

Investigating the particle amount hanging in the air in the operating room during instrumented and non-instrumented neurosurgery operations

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Ethics Committee Approval

Administrative permission and local ethics board
consent (Kutahya Health Sciences University -
approval date and number: 2019/5) were obtained
for the study.

All procedures in this study involving human
participants were performed in accordance with
the 1964 Helsinki Declaration and its later
amendments.

Conflict of Interest

No conflict of interest was declared by the
authors.

Financial Disclosure

The authors declared that this study has received
no financial support.

Published

2021 March 19

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Published by JOSAM

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Abstract

Background/Aim: To improve patient safety and surgical results, it is highly significant to understand the factors which cause high particle matter (PM) levels in the air of the operating room. The objective of this study was to investigate the particle amounts hanging in the air in the operating room in instrumented and non-instrumented cases during Neurosurgery operations.

Methods: This was an analytical study comparing PM amounts measured in 21 non-instrumented and 22 instrumented cases performed in Kutahya Evliya Çelebi Training and Research Hospital NRS operating room between March-May 2019. Five spots were identified in the operating room and measurements were performed at these spots by the same researcher during the operation. "Particles Plus 8306" particle measurement device was used for the measurements performed for 11 weeks. Also, detailed information such as operation duration, number of team members in the operating room and operating time of vaporizers per operation were registered on a form.

Results: PM0.5 and PM1 amounts were higher in instrumented operations compared to non-instrumented operations. All PM amounts (except PM 0.5) measured in instrumented and non-instrumented operations decreased towards the end of the operation compared to the beginning ($P=0.001$, $P=0.001$, $P=0.001$, $P=0.001$ for all).

Conclusions: PM smaller than one micron were detected more in instrumented operations compared to non-instrumented operations, and the amounts of these particles increased with the number of team members present. All PM amounts increased with operation durations, and all PM (except PM 0.5) amounts measured in non-instrumented and instrumented operations gradually decreased towards the end of the operation compared to the beginning. Regularly checking the air flow and restricting entry and exit in and out of the operating room are necessary.

Keywords: Clean room, Instrumentation, Neurosurgery, Operating room, Particles

Introduction

To prevent the wound site infections and contamination during the surgical operations, it is important to provide sterility in the operating room and observe the air quality [1]. Although no consensus exists regarding the best method, the correlation between the number of particles hanging in the air and microbial contamination was reported in some studies and it was suggested that the particle count could be used to observe contamination [1-3]. This measurement is performed by counting particle matters (PM) of 0.3, 0.5, 1.0 and 5.0 µm present in one m³ to check whether the room meets ISO standards (ISO-14644-1 “Cleanrooms & Association Controlled Environment Part 1 Classification of Air Cleanliness”).

To improve patient safety and surgical results, it is of great importance to understand factors such as staff mobility, which causes high particle levels in the operating room air, the type of the instruments used during the operation and the duration [2, 3]. The objective of this study was to investigate the particle amounts hanging in the air in the operating room in instrumented and non-instrumented cases during Neurosurgery (NRS) operations. Correlations between other variables such as particle count and door opening frequency, number of individuals in the operating room and duration of the surgical operation were also assessed.

Materials and methods

Descriptions

The neurosurgery clinic in our hospital performs 570 operations per year and twelve operations per week. In these, instruments exclusive for Neurosurgery operations, namely, cervical plate, monoaxial, polyaxial, transpedicular screw, lumbar intervertebral cage and implants are used, along with the routine surgical sets used during opening and closure in all operations. In this study, all operations performed with titanium screw to provide spinal stabilization were included in "instrumented" operations and the measurements used in these operations were included in the study group. Measurements made in all non-instrumented operations were included in the control group.

Measurement locations

Neurosurgery operating room where the study was conducted is a 24 square meter area and its ventilation is provided by a HEPA filter cleaning PM over 0.5µm. Measurements were performed five steps away from the door and near the air conditioner by the same researcher during the operation. The measurements began when the whole team was ready, and anesthesia was completely provided. “*Particles Plus 8306 particle measurement device*” was used for measurements performed for 11 weeks. This manual and mobile device with a sensor counts PM values between 0.3-25 µm with 0.1 CFM (2.83 LPM) air flow rate. It also measures temperature and relative humidity values. Measurements performed can be reported according to ISO 14644-1, E GMP Annex 1 or FS 209. Detailed information such as operation duration, number of team members in the operating room and operating time of vaporizers per operation were registered on a form for each operation.

Statistical analysis

Data were evaluated with SPSS 18 program. Mean, standard deviation (SD), median, minimum, and maximum values were provided for measurement data. Since data was not normally distributed, Mann Whitney U test was performed for the comparison of group medians. Normal distribution was used for the analysis of the linear logarithm and PM amount, which are dependent variables. Operation duration, number of individuals in the operating room, operating time of vaporizers per operation, temperature, and moisture measurement results, which were independent variables, were assessed with Pearson correlation test. The statistical significance of PM measurement results at the beginning and end of the operation were examined with Wilcoxon test for paired comparisons. $P < 0.05$ was considered statistically significant.

Results

G*Power 3.1.9.2 software was used to determine sample size. The power of this data was $1 - \beta = 0.80$ with $\alpha = 0.07$ and an effect size of $d = 0.73$, with 22 samples in each group.

This was an analytical study comparing PM amounts measured in 21 non-instrumented and 22 instrumented cases performed in Kutahya Evliya Celebi Training and Research Hospital NRS operating room between 4 March and 22 May 2019. A total of 644 measurements were made in forty-three operations.

Operation type-related comparison of Mean (SD), Median, Min-Max values of PM and factors such as operation duration, number of team members, operating time of vaporizer are provided in Table 1. The number of team members was higher in non-instrumented operations compared to instrumented operations. PM 0.5 and PM 1 amounts were higher in instrumented operations compared to non-instrumented operations ($P = 0.011$, $P = 0.010$, respectively) (Table 1).

Table 1: Factors affecting the operation and the comparison of PM measurements according to operation type

	Non-instrumented (n=21)	Instrumented (n=22)	Statistics
Operation duration (min)			
Mean (SD)	70.0 (23.76)	76.59 (17.95)	Z=-0.706
Median (Min-max)	80 (30-100)	80 (45-120)	P=0.480
Number of team members			
Mean (SD)	7.04 (0.97)	6.09 (0.29)	Z=-3.563
Median (Min-max)	7 (6-8)	6 (6-7)	P<0.001
Operating time of vaporizer			
Min, Mean (SD)	-	38.19 (9.19)	-
Median (Min-max)		40 (20-60)	
PM 0.5 (µg/m ³)			Z=-2.541
Median (Min-max)	0.10 (0.04-7.21)	0.31 (0.05-0.60)	P=0.011
PM 1 (µg/m ³)			Z=-2.564
Median (Min-max)	0.31 (0.10-15.07)	0.69 (0.12-1.54)	P=0.010
PM 2.5 (µg/m ³)			Z=-1.847
Median (Min-max)	1.85 (0.60-47.75)	2.46 (0.65-5.24)	P=0.065
PM 5 (µg/m ³)			Z=-0.632
Median (Min-max)	7.85 (3.14-177.17)	8.49 (3.83-15.93)	P=0.528
PM 10 (µg/m ³)			Z=-0.632
Median (Min-max)	21.22 (10.36-37.21)	20.34 (12.26-36.77)	P=0.528
Temperature			
Mean (SD)	19.89 (1.29)	19.32 (1.25)	Z= -1.555
Median (Min-max)	19.07 (17-21)	19.13 (17-21)	P=0.120
Moisture			
Mean (SD)	33.06 (7.26)	30.91 (6.57)	Z= -1.057
Median (Min-max)	33.07 (19-49)	28.90 (19.8-40.53)	P=0.291

The operation duration was a factor affecting all PM amounts and PM amounts increased with operation durations ($r = 0.575$ $P < 0.001$, $r = 0.576$ $P < 0.001$, $r = 0.528$ $P < 0.001$, $r = 0.439$ $P = 0.003$, $r = 0.339$ $P = 0.029$, respectively). PM5 and PM10 amounts increased in line with the number of team members participating in the operation and the moisture ratio during the

operation ($r=0.321$ $P=0.036$, $r=0.380$ $P=0.012$, respectively). No significant correlation was found between operation type (case-control), temperature, PM5 and PM10 amounts or between PM0.5, PM1 and PM 2.5 amounts and operation type (case-control), number of team members, moisture, and temperature (Table 2).

Table 2: Correlation results between dependent and independent variables

	PM0.5		PM1		PM2.5		PM5		PM10	
	r	P	r	P	r	P	r	P	r	P
Instrument	0.272	0.072	0.233	0.132	0.100	0.522	-0.054	0.733	-0.180	0.249
Time	0.575	<0.001	0.576	<0.001	0.528	<0.001	0.439	0.003	0.339	0.029
Number of team members	0.191	0.221	0.193	0.214	0.251	0.105	0.321	0.036	0.380	0.012
Temperature	0.089	0.569	0.098	0.534	0.157	0.314	0.196	0.207	0.186	0.232
Moisture	0.203	0.193	0.211	0.174	0.270	0.080	0.305	0.057	0.299	0.051

All PM (except PM 0.5) amounts measured in non-instrumented and instrumented operations decreased towards the end of the operation compared to the beginning ($Z=-5.414$ $P=0.001$, $Z=-6.520$ $P=0.001$, $Z=-6.437$ $P=0.001$, $Z=-6.200$ $P=0.001$, respectively for non-instrumented operations, and $Z=-9.062$ $P=0.001$, $Z=-9.059$ $P=0.001$, $Z=-8.972$ $P=0.001$, $Z=-8.560$ $P=0.001$, respectively, for instrumented operations) (Figures 1, 2). PM0.5 amounts measured in non-instrumented and instrumented operations were similar at the end and beginning of the operation ($Z=-2.591$ $P=0.296$, $Z=-2.301$ $P=0.212$, respectively) (Figures 1, 2).

Figure 1: Comparison of the mean PM amounts measured at the beginning, middle and end of non-instrumented operations

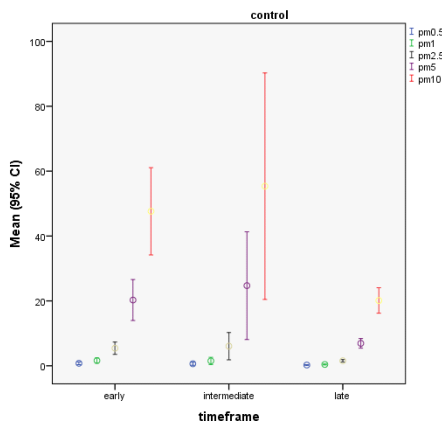
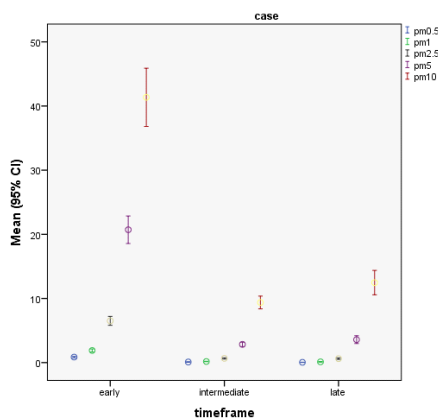


Figure 2: Comparison of the mean PM amounts measured at the beginning, middle and end of instrumented operations



Discussion

Isolated areas in healthcare services and the manufacturing sector involving medications and microelectronics, where the particle number in the environment is kept under control and the temperature, moisture and ventilation values are kept within a certain range, are called

“Clean Rooms.” [4-7]. Neurosurgery operating rooms should meet and sustain clean room standards [4]. The size and amount of the particles present in the ambient air constitute the main criteria used for the classification of clean rooms in the medical field. Microorganisms hold on to dust particles, shed skin and cloth pieces. They contaminate open wounds during an operation. They may cause infection if the wound location is convenient, and the defense system of the patient is inadequate. In our study, PM amounts measured in 21 non-instrumented and 22 instrumented cases operated in the Neurosurgery operating room were compared and analyzed.

ISO 14644-1 standard classifies air cleanliness in terms of the concentration of the particles in the air in a clean room and area [8]. In studies performed by Seal and Clark [9] and Stocks et al. [10], a correlation was found between the number of particles in the air and number of colony-forming units (CFU). Our operating room measurement results were within clean room limits and in accordance with ISO 14644-1 standards.

In our study, the number of team members was higher in non-instrumented operations compared to instrumented operations. Cranial cases constitute 66.6% of non-instrumented cases ($n=14$), and individuals other than the operating team are highly involved in cranial surgeries (neuromonitor, navigation, etc.). Thus, the number of individuals was higher in non-instrumented cases. In the literature, it was reported that increasing number of individuals in the operating room caused the increase in PM amount [11, 12]. In our study, PM 0.5 and PM 1 amounts in instrumented operations were significantly higher compared to non-instrumented operations. This result was related to longer operation duration in instrumented cases and the implants used. In the literature, implant use-related PM amount increased parallel to increasing operation duration [1, 11, 13].

Proper ventilation systems lower the infection risk. To suppress the static electricity and prevent bacterial grouping, the temperature should be between 20-23 degrees, the moisture, between 30-60% and to prevent the entrance of microorganisms and dust, the positive pressure should be 15% [14].

The number of individuals and the moisture ratio in the operating room were factors which increased PM amount and postoperative infection risk [6, 12]. In some studies, the number of individuals in the operating room was the key factor increasing the microorganism count [6]. In this aspect, our results were compatible with the literature and we found that moisture ratio and number of team members increased with PM5 and PM10.

The number of bacteria in the air is directly related to the human traffic in the room. Minimizing the number of people and human traffic in the operating room is important to prevent CAE by lowering the number of bacteria in the air. In modern operating rooms, conventional ventilation is available for filtering air particles $\geq 5\mu\text{m}$. In the studies performed, staff activity in the room was the crucial reason for bacterial contamination of the air in the operating room [6, 15]. In the middle of the operation and towards the end, the operating room environment becomes more stabilized in non-instrumented cases (cranial and spinal) and the individuals in the room move less. Towards the middle of instrumented cases, there is more

movement. This is due to the variability of the mobility of the individuals and objects in the room.

Limitations

This study has several limitations. The sample group was small, and the microbiological population was not evaluated. Therefore, we believe that our results should be supported by studies conducted in different operations with larger samples and microbiological measurements.

Conclusion

PM smaller than one micron were detected more in instrumented operations compared to non-instrumented ones. The amounts of these particles increased with the number of team members during the operation. All PM amounts also increased with operation duration.

PM amounts measured in non-instrumented and instrumented operations gradually decreased towards the end of the operation compared to the beginning.

Considering these results, regular inspection of ventilation related policies and procedures, changing of air filters, regular checking of air flows entrances and exits, always keeping the doors of the operating rooms closed, and restricting the entrances and exits to the room are necessary in our hospital. This way, sterile room conditions including only filtered air entry without any particles can be provided for surgeries involving implants and prostheses.

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