Component Analysis of Surgical Smoke and Evaluation of Reduction through the Use of Smoke Evacuator Devices

Research Protocol

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Title of Research

		Page
1.	Title of research	3
2.	Organization of the research	3
3.	Purpose and significance of the research	4
4.	Method and duration of the research	5
5.	Selection of research subjects	7
6.	The rationale for the scientific rationale of the research	8
7.	Procedures for receiving IC	9
8.	Handling personal information, etc.	9
9.	Burden, risk, and benefit to research subjects	10
10.	Storage and disposal of samples and information	10
11.	Reporting to the head of the research institution	12
12.	Sources of funding/conflicts of interest	12
13.	Disclosure of information on research	12
14.	Consultation with research subjects	12
15.	Obtaining IC from surrogate donors	12
16.	Obtaining assent	12
17.	Confirmation of requirements for obtaining consent	13
18.	Financial burden/gratuity	13
19.	Response to serious adverse events	13
20.	Health Damage Compensation	13
21.	Provision of medical care after research is conducted	14
22.	Handling of important findings and research results	14
23.	Outsourcing of work, supervision of contractors	14
24.	Future research use of samples and information	14
25.	Monitoring and auditing	14

1. Name of research

Component Analysis of Surgical Smoke and Evaluation of Reduction through the Use of Smoke Evacuator Devices

2. Research implementation organization

Principal Research Institution
Hepato-Biliary-Pancreatic Surgery Division, Department of Surgery,
Graduate School of Medicine, The University of Tokyo, Tokyo Japan
Responsible for: Data collection, anonymization, data analysis

Collaborating Institution
Environmental Technology Center co., Ltd, Saitama, Japan
Responsible for: Analysis of surgical smoke

Research Institution
Principal Research Institution
Hepato-Biliary-Pancreatic Surgery Division, Department of Surgery,
Graduate School of Medicine, The University of Tokyo

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3. Purpose and Significance of the Study

[Background] It is known that smoke (surgical-related smoke) is generated when energy devices (electrocautery, vascular coagulation devices, etc.) are used during surgery. It is known that smoke contains toxic substances [1, 2], but it is unknown which components and to what extent, and how much of the toxic substances in the smoke can be removed by using surgical smoke evacuation devices that are commercially available for medical use. Several companies sell smoke evacuation devices for medical use, but their use is not widespread. Our operating room does not have a surgical smoke evacuation system, and it is not used during surgery. We hypothesized that the use of surgical smoke evacuation devices removes toxic substances from smoke, and planned a clinical study to verify this hypothesis.

[Purpose] In this study, we will conduct a multicenter study on the types and amounts of toxic substances in surgical smoke by randomly assigning patients to use or not to use surgical smoke evacuation devices to verify our hypothesis and the preliminary results of a small number of cases. The findings of this study will lead to a wider recognition of the harmfulness of surgical smoke and the usefulness of surgical smoke evacuation devices and may lead to the prevention of health hazards for healthcare workers in the operating room in the future.

[In this study, we randomly assigned patients to use or not to use surgical smoke evacuation devices to examine the types and amounts of hazardous substances in surgical smoke to verify the hypothesis and the results of a preliminary study using a small number of cases. The findings of this study will lead to a wider awareness of the

harmfulness of surgical smoke and the usefulness of surgical smoke evacuation devices and may lead to the prevention of health hazards for healthcare workers in the operating room in the future.

[References]
1. Limchantra, I. V., et al. (2019). "Surgical Smoke Exposure in Operating Room Personnel: A Review. "JAMA Surg.
2. Al Sahaf, O. S., et al. (2007). "Chemical composition of smoke produced by high-frequency electrosurgery," Ir J Med Sci 176(3): 229-232.

4. Methods and duration of the study

[Methods]
This is an observational study without invasive intervention.
The study will be conducted with those who have obtained a consent form (page 16) after the explanation of the study is provided in the Explanation Document (pages 13-15). The Consent Withdrawal Document (page 17) will also be distributed to provide an opportunity for withdrawal after consent has been given.
2. Patients who meet the inclusion criteria and have given consent will be assigned to the surgical smoke evacuation device use group (A) or non-use group (B) without the knowledge of the operating physician. At this point, patients will be anonymized with a "subject identification code" that will be set up at the facility to enable the linking of subjects.
3A. Intervention group (surgical smoke evacuation system)
A surgical smoke evacuation device (Vigilia Smoke Evacuation System, model no. VC120, ConMed) and smoke suction tube (22 mm x 3.0 m smoke evacuation tube, model no. VTWT624, ConMed) were used (ConMed). ConMed) (Figure 1). The smoke suction tube is placed so that the tip of the tube is 5 cm from the planned incision at the time of laparotomy, as it is used in actual clinical practice. The surgical smoke evacuation device is placed about 1 m away from the operating table, as used in actual clinical practice. The smoke evacuation device is switched on at the start of the laparotomy procedure.

Figure1

3B. Control group (no use of surgical smoke evacuation device)
The same preparation and procedures as in 3A are performed, but the surgical smoke evacuation device is not connected to the smoke suction tube. (This is to reduce the bias of the surgeon to know whether the smoke evacuation device is used or not.
4. A sterile cover is placed over a table (20 cm headward and 20 cm above the upper edge of the planned incision) on which a small smoke collection device is placed approximately above the patient's face (1) Mini-pump, model number: MP-W5P, Shibata Scientific Corporation, [Figure 2]) (2) Particle counter, model number: Model 804, Shibata Kagaku Corporation, [Figure 3]). Collect for 10 minutes from the start of the operation. 5.
5. The collected smoke is analyzed at the Environmental Technology Center co., Ltd outside the university to which the co-researcher belongs, with a subject identification code assigned.

Figure 2

Figure 3

[Period]

Registration Period/Subject Period: From the date of approval to March 31, 2022
Institution: From the date of approval to March 31, 2023

[Anonymization]
Subjects will be anonymized by the "subject identification code" set in the institution as described above to enable linking. The principal investigator or co-investigator at the collaborating institution will use a "subject identification code" that is unrelated to the subject's name and hospital ID and register the subject with that number. The code will be used only for this study. No personally identifiable information will be used when the results of the study are published.

[Analysis method]
The Student's t-test will be used to compare the detected amounts of acetaldehyde, formaldehyde, and emissions by particle size in the two groups (surgical smoke evacuation device-using group vs. non-user group).

[primary endpoint]
Quantitative measurement of acetaldehyde in surgical smoke.
To verify whether the surgical smoke evacuation device reduces the amount of the above toxic substances.

[Secondary endpoint]
Quantitative measurement of formaldehyde in surgical smoke.
Measurement of emissions by particle size in surgical smoke (measurement by 0.3μm, 0.5μm, 1μm, and 2μm is possible).
Also, evaluate the differences in formaldehyde and particle size emissions using surgical smoke evacuation equipment.

5. Selection of research subjects
[Number of research subjects] Overall expected number of subjects: 40 cases (40 cases at the University of Tokyo)

[Selection criteria]
1. Inclusion criteria
Patients aged 20 years or older undergoing laparotomy at the primary research

institution. Patients who have given their own consent for this study. Since the amount of surgical smoke emission during laparotomy is considered to be affected by the amount of subcutaneous fat and gender, patients will be randomly assigned to a group with or without surgical smoke evacuation device based on age, gender, and body mass index.

2. Exclusion Criteria

Patients under 19 years of age. Patients who did not give consent for this study.

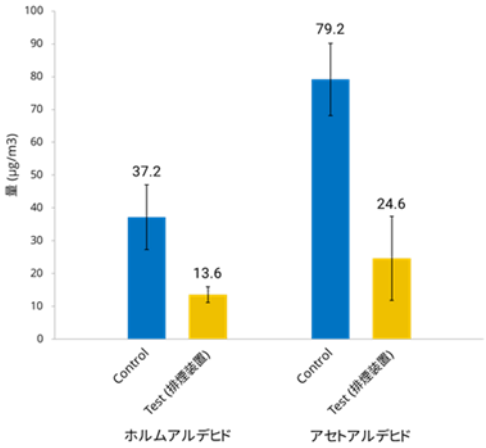
6. Rationale for the scientific rationale of the study

Smoke generated during surgery was collected and measured for the purpose of evaluating the operating room environment. After a close examination of the evaluation procedure, we found that there was no process that interfered with normal medical treatment or surgery, and that there was no invasiveness to the patient because we were only collecting smoke generated in the operating room. After explaining the situation to the head of the surgery department, smoke samples were collected and analyzed in the operating room. The operating room environment was evaluated under the following conditions: 3 patients were not using smoke evacuation devices, and 3 patients were using smoke evacuation devices (the smoke evacuation devices were used as samples for clinical evaluation purposes). Toxic substances that were noticeably elevated in the surgical smoke were formaldehyde and acetaldehyde. The results of detected amounts by use vs. non-use of smoke evacuation devices are shown in Figure 4. Comparing the results of the preliminary study with the guideline values of the Ministry of Health, Labor and Welfare's "Study Group on Indoor Air Pollution Problems," it was found that the amount of acetaldehyde detected was higher than the guideline values. Based on these results of the environmental assessment in the operating room, further scrutiny was considered necessary, and this study was planned to take into account various factors such as patients' clinical information (age, gender, body mass index, and with/without smoke evacuation devices).

The results of environmental measurements in the same operating room were used as a reference to calculate the sample size for this study. A sample size test was conducted using SAS, version 9.4 (SAS Institute Inc.) to test the hypothesis that acetaldehyde emissions, which were above the standard value, would decrease from 79.2 μg/m3 to 24.6 μg/m3 when smoke evacuation devices were used, with α: 0.05 and β: 0.1. The required number of subjects was 6 in both groups. The number of persons required for the hypothetical decrease to the guideline value of 48 μg/m3 was 10 for

both groups. Considering the possibility of sample collection errors, 40 patients in both groups will be included. Because this study also requires the collection of clinical information on patients, it will be conducted after ethical review.

Figure 4



7. procedure for receiving IC

After patients undergoing surgery at the Department are admitted, an xplanation and consent for this study will be obtained at the time when other Department-led research is explained during the IC regarding surgery prior to surgery. Patients who have had this study explained to them using the Explanation Document (pp. 13-16) and who have obtained a Consent Form (p. 17) will be considered for this study. A Consent Withdrawal Document (p. 18) will also be distributed to provide an opportunity for withdrawal after consent is given.

8. Handling personal information

Surgical-related smoke to be dispersed during surgery will be collected, and clinical information will be collected. Both will be anonymized at the University of Tokyo by creating a correspondence table. The former will be handed directly to the co-researcher at the University of Tokyo in anonymized form on the day the smoke is collected, and the components will be analyzed at the Environmental Technology Center co., Ltd, which is a joint research facility. Clinical information will be collected at the University of Tokyo, and this data will not be passed on to outside parties.

9. Burden, risks, and benefits to research subjects

(1) Physical and psychological burden and potential risks (including cost burden, time, and information leakage)

There is no physical risk because the research will only collect smoke generated during surgery in actual clinical practice. Although the utmost care will be taken in the handling of personal information, there is a possibility of psychological burden in the event of information leakage.

(2) Details of cases in which there is a benefit to the research subject

By analyzing the smoke generated during surgery and elucidating the benefits of using smoke evacuation devices, we may be able to provide insight into the smoke that may be passively taken in by the research subjects themselves. In addition, there is value in contributing to society by elucidating the risks associated with surgical smoke in operating room workers through this research.

(3) Reasons why (1) is inevitable to obtain research results

Because it is essential to handle clinical information of patients (age, gender, body mass index, etc.) in order to compare and study surgery-related smoke.

(4) Measures to minimize the contents of (1)

Maximum care in handling personal information.

10. Storage and disposal of samples and information

This study requires the collection of surgical smears as samples and clinical information as materials.

[Storage and disposal of samples]

Surgical smoke

Storage location: Environmental Technology Center co., Ltd Storage

Method: Refrigerator in the Environmental Technology Center co., Ltd

Time and method of disposal: Date of smoke collection

Clinical information before anonymization

1. Clinical information

Storage location: Medical records of Hepato-Biliary-Pancreatic Surgery Division, Department of Surgery,Graduate School of Medicine, The University of Tokyo

Storage method: In accordance with hospital regulations for medical records

Disposal timing and method: In accordance with hospital regulations for medical records
2. Consent and Consent Withdrawal Form
Storage location: Secretarial Office, Hepato-Biliary-Pancreatic Surgery Division, Department of Surgery, Graduate School of Medicine, The University of Tokyo
Storage method: In a locked cabinet
Time and method of disposal: Shredded 10 years after the publication of research results

Information after anonymization and information related to the results of the analysis
Storage location
The University of Tokyo: Secretariat Office, Hepato-Biliary-Pancreatic Surgery Division, Department of Surgery, Graduate School of Medicine, The University of Tokyo (electronically lockable)
Environmental Technology Center co., Ltd: Research room accessible only to research personnel (electronically lockable)
Method of storage
The University of Tokyo: stored in a password-protected computer that cannot be taken out.
Environmental Technology Center co., Ltd: stored on a password-protected computer that cannot be taken out of the building.
Timing and method of disposal
The University of Tokyo: Deleted using data deletion software 10 years after publication of research results.
Environmental Technology Center co., Ltd: 10 years after the publication of the research results, the data will be deleted using data deletion software.

[Correspondence table]
Storage location: Secretarial office of Hepato-Biliary-Pancreatic Surgery Division, Department of Surgery, Graduate School of Medicine, The University of Tokyo (electronically lockable)
Method of storage: In a password-protected computer that cannot be removed from the anonymized database.
Time and method of disposal: Deleted by data deletion software 10 years after the publication of the study results.

11. Reporting to the head of the research institution

Although the risks in this study are not expected to be significant, reports will be made to the head of the primary research institution in the event of unforeseen circumstances.

12. Funding source/conflict of interest

The research will be supported by a research grant from the JFE (The Japanese Foundation for Research and Promotion of Endoscopy) Grant.
Title: "Evaluation of Toxic Substances in Surgical Smoke during Laparoscopic and Open Surgery: Investigation of Effects on Human Health and Effectiveness of Smoke-Eliminating Devices to Remove Toxic Substances and Viruses", Principal Investigator: Yoshikuni Kawaguchi

There are no conflicts of interest to report in this study.

13. Disclosure of information on the research

The results of the research will be made public through conference presentations, academic journals, domestic and international databases, etc., after anonymization.

14. Consultation with research subjects

No disclosure of individual research results will be made in response to personal inquiries, as it is unlikely that any important health findings (e.g., adverse health effects) will be obtained that can be returned to individual research participants.

15. Obtaining informed consent from a surrogate

This study will not cover the acquisition of IC from a surrogate when it is necessary. With regard to the withdrawal form, it will be possible for the consenter to withdraw the form.

16. Obtaining assent

Since the subjects are 20 years of age or older, this does not apply to obtaining assent and will not be conducted.

17. Confirmation of requirements for obtaining consent

Patients over 20 years old undergoing laparotomy in our group. Patients who have given their own consent to this study. Exclusion criteria are patients under 19 years of age and those who have not given their consent for this study.

18. Financial burden and honorarium

This ancillary study is a study to collect clinical information within the scope of normal insurance treatment, and there will be no additional costs associated with participation. There will be no increase in costs due to participation in this study.

19. Handling of serious adverse events

Not applicable as the study is based on clinical practice. In the event of a serious adverse event caused by a drug, the responsible physician or sub-researcher will report it in the usual way. Reporting in the usual way refers to reporting to the head of the medical institution to which one belongs, spontaneous reporting from a medical institution to the Pharmaceutical Affairs Bureau of the Ministry of Health, Labour and Welfare under the "Safety Information Reporting System for Drugs and Medical Devices," a project of the Ministry of Health, Labour and Welfare, and voluntary reporting from a medical institution to a company under the "Company Reporting System" based on the "Law Concerning Quality, Effectiveness and Safety Assurance of Pharmaceuticals, Medical Devices and Other Products". The medical institution shall make a voluntary report to the company based on the "Company Reporting System" in accordance with the "Act on Quality, Efficacy and Safety Assurance of Drugs and Medical Devices, etc.".

20. Health damage compensation

Since this research will be conducted within the scope of normal insurance treatment, no financial compensation will be provided. In the event of an adverse event in this study, appropriate treatment will be provided in the same manner as a treatment for health hazards in normal medical care and will involve partial co-payment by the research subject's medical insurance. Since this is research to collect information associated with actual clinical practice, no compensation or insurance coverage for health hazards is

envisaged.

21. Provision of medical care after the study is conducted

Since this is an observational study that does not involve interventions conducted within the scope of normal insurance treatment, the provision of medical care after the study is conducted will involve partial co-payment by the research subjects' medical insurance, as appropriate treatment similar to that provided within the scope of normal clinical practice will be provided.

22. Handling of important findings and research results

When information is obtained that the researcher deems necessary to disclose from a medical point of view, etc., it will be disclosed in consideration of ethical aspects. In principle, information that has been conducted as part of medical treatment will be disclosed. If the researcher does not wish to disclose the results, he/she will be asked to notify us in the confirmation section of the consent form.

23. Outsourcing and supervision of contractors

This research will not be outsourced.

24. Future research use of samples and information

No secondary use of materials/information collected in this study will be made.

25. Monitoring and auditing

Monitoring and auditing will not be conducted in this study.