Fluorescein was instilled through a 4-mm burr hole drilled into the middle cranial fossa floor, and presence in the middle ear was confirmed via microscopic ear examination. Myringotomy with ventilation tube placement and mastoidectomy were performed, and the distribution and distance of resulting droplet splatter patterns was systematically evaluated.

Results: There were no fluorescein droplets or splatter contamination observed in the measured surgical field in any direction after myringotomy and insertion of ventilation tube. Gross contamination from the surgical site to 6 feet was noted after complete mastoidectomy, though, when performed in standard fashion.

Conclusion: Our results show that is no droplet generation during myringotomy with ventilation tube placement in an OR setting. Mastoidectomy, however, showed gross contamination 3 to 6 feet away in all directions measured. Additionally, there was significantly more droplet and splatter generation to the left of the surgeon when measured at 1 and 3 feet compared to all other measured directions.
Introduction

The current global pandemic brought about by the novel coronavirus 2019 (COVID-19) has led to sweeping transformative change in the healthcare sector. United States hospitals have essentially ceased all elective non-urgent surgical cases in accordance with Centers for Disease Control guidelines, and much uncertainty remains on how to resume safely. In the current climate, the safety of otolaryngology procedures is of particular concern, as current evidence suggests elevated risk due to close contact with upper respiratory mucosa, which harbors a high viral load.

Viral transmission is thought to be primarily via respiratory droplets, which can travel greater than 2 meters and linger on contaminated surfaces for hours if not days. This has led to significant concern for the transmission of the novel coronavirus due to aerosol generating procedures (AGP). As a result, the American Academy of Otolaryngology-Head and Neck Surgery has issued a position statement to limit elective procedures requiring interaction with upper airway mucosal surfaces or those with increased risk of aerosolization which may include otologic procedures such as myringotomy and mastoidectomy.

However, to our knowledge, no published literature exists to guide decision making on the safety of these common otologic procedures. This is an important area of investigation due to the potential for the middle ear and mastoid to harbor respiratory pathogens and for droplet dispersion and aerosol generation while using high speed
drills. This study seeks to investigate and clarify these risks by evaluating droplet dispersion patterns resulting from otologic procedures in a cadaver-simulated series.

Materials and Methods

Supplies and Equipment

The study was exempt from institutional review board (IRB) because it involved the use of non-living human cadaveric tissue specimens (IRB protocol # 2004100753). The experiments in this study were all conducted in a dedicated surgical laboratory on two fresh-frozen cadaver head specimens prepared in identical fashion and placed in a standard position for the procedures.

Using the following technique, a middle cranial fossa (MCF) approach was performed bilaterally on both specimens to expose the floor of the MCF. An approximately 6 x 8 cm posteriorly based trapdoor incision was made superior to the auricle down to the calvarium, and then a 6 x 6 cm bone flap, centered above the temporal root of the zygoma, was fashioned with a size 4-mm cutting burr. After the MCF floor was completely exposed, a 4-mm port was drilled into the middle ear through the tegmen.

Fluorescein solution at a concentration of 1 mg/ml was created by mixing 500 mg of fluorescein 10% (100 mg/mL) AK-Fluor® (fluorescein injection, USP) with 495 ml of sterile saline. The 1 mg/ml fluorescein solution was instilled using a 14 G angiocath through the port into the middle ear space (Figure 1A). The presence of fluorescein in
the middle ear space was confirmed endoscopically by visualization through the
external auditory canal (Figure 1B).

Experimental Setup

Each cadaver head was placed in the standard otologic position. Procedures were
performed by a right-handed surgeon. Three sets of 183 cm (6 feet) x 50 cm (1.64 feet)
pieces of nonabsorbent blue paper affixed to a rigid backing were placed 90 degrees
from each other in the following directions: 1) left of the surgeon 2) anterior to the head
or across from the surgeon 3) right of the surgeon (Figure 2). A 25 x 25 cm piece of
nonabsorbent blue paper was also affixed to the surgeon’s gown on the chest. The
surgeon also wore a face-shield throughout the procedure.

Experiment

The following surgical procedures were performed systematically on each head: 1) left-
sided myringotomy with insertion of a ventilation tube (MVT) 2) left-sided complete
mastoidectomy, including entry into the mastoid antrum and exposure of the tegmen,
sigmoid sinus, and lateral semicircular canal 3) right-sided myringotomy with insertion of
a ventilation tube 4) right-sided complete mastoidectomy. A Stryker S2 πDrive Drill with
a 6mm Multi Flute burr was utilized for each mastoidectomy procedure. Table 1
summarizes the procedures that were performed on the two cadaver heads and the
duration.
Following each of the above listed surgical procedure, the number and distance of the
droplets and splatter on the non-absorbent blue paper was evaluated and measured by
the following technique. 25 x 25 cm transparent grid graphs were laid side-by-side at 1,
3, and 6 feet from the surgical site. The blue paper on the surgeon’s chest was
removed, laid flat, and a grid was placed on it as well. The surgeon’s face shield was
removed, laid flat, and blue paper with an overlying grid was placed underneath it.

Since fluorescein fluoresces yellow under ultraviolet light and blue paper does not, the
evaluators used an ultraviolet light to visualize the droplets and splatter from each
experimental condition. The evaluators then counted and recorded the number and
distance of any 1 cm$^2$ area containing any illuminated fluorescent spot or any gross
contamination. Fluorescein did not penetrate the bone, but was limited to the mucosa.

**Results**

No observable fluorescein droplets were noted in the measured surgical field in any
direction after myringotomy and insertion of ventilation tube. Visible fluorescein
contamination was noted only on surfaces in direct contact with surgical instruments. In
contrast, gross contamination was measured 3 feet in all cardinal directions after every
mastoidectomy. The number of droplets identified at 1 and 3 feet to the left of the
surgeon was significantly than the number on the right of the surgeon or across from the
surgeon. The right side of the surgeon was found to have significantly more splatter
and droplets then across at 1 foot (Table 2). After each mastoidectomy, the surgical
fields within 6 inches, the hands and arms, face-shield as well as the chest were also grossly contaminated by droplets and splatter after all mastoidectomies.

**Discussion**

COVID-19 has rapidly disseminated from the Hubei province of China across the globe, with over 3 million confirmed cases in 212 countries as of April 29th, 2020. The primary mode of viral transmission of SARS-CoV-2 is believed to be through the spread of respiratory droplets, which has led to significant community spread of the disease. The potential for spread through opportunistic aerosolization during aerosol generation procedures is also a concern. Since the upper respiratory tract harbors a high viral load, otolaryngologists are vulnerable to SARS-CoV-2 transmission while performing head and neck procedures utilizing suction and powered instrumentation such as the surgical drill, especially if they are doing so without appropriate protective personal equipment (PPE). With its connection to the nasopharynx through the eustachian tube, the middle ear can serve as a possible source of transmission for upper respiratory tract pathogens while performing routine otologic procedures, such as myringotomy and mastoidectomy. With the persistence of SARS-CoV-2 in the general population for the foreseeable future, we will need to navigate these risks as we resume elective surgical procedures and perform urgent operations on patients whose SARS-CoV-2 status is unknown or positive.

In conducting this cadaveric simulation study, the authors confirmed that performing a myringotomy with insertion of ventilation tube caused no droplet or splatter contamination. The potential for aerosolization remains, however, when suction is used across a mucosal surface. In contrast, a complete mastoidectomy performed in standard fashion resulted in gross contamination up to 6 feet from the surgical site,
which was the farthest distance measured. Aerosol generation with surgical drills has previously been established in the orthopedic literature\textsuperscript{13}. This is likely secondary to the nature of the operation, which involves high-speed drilling of the temporal bone under irrigation creating visible splatter from bone dust and irrigation droplets. Our study also demonstrated that significantly more droplet and splatter occurs to the left of the surgeon which corresponds to the direction of rotation of the drill. Those within 1 to 3 feet of the drill are at increased risk of exposure. In teaching institutions where multiple members of the team may be directly adjacent to the primary surgeon, this must be taken into account. While the drill is being operated, all steps should be taken to reduce the number of other people within a 3 to 6-foot radius.

There are several limitations to this cadaveric simulation study that deserve consideration. These procedures were not conducted in a normal adult clinic setting with an actively respiring patient. Patients can have a cough reflex when maneuvering within the external auditory canal that may result in increased risk of viral transmission. Moreover, there was no assessment of aerosolization, either forced (e.g. sneezing) or from drilling, in this experimental model. However, we believe it is still vital to understand the quantity, quality, and range of droplet and splatter contamination involved during these common procedures, as respiratory droplets are considered to be the primary mode of transmission of SARS-CoV-2. Another limitation is that only droplets and splatter visible to the human eye were measured. Furthermore, instead of a complete 360-degree assessment, the design model allowed for measurements only in the cardinal directions surrounding the specimen.

In the context of the findings from this study, we believe it is important to devise techniques to limit the spread of gross contamination from mastoid surgery. This will not be easily accomplished, because it is difficult to operate using a microscope while
wearing a face shield or powered air purifying respiratory (PAPR). Risks to the rest of the surgical staff and anesthesia team also are present in the operating room, which highlights that additional PPE is necessary for the surgical team, not just the operating surgeon. Carron et al. recently published a simple technique involving the use of two readily available clear surgical drapes to control droplet and splatter contamination during mastoidectomy. They reported that surgical visualization was not affected. Although a good step in the right direction for preventing the spread of gross contaminant, this methodology does not create an air-tight surgical field, and droplet or splatter contamination were not measured in any objective way. Further studies should be performed comparing different techniques to determine the extent of prevention of droplet contamination and aerosolization.

Conclusion

It is essential to evaluate all procedures that have a risk of disrupting respiratory epithelium and spreading SARS-CoV-2. Our results indicate that there is no droplet generation during myringotomy with ventilation tube placement in an OR setting. For mastoidectomy however, gross contamination was visualized 3 to 6 feet away in all cardinal directions, and significantly more occurred on the left side of the surgeon when compared to the other sides, corresponding to the direction of rotation of the drill. It is critical to develop techniques to contain contamination as much as possible.
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doi/10.1001:jamaoto.2020.1064
### Tables

#### Table 1: Droplet Splatter Results

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Duration</th>
<th>Droplet or Splatter Contamination</th>
<th>Across</th>
<th>Left</th>
<th>Right</th>
<th>Chest</th>
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<tbody>
<tr>
<td>Left MVT in Cadaver 1</td>
<td>57s</td>
<td>No</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Left MVT in Cadaver 2</td>
<td>51s</td>
<td>No</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Right MVT in Cadaver 2</td>
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<td>0</td>
<td>0</td>
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<td>0</td>
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<tr>
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<td>Yes</td>
<td>36 (1)</td>
<td>11 (3)</td>
<td>625 (1)</td>
<td>190 (1)</td>
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<tr>
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<td>Yes</td>
<td>160 (1)</td>
<td>2 (3)</td>
<td>625 (1)</td>
<td>176 (1)</td>
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<td></td>
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<td></td>
<td>2 (6)</td>
<td>56 (3)</td>
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<tr>
<td>Right Mastoidectomy in Cadaver 1</td>
<td>9m, 25s</td>
<td>Yes</td>
<td>34 (1)</td>
<td>4 (3)</td>
<td>577 (1)</td>
<td>236 (1)</td>
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<td>47 (3)</td>
<td>11 (3)</td>
<td>0 (6)</td>
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<td>Right Mastoidectomy in Cadaver 2</td>
<td>5m, 26s</td>
<td>Yes</td>
<td>115 (1)</td>
<td>6 (3)</td>
<td>599 (1)</td>
<td>201 (1)</td>
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<td>17 (3)</td>
<td>13 (3)</td>
<td>0 (6)</td>
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</table>

Directions specified with respect to the operating surgeon. MVT = myringotomy with ventilation tube placement; m = minutes; s = seconds; (1) = 1 foot; (3) = 3 feet; (6) = 6 feet.

#### Table 2: Droplet Splatter Analysis

<table>
<thead>
<tr>
<th>Distance (ft)</th>
<th>Across</th>
<th>Left</th>
<th>Right</th>
<th>Two-tailed t test Left vs. Right</th>
<th>Two-tailed t test Left vs. Across</th>
<th>Two-tailed t test Right vs. Across</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>86.25</td>
<td>606.50</td>
<td>200.75</td>
<td>&lt; 0.0001**</td>
<td>&lt; 0.0001**</td>
<td>0.0142*</td>
</tr>
<tr>
<td>3</td>
<td>5.75</td>
<td>42.75</td>
<td>10.00</td>
<td>0.0109*</td>
<td>0.0062**</td>
<td>0.1812</td>
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<tr>
<td>6</td>
<td>0.75</td>
<td>1.50</td>
<td>3.25</td>
<td>0.5010</td>
<td>0.5801</td>
<td>0.2969</td>
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</tbody>
</table>

* p-value < 0.05, ** p-value < 0.01; ft = feet
Figure Legends

Figure 1A: Instillation of Fluorescein into the middle ear via MCF approach

Figure 1B: Endoscopic confirmation of Fluorescein behind the tympanic membrane

Figure 2: Schematic of experimental set up for cadaveric simulation
This manuscript has been accepted for publication in Otolaryngology-Head and Neck Surgery.
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