Project Title: Determining the impact of external sensory stimuli on patient preferences during outpatient surgery

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1. Abstract

The dermatologic Surgery Unit at the University of Missouri Department of Dermatology does over 2000 procedures annually on an outpatient basis under local anesthesia with patients completely awake for their procedures. Most of these procedures are on the head and neck, and as such, electrosurgical smoke is produced near the nose and mouth of the patients with no means for minimizing that exposure because, as yet, there is no institutional policy on surgical smoke evacuation. It has been our experience that patients uniformly find the odor of the smoke offensive, with a few patients experiencing wartime PTSD episodes due to the smell. It has recently been highlighted in the medical literature that there are health risks for medical providers and staff related to inhalation of electrosurgical smoke. We seek to define patient attitudes toward the use of smoke evacuation and the potential impact of an outpatient smoke evacuation protocol on patient satisfaction.

2. Objectives

Perform a randomized controlled trial to prospectively determine the effect of smoke evacuation on the patient experience by studying:

1. The degree to which patients notice surgical smoke
2. The effect that smoke evacuation has on patient satisfaction with their procedure
3. The relative value of smoke evacuation to the patient

3. Background

During surgery, use of electrosurgical units causes thermal destruction of tissue and generates smoke that has been shown to contain harmful chemicals as well as live cellular material.[1-9] A study has shown that treating one gram of tissue with an electrosurgical unit produces chemical byproducts equivalent to smoking six unfiltered cigarettes.[9] Electrosurgical smoke has been shown to include nitriles, benzenes, carbon monoxide, hydrogen cyanide, indoles, phenols, pyridine, pyrrole, styrene, toluene, and xylene.[3] Benzene is a known trigger for leukemia. Surgical smoke exposure has been shown to cause pathologic lung changes in rats including interstitial pneumonia, bronchiolitis, and emphysema in a dose-dependent manner.[4] Exposure to surgical smoke in humans has also been linked to illness and symptoms including acute and chronic inflammatory changes of the lungs, anemia, eye irritation, hypoxia, dizziness, nasopharyngeal lesions, vomiting, sneezing, throat irritation, and weakness.[5] Because blood particles, viruses, and bacteria can travel via smoke it may transmit diseases such as human papilloma virus (HPV) which have been recovered from plume samples.[7] HIV DNA has also been identified in surgical smoke with transmission to cultured cells.[7] In one study, smoke specimens taken from thirteen procedures grew coagulase-negative Staphylococcus, Corynebacterium, and Neisseria species.[8] Citing these known health risks and our experience of patients almost uniformly objecting to the smell and presence of the smoke during their procedures, we seek to define patient attitudes

toward smoke evacuation as this information will be useful in forming hospital policy and possibly national policies on the value of smoke evacuation.

4. Study Procedures

a. Study design:
    i. Randomized Controlled Trial
    ii. Patients: All adult (> 18 years old) patients presenting for Mohs surgery and reconstruction for the treatment of nonmelanoma skin cancer on the head and neck
    iii. To avoid response bias, patients will be asked to participate in a research study that determines the impact of external sensory stimuli (lights, smoke, and noise) on their preferences during outpatient surgery. Patients will not be made aware of the smoke evacuation randomization component of study until debriefing following questionnaire completion.
    iv. After obtaining informed consent, patients will be randomized into two arms, a treatment arm where patients will have smoke evacuation used during the entirety of their procedure and a control arm where patients will have surgery carried out with standard electrosurgery without smoke evacuation. The control arm represents the current standard of care for patients receiving this type of procedure both inside our institution and nationwide.
    v. Immediately following surgery and prior to departure from their clinical visit, patients will be asked to respond to a questionnaire. To prevent response bias patients will be asked questions about their experience with surgical lights, surgical smoke, and surgical noises during their procedure. Questionnaires have no identifiers and subjects will deposit completed forms into a collection box to maintain anonymity.
    vi. After completing the questionnaire, patients will be debriefed to explain deception involved in smoke evacuation randomization and asking questions about light, noise, and smoke when goal of the study is only to determine patients experience with smoke.

b. Study duration and number of study visits required of research participants.
    i. Duration sufficient to enroll approximately 160 patients (80 per treatment arm). No additional patient visits will be required beyond the visit normally required for their procedure.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.
    i. N/A.

d. Justification of why participants will not receive routine care or will have current therapy stopped.
    i. Care will be identical in both arms except for the introduction of smoke evacuation in the treatment arm. Smoke evacuation is not our institutional policy presently and is not the nationwide norm.

e. Justification for inclusion of a placebo or non-treatment group.
    i. As stated, the "non-treatment" group is still being cared for in accordance with the current nationwide standard of care.

f. Definition of treatment failure or participant removal criteria.
    i. We do not foresee a scenario where treatment failure would be possible as this research is targeting the effect on patient experience of an intervention with a tool in our operating suite. A patient would be removed from the study if they did not complete their procedure. This is an exceedingly rare occurrence.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

i. There would be no effect on the patient.

5. Inclusion/Exclusion Criteria

a. Adult (18 years old and older) patients being treated for nonmelanoma skin cancer on the head and neck with Mohs surgery and a subsequent repair will be included in this study

6. Drugs/ Substances/ Devices

a. The smoke evacuation device being used does not make contact with patients or pose any additional risk to study patients. There is evidence to suggest that use of smoke evacuation may decrease risk to patients during surgical procedures by eliminating hazardous smoke.

7. Study Statistics

a. Primary outcome variable.
   i. Degree to which patient notices surgical smoke
   ii. Degree to which surgical smoke affected patient satisfaction
   iii. Perceived value of smoke evacuation for the patient
b. Secondary outcome variables.
   i. None
c. Statistical plan including sample size justification and interim data analysis.
   i. Results of a completed pilot study were used to determine a sample size of 140-150 is necessary to test with a 0.05 significance level and greater than 90% power to reject the null hypothesis.
   ii. All of the responses to the questions will be on an ordinal scale. Outcomes will be compared using the Cochran-Armitage test for trend.
d. Early stopping rules.
   i. None.

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.
   i. The smoke evacuation device is FDA approved and does not make contact with patients and poses no risk during the surgical procedure.
b. Steps taken to minimize the risks.
   i. N/A
c. Plan for reporting unanticipated problems or study deviations.
   i. Will report all deviations and problems to IRB.
d. Legal risks such as the risks that would be associated with breach of confidentiality.
   i. N/A.
e. Financial risks to the participants.
   i. N/A.

9. Benefits

a. Description of the probable benefits for the participant and for society.
   i. Elimination of harmful smoke from the operating environment has health benefits for the individual patient. Determining the degree to which patients notice the intervention, how much the intervention affects patient satisfaction with their procedural experience, and what value patients assign to the ability to eliminate smoke will help inform policy both in our institution and possibly nationwide.

10. References

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