# DEPARTMENT OF ANESTHESIOLOGY

# JOURNAL CLUB

**Monday May 7, 2018**
**1800 HOURS**

**LOCATION:**
**Mino's Downtown**
**340 Barrie Street**

**PRESENTING ARTICLES:**
**Dr. Stacy Ridi & Dr. Emily Cook**

**Sponsored by The Department of Anesthesiology & Perioperative Medicine, Queen's University**

**SUGGESTED GUIDELINES FOR CRITICAL APPRAISAL OF PAPERS**
**ANESTHESIOLOGY JOURNAL CLUB**
**QUEEN'S UNIVERSITY**
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Two presenters will be assigned to choose and present summaries of their papers. Ideally the two papers will represent similar topics but contrasting research methodologies. The focus remains on critical appraisal of the research and manuscript, more than on the actual contents of the article. Each presenter will then lead an open discussion about the article, based around the guidelines below. The object is to open up the appraisal to wide discussion involving all participants.

**GENERAL**

1. Title of paper: Does it seem like an important problem? Does it reflect the purpose/results?
2. Authors, institution and country of origin

**INTRODUCTION**

1. What is the problem being addressed?
2. What is the current state of knowledge of the problem studied?
3. What is the hypothesis being tested?
4. How does testing the hypothesis help solve the stated problem?

**METHODOLOGY**

1. Study design:
    a) Clinical trial vs. systematic review/meta-analysis
    b) Prospective vs. retrospective
    c) Observational vs. Experimental
    d) Randomized or not
    e) Blinded or not

2. Population studied:
    a) Human, animal, other
    b) Justification
    c) Control groups: experimental vs. historical
    d) Is the sample size/power calculated, and how?
    e) Is the population similar to your own practice?
    f) Single vs. multi-centre

3. Is the study ethically sound?
    a) Clinical equipoise
    b) Does treatment meet standard of care (esp controls)?
    c) Appropriate consent and institutional ethics approval

4. Exclusions: what groups are excluded and why?

5. Experimental protocol
    a) Is it designed to test the hypothesis?

b) Is it detailed enough to be reproducible?
c) Is the methodology validated?
d) Are the drugs/equipment used detailed?
e) How does the randomization take place?

6. What are the primary endpoints?
7. Is power sufficient to justify secondary endpoints?
8. Is the protocol clinically relevant?
9. Data collection and analysis
10. Statistical analysis: Is it appropriate? Are results

**RESULTS**

1. Are the groups comparable?
2. Were any subjects/data eliminated?
3. Analyzed by intent to treat?
4. Are adequate details of results provided? - data, graphs, tables

**DISCUSSION**

1. What is the main conclusion of the study?
2. Do the results support this conclusion?
3. Do the results address the stated purpose/hypothesis of the study?
4. How do the authors explain the results obtained?
5. Are there any alternative interpretations to the data?
6. Are the results clinically as well statistically relevant?
7. How do the results compare with those of previous studies?
8. What do the results add to the existing literature?
9. What are the limitations of the methods or analysis used?
10. What are the unanswered questions for future work?

**APPLICABILITY OF THE PAPER**

1. Have you learned something important from reading this paper?
2. Will the results of this study alter your clinical practice?

BJA

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Clinical Practice

CLINICAL PRACTICE

# Perioperative α-receptor blockade in phaeochromocytoma surgery: an observational case series†

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## Abstract

**Background.** Mortality associated with surgery for phaeochromocytoma has dramatically decreased over the last decades. Many factors contributed to the dramatic decline of the mortality rate, and the influence of an α-receptor blockade is unclear and has never been tested in a randomized trial. We evaluated intraoperative haemodynamic conditions and the incidence of complications in patients with and without α-receptor blockade undergoing surgery for catecholamine producing tumours.

**Methods.** Haemodynamic conditions and perioperative complications were assessed in 110 patients with (B) and 166 without (N) α-receptor blockade. Data were analysed as a consecutive case series of 303 cases and subsequently via propensity score matching, and presented as mean and confidence interval (CI).

**Results.** No difference in maximal intraoperative systolic arterial pressures (B = 178 mm Hg (CI 169-187) *vs* N = 185 mm Hg (CI 177-193; $P = 0.2542$) and hypertensive episodes above 250 mm Hg were found ($P = 0.7474$) for the closed case series. No major complications occurred. Propensity score matching (75 pairs) revealed a significant difference of 17 mm Hg in maximal intraoperative systolic bp for these selected pairs ($P = 0.024$).

**Conclusions.** Only a slight difference in mean maximal systolic arterial pressure was detected between patients with or without an α-receptor blockade. There was no difference in the incidence of excessive hypertensive episodes between groups and no major complications occurred. The basis for the general recommendation of perioperative α-receptor blockade for phaeochromocytoma surgery demands further study.

**Key words:** doxazosin; paraganglioma; phaeochromocytoma; phenoxybenzamine

Phaeochromocytoma and extra-adrenal paraganglioma are catecholamine-producing tumours, which without treatment can lead to cardiovascular decompensation and death. Surgical removal offers a definitive cure.[1–3] However, unavoidable intraoperative manipulation of the tumour can cause release of catecholamines and hypertensive crisis. Therefore, adrenalectomy for phaeochromocytoma is regarded as high risk surgery with a historical mortality rate exceeding 40% in some case series.[1–3]

During the second half of the 20th century the mortality rate decreased dramatically to a rate of 1.0 to 3.0%, which has often been credited to the introduction of perioperative α-receptor blockade.[1–10] However, this development can also be explained

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**Editor's key points**

- Perioperative pharmacological blockade of α-receptors is routinely used in preparation for surgery for phaeochromocytoma, but its clinical impact has not been conclusively established.
- Arterial pressure and complications were analysed in a consecutive case series of 303 cases of surgery for phaeochromocytoma removal with or without perioperative α-receptor blockade.
- There was only a small difference in maximal systolic arterial pressure and no difference in complications with or without α-receptor blockade.

by significant improvements in diagnostics, surgery, and anaesthesia. Improvement in diagnostic techniques led to earlier diagnosis and more precise localization of tumours,[5 11 12] while surgical techniques developed from extensive abdominal to minimally invasive endoscopic procedures.[5 11 12–20] Moreover, development of invasive haemodynamic monitoring and improved management including the use of sodium-nitroprusside allowed better handling of acute hypertensive episodes intraoperatively.

The clinical impact of these factors has never been properly investigated.[1–3 21] Although pre-treatment with an α-receptor blocker has never been tested in a controlled randomized trial, this treatment is considered obligatory according to international guidelines.[1–3 7 10 12] However, many case series report intraoperative hypertensive episodes exceeding 200 mm Hg systolic arterial pressure despite use of an α-receptor blocker, which is not without side-effects.[7–10 17 22–23] In contrast, phaeochromocytoma surgery without α-receptor blockade has been successfully performed in selected patients without increased perioperative complications.[8 24 25]

To explore the need for and effectiveness of perioperative α-receptor blockade, we performed an observational study and evaluated perioperative bp in 303 consecutive procedures in patients undergoing excision of chromaffin tumours with or without α-receptor blockade.

## Methods

After approval by the local ethics committee (Board of Physicians Ärztekammer Nordrhein reg.no.: 2008126) 276 consecutive patients undergoing surgery between June 2008 and June 2016 gave informed written consent to have their data analysed in this observational study. Patients suffered from neurofibromatosis (n = 5), von Hippel-Lindau disease (VHL; n = 73), multiple endocrine neoplasia Type 2A (MEN 2A; n = 42), or sporadic phaeochromocytoma and not further described entities (n = 156). In 27 patients bilateral tumours were removed. In addition, 26 patients had extra-adrenal paraganglioma. There was no statistical difference ($P = 0.2488$) in the pattern of catecholamines produced by the tumours with regard to the use of α-receptor blockade or not. Epinephrine was secreted by 24, norepinephrine in 45, and both in 33 tumours of patients with α-receptor blockade. In patients without α-receptor blockade, tumours produced epinephrine in 23, norepinephrine in 81, and both in 43. In 19 patients of the patients with α-receptor blockade and 35 of the patients without blockade, no elevated catecholamine concentrations could be detected. In 4 patients the tumour was regarded as incidental and the diagnosis of a phaeochromocytoma was missed until the time of surgery, therefore no catecholamine concentrations were determined.

## Preoperative management

Whenever a physician or patient contacted our institution for referral of a patient with a catecholamine = producing tumour, they were asked not to initiate α-receptor blockade. Over the last four yr many physicians and patients contacted our institution explicitly because they did not want α-receptor blockade. In case α-receptor blockade had already been started, it was continued until the day of surgery (n = 121). 98 patients received phenoxybenzamine (1.1mg $kg^{-1}$ per day [CI 1.0-1.3 mg $kg^{-1}$ per day]) and 23 patients doxazosin (0.14 mg $kg^{-1}$ per day [CI 0.11 - 0.17 mg $kg^{-1}$ per day]). Usually, patients were admitted the day before surgery, and patients were hospitalized < 24 h until they underwent surgery. The number of antihypertensive drugs prescribed before surgery was assessed.

## Anaesthesia and surgery

On the day of surgery after patients arrived in the anaesthesia induction room, non-invasive monitoring was applied and an arterial line was placed under local anaesthesia. Subsequently, general anaesthesia was induced with propofol, remifentanil, and mivacurium. After tracheal intubation, a 3-lumen central venous catheter was placed in the right or left internal jugular vein. Depending on the surgical approach, patients were placed in prone or supine position. Sodium nitroprusside was connected to one lumen of the central venous catheter and run at a minimal dose (1mg per h) to have it ready for rapid titration as needed. Anaesthesia was maintained with isoflurane in an oxygen/air mixture and continuous i.v. administration of remifentanil.Baseline systolic, highest systolic, and lowest mean arterial pressure, number and duration of systolic arterial pressure episodes > 250 mm Hg and episodes of mean arterial pressure < 60 mm Hg were assessed. Intraoperatively, the dose of sodium nitroprusside was individually increased if systolic arterial pressure exceeded 160 mm Hg. Esmolol was administered at the discretion of the responsible anaesthetist (n = 21).

Two-hundred-ninety operations were performed by the retroperitoneoscopic approach, four by the laparoscopic route, and one thoracoscopically. Eight patients were initially or secondarily operated upon by an open procedure (part of a multivisceral open resection n = 5, conversion to open surgery n = 2, paraganglioma in the wall of the bladder n = 1). The surgical techniques of the retroperitoneoscopic and laparoscopic approach have been described in detail.[16 26]

The incidence of complications potentially related to arterial hypertension such as myocardial infarction, acute congestive heart failure, pulmonary oedema, and cerebral stroke as a result of haemorrhage was assessed. Testing (troponin concentrations and postoperative ECG) was initiated in case of clinically suspected myocardial ischaemia and in patients with a history of myocardial ischaemia. Testing was not performed in asymptomatic patients without a history of myocardial ischaemia or a history of cardiac decompensation.

## Data analysis

Data are presented as mean (95% confidence interval). The null hypothesis was no significant difference in maximal systolic arterial pressure between patients who received α-receptor

blockade as perioperative prophylaxis *vs* patients who received no prophylaxis. Data were analysed as a consecutive case series and following propensity score matching.[27] After linear regression, age, duration of surgery, tumour size, tumour aetiology, catecholamine production, and presence or absence of typical symptoms were used as matching criteria. To optimize matching, patients with open surgery (n = 8) and patients, with preoperatively missed diagnosis of phaeochromocytoma (n = 4) were not included. For patients with bilateral tumours, only the first operation was included (Fig. 1).

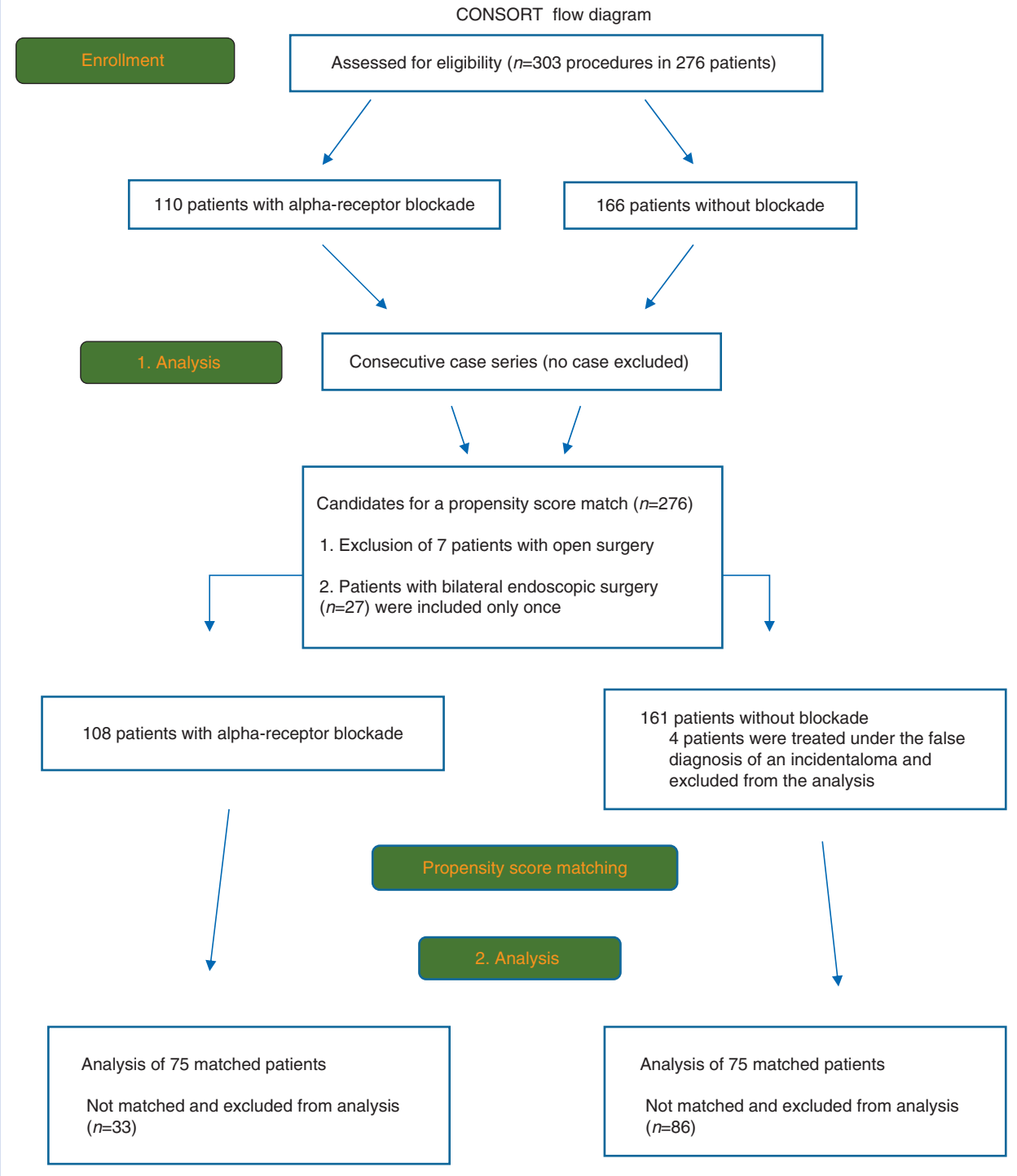


Fig 1. Consort flow diagram.

In addition, correlation of individual doses of the respective α-receptor blocking agent and maximal systolic arterial pressure was evaluated. Data were analysed with Statview software (Version 5.0.1, SAS Institute inc., Cary NC, USA) and SAS (propensity score matching). After Kolmogorov-Smirnov tests for a normal distribution, data were tested by paired Student's t-test for continuous data and $\chi^2$ test for categorical variables. Significant differences were assumed with $P$ values $< 0.05$.

## Results

None of the patients developed complications related to intraoperative hypertension. In particular no myocardial infarctions or signs of acute cardiac decompensation and acute insufficiency were detected.

Table 1 Characteristics of 276 patients with (n = 110) or without (n = 166) α-receptor blockade. Continuous values are presented as mean and CI, except for age (mean and range)

| | α-receptor blockade | no blockade |
|---|---|---|
| Height (cm) | 174 (172-176) | 172 (170-174) |
| Weight (kg) | 78 (75-81) | 75 (72-78) |
| Age (yr; range) | 43 (18-82) | 43 (18 - 79) |
| Sex (female/male) | 51 / 70 | 99 / 83 |
| Tumour Size (diameter; cm) | 3.8 (3.4-4.2) | 3.4 (3.1-3.7) |
| Antihypertensive Drugs (0/1/2/3/4/5) | 54/23/18/7/5/3 | 102/24/27/9/3/1 |
| Symptomatic Patients (n) | 91 | 122 |
| Systolic Arterial Pressure (mm Hg) | 144 (140-148) | 146 (142-150) |
| Time for surgery (min) | 67 (61-73) | 62 (57-67) |

Haemodynamic baseline before induction of anaesthesia did not differ between groups (Table 1). For procedures of the closed case series, mean maximal systolic arterial pressure was not different between groups (α-receptor blockade: 178 mm Hg (169-187) *vs* no blockade: 185 mm Hg (177-193; $P = 0.2542$; Fig. 2). Eighteen patients (eight with α-receptor blockade and 10 without α-receptor blockade) had sustained arterial pressure above 200 mm Hg of > 1 min but < than 3 min. During surgery 11 patients with α-receptor blockade and 16 patients without α-receptor blockade developed systolic arterial pressure increases to above 250 mm Hg ($P = 0.7474$).

Propensity score matching of 75 pairs of patients revealed a significant difference in maximal systolic arterial pressure (α-receptor blockade: 170 mm Hg (160-180 *vs* no blockade: 187 mm Hg (175-198; $P = 0.024$; Fig. 3). Correlation of individual daily doses of phenoxybenzamine or doxazosin with maximal systolic arterial pressure did not reveal any correlation (Figs 4 and 5). Systolic arterial pressure increases above 200 mm Hg occurred even under the highest doses of α-receptor blocking agents (Figs 4 and 5). In contrast, the incidence of intraoperative hypotension was significantly higher in patients with α-receptor blockade (51% with α-receptor blockade *vs* 38% without blockade; $P = 0.0315$). Accordingly, the number of patients who received continuous administration of norepinephrine during surgery was significantly different ($P = 0.0073$). Out of 110 patients with α-receptor blockade 32 received norepinephrine, compared with 26 patients out of 166 without α-receptor blockade.

One operation had to be converted to an open procedure because of arterial bleeding that could not be managed endoscopically. Three patients developed $CO_2$-embolism as a result of a lesion of the vena cava, which was closed endoscopically and resolved after 10 min of circulatory support with catecholamines without sequela. Five patients had accidental capnothorax, which was drained intraoperatively. Chest drains were removed at the end of the procedures.

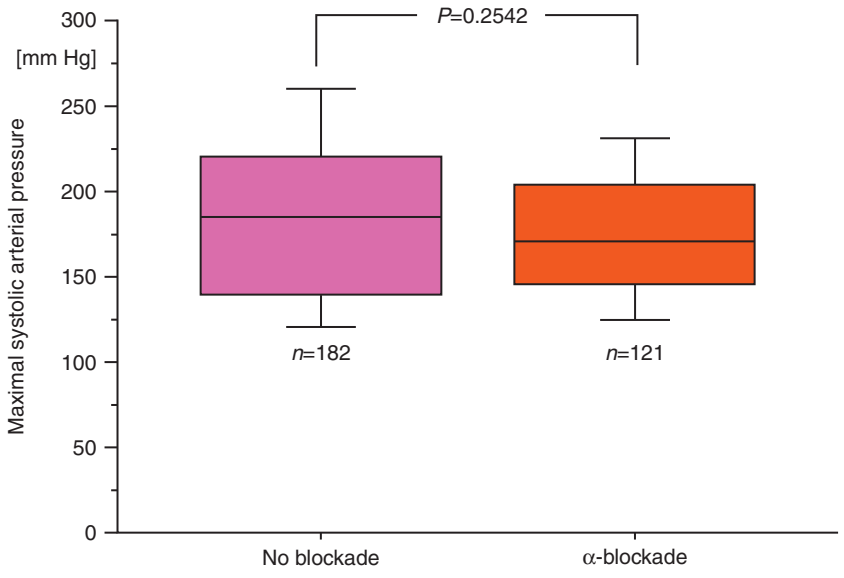


Fig 2. Box plots of intraoperative maximal systolic arterial pressure. Presented are maximal systolic arterial pressure values for patients without (left box) or with α-receptor blockade (right box). Data are shown for the full case series of 303 procedures. There was no significant difference in maximal systolic arterial pressure between groups.

Postoperative recovery was uneventful in all patients except for one, allowing hospital discharge generally on the second to third postoperative day (range 2 – 9 days). A 77 yr old normotensive patient developed an ischaemic stroke on the 3rd postoperative day after an uneventful course during surgery.

There were no significant differences in patient characteristics with or without α-receptor blockade (Table 1), or in catecholamine concentrations of patients with increased catecholamine concentrations (Table 2). As a result of the differing reference values for upper normal concentrations from various laboratories, concentrations were expressed as percent of the upper normal values of the respective laboratory. Similarly, there was no difference in the aetiology of tumours and the pattern of catecholamine between patients with or without α-receptor blockade ($P = 0.0746$ and $P = 0.2488$, respectively). Both groups did not differ in operating time, blood loss, tumour size, and complication rate.

There was no difference in the number of preoperative antihypertensive drugs prescribed to the patients (Table 1). In patients without α-receptor blockade the prescription of a ß-receptor blocking agent (n = 37) led to significantly higher baseline systolic arterial pressure (157 mm Hg (149-165)) compared with patients without ß-receptor blocking agents (n = 129; 143 mm Hg (138-148); $P = 0.0003$). There was no difference between patients with (n = 47) or without (n = 63) ß-receptor blocker in patients also with α-receptor blockade (with ß-blockade 144 mm Hg (138-150) *vs* without ß-blockade 144 mm Hg (139-149); $P = 0.9256$). All tumours were histologically verified as phaeochromocytoma or paraganglioma.

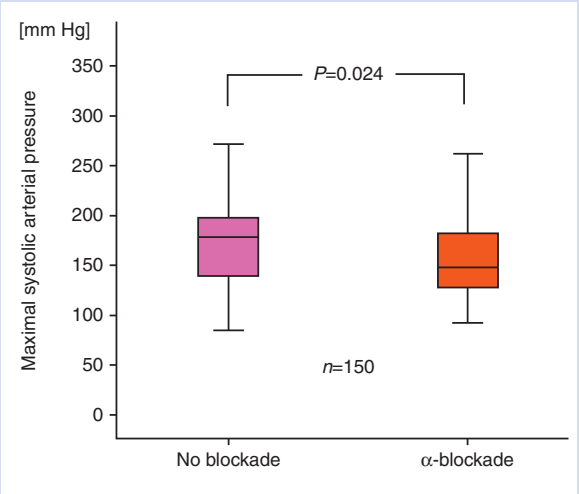


Fig 3. Box plots of intraoperative maximal systolic arterial pressure. Presented are maximal systolic arterial pressure values for patients without (left box) or with α-receptor blockade (right box). Data include 150 patients matched by propensity score matching. There was a significant difference in maximal systolic arterial pressure between groups.

## Discussion

Intraoperative release of catecholamines from catecholamine-producing tumours can lead to haemodynamic instability and death. During almost a century of experience with phaeochromocytoma and paraganglioma surgery, advances in understanding and management of these tumours have led to a decrease in perioperative mortality from more than 40% to 3% or less.[1–4 6 11 12] The introduction of preoperative α-receptor blockade has been considered to contribute substantially to this success.[1–3 5 6–9] However, the effect of an α-receptor blockade

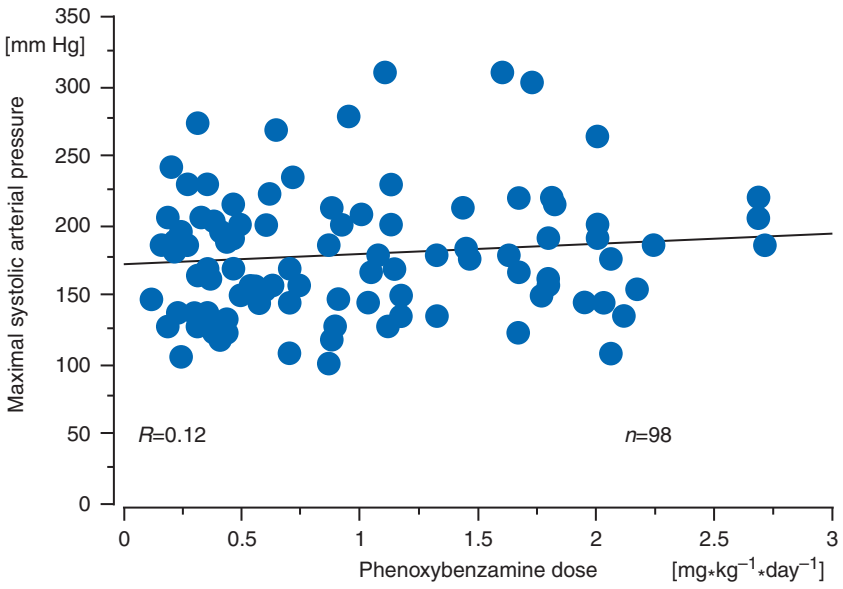


Fig 4. Correlation of maximal systolic arterial pressure and individual dose of phenoxy-benzamine. Presented are the individual daily dose of phenoxybenzamine for each patient and maximal systolic arterial pressure during surgery. Even high doses of phenoxybenzamine did not prevent hypertensive episodes above 200 mm Hg.

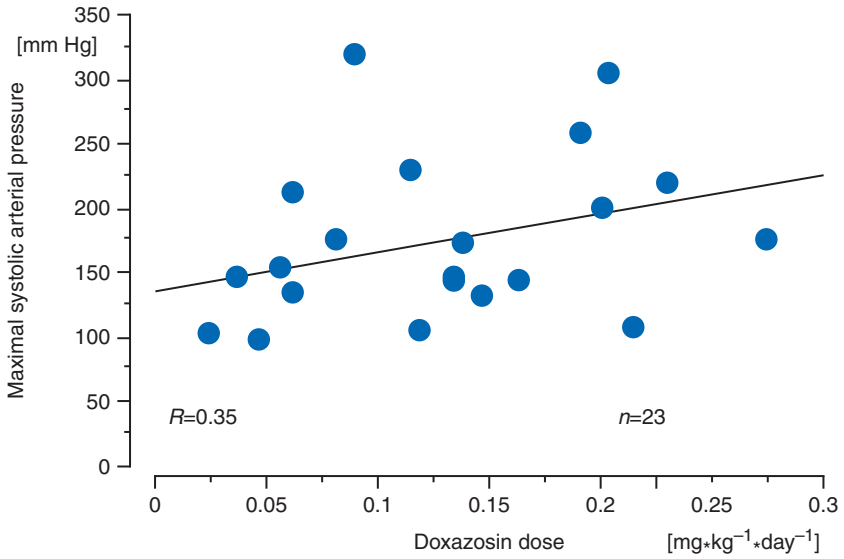


Fig 5. Correlation of maximal systolic arterial pressure and individual dose of doxazosin. Presented are the individual daily dose of doxazosin for each patient and the patients' maximal systolic arterial pressure during surgery. Even high doses of doxazosin did not prevent hypertensive episodes above 200 mm Hg.

Table 2. Percent of upper normal catecholamine reference values of patients with or without α-receptor blockade and increased catecholamine concentrations (mean, (CI))

| | α-receptor blockade | no blockade |
|---|---|---|
| Epinephrine (%) | 685 (512-858) | 535 (382-688) |
| Norepinephrine (%) | 744 (551-937) | 634 (458-810) |

has never been tested in a randomized trial.[1–3 7 10 28] In our study, independent of perioperative α-receptor blockade, intraoperative hypertensive episodes did not lead to cardiovascular complications. Intraoperative maximal systolic arterial pressure was not different with or without α-receptor blockade for the whole closed case series, but for the subgroup of patients matched according by propensity scoring. The incidence of systolic arterial pressure increases above 250 mm Hg was not affected by perioperative α-receptor blockade, while hypotensive episodes occurred more with α-receptor blockade.

α-Receptor blockade can cause significant side-effects. Patients with coexisting cardio- or cerebrovascular diseases are at risk because of hypotension. It can take several weeks to establish α-receptor blockade and the effect exceeds the operation by several days, which can be responsible for a prolonged postoperative stay.[8 23 28 29] In reports, patients managed intraoperatively without pretreatment compared with patients with pretreatment with phenoxybenzamine or prazosin, there was no difference in the incidence of stroke and myocardial infarction.[8 25 28] Similarly, Lentschner and colleagues[22] reported a series of 96 patients operated without specific pre-treatment with only one patient experiencing transient myocardial ischaemia.

Based on experience gained with surgical treatment of chromaffin tumours in patients who stopped medical pre-treatment because of major side-effects and on incidentally discovered phaeochromocytomas (and therefore not pretreated), we felt that medical pre-treatment could be avoided at least in selected patients. Starting in 2008, all consecutive retroperitoneoscopic resections of catecholamine producing tumours were evaluated and data prospectively collected. Including consecutive cases without exception eliminates possible selection bias compared with studies where selected cases were evaluated.[30] Analysis of this consecutive case series showed no statistical difference in maximal intraoperative arterial pressure in patients with or without α-receptor blockade.

In addition to the consecutive case series approach, we also analysed our data following propensity score matching, which revealed a significant difference in maximal systolic arterial pressure of this selected group of patients. Nevertheless, arterial pressure measurements of the group without α-receptor blockade were well within in the range of measurements of patients with α-receptor blockade reported in the literature.[7 10 13 28 29 31 32] No complications related to hypertensive episodes were found. The incidence of excessive hypertension with maximal systolic arterial pressure increase above 250 mm Hg was not different between groups. Moreover, we did not observe a correlation between the individual dose of α-receptor blocking agents with maximal systolic arterial pressure, although the doses administered were within the range described in the most recent guidelines.[1–3]

Our data represent the largest number of patients without α-receptor blockade reported to date, and demonstrate that phaeochromocytoma surgery without medical pre-treatment is feasible and safe. International guidelines for the perioperative treatment of patients with phaeochromocytoma and paraganglioma state that this treatment has never undergone scientific investigation. To statistically evaluate the effect of α-receptor blockade on mortality with a current mortality rate of ~1%, a study of 2000 to 8000 patients would be required. Acquisition of

such a large number of patients, in a rare disease such as phaeochromocytoma, is almost impossible, such that a clinical trial to test the effects of α-receptor blockade is unlikely.

α-Receptor blockade is not without side-effects. Besides the intraoperative increase in hypotensive episodes, there are several reports of significant side aspects. Sprung and Weingarten[23] report two cases with extensive α- and β-receptor blockade that required excessive doses of α- and β-receptor stimulation and even transcutaneous pacing to maintain stable haemodynamic conditions.

Interpretation of our results is limited mainly by the low number of patients enrolled, because phaeochromocytoma is a rare disease, and by the lack of randomization. As pointed out above, the number of patients needed for evaluation of morbidity and mortality is so high that is seems unrealistic to accomplish such a study. For evaluation of maximal intraoperative arterial pressure the number of patients might be sufficient, but the meaning of a pressure difference of 10 or 20 mm Hg is clinically questionable in patients used to hypertensive episodes. Furthermore, our interpretation is limited by a lack of standardization in treatment. However, it represents usual clinical practice of all consecutive cases without bias as a result of selection by artificial study criteria.

We conclude that with modern minimally invasive surgical techniques, improved diagnostic tools for identification and localization of tumours, and highly effective short acting drugs to control haemodynamic conditions intraoperatively, one must question whether a time consuming, unreliable pre-treatment burdened with significant side-effects is still needed for all patients. Intraoperative hypertensive episodes occurred independently of perioperative α-receptor blockade. No major complications related to intraoperative haemodynamics with or without an α-receptor blockade were found. The general recommendation for perioperative α-receptor blockade as a prophylactic treatment for all patients with phaeochromocytoma and paraganglioma must therefore be questioned. The use of α-receptor blocking agents as a continuous treatment for excessive hypertension (for example in patients with malignant phaeochromocytoma or very large tumours) is not questioned by our evaluation.

## Authors' contributions

Study design/planning: H.G., P.F.A., H.P.N., M.K.W.
Study conduct: H.G., B.-J.N., P.F.A., H.P.N., M.K.W.
Data analysis: A.T., H.G.
Writing paper: H.G., B.-J.N., H.P.N.
Revising paper: all authors

## Declaration of interest

None declared.

## Funding

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# Hats Off: A Study of Different Operating Room Headgear Assessed by Environmental Quality Indicators

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**BACKGROUND:** The effectiveness of operating room headgear in preventing airborne contamination has been called into question. We hypothesized that bouffant style hats would be as effective in preventing bacterial and particulate contamination in the operating room compared with disposable or cloth skull caps, and bouffant style hats would have similar permeability, particle penetration, and porosity compared with skull caps.

**STUDY DESIGN:** Disposable bouffant and skull cap hats and newly laundered cloth skull caps were tested. A mock surgical procedure was used in a dynamic operating room environment. Airborne particulate and microbial contaminants were sampled. Hat fabric was tested for permeability, particle transmission, and pore sizes.

**RESULTS:** No significant differences were observed between disposable bouffant and disposable skull caps with regard to particle or actively sampled microbial contamination. However, when compared with disposable skull caps, disposable bouffant hats did have significantly higher microbial shed at the sterile field, as measured by passive settle plate analysis ($p < 0.05$). When compared with cloth skull caps, disposable bouffants yielded higher levels of 0.5 μm and 1.0 μm particles and significantly higher microbial shed detected with passive analysis. Fabric assessment determined that disposable bouffant hats had larger average and maximum pore sizes compared with cloth skull caps, and were significantly more permeable than either disposable or cloth skull caps.

**CONCLUSIONS:** Disposable bouffant hats had greater permeability, penetration, and greater microbial shed, as assessed by passive microbial analysis compared with disposable skull caps. When compared with cloth skull caps, disposable bouffants yielded greater permeability, greater particulate contamination, and greater passive microbial shed. Disposable style bouffant hats should not be considered superior to skull caps in preventing airborne contamination in the operating room. (J Am Coll Surg 2017;225:573–581. © 2017 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Hospital-acquired infections cost nearly $10 billion annually, with surgical site infections comprising nearly one-third of that cost.[1] Therefore, finding ways to reduce surgical site infections is of utmost importance, both for patient care and for optimal resource use within hospital systems. In this regard, controlling airborne contamination and reducing microbial shed from personnel in the operating room may help reduce surgical site infections. Several organizations, including the

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Joint Commission, the CDC, and the Association of periOperative Registered Nurses, publish guidelines to govern operating room practices.[2] One such area of focus has been on surgical attire, which attempts to create a functional barrier between the care team and the patient. Only the use of specific articles of surgical clothing, such as sterile gloves and impervious surgical gowns, have actually been shown to reduce surgical site infections.[2] In fact, the most beneficial factor in the modern operating room has been the development of appropriate and effective ventilation strategies, which help to cleanse the air and reduce bacterial load.[3,4]

Surgical scrubs have become standard in the operating room since the middle of the 20th century.[5] There have been multiple studies that have looked at the type of fabric used for the scrubs, and whether the cuffs and ankles should be tucked.[6] Over the last several decades, the type of surgical headgear worn by the surgeon and other operating room personnel have been called into question. A study in 1991 suggested that wearing any type of head gear in the operating room did not decrease bacterial counts. However, the use of proper ventilation techniques drastically reduced these counts.[4] Authors concluded that nonscrubbed individuals did not need to wear head gear because proper ventilation likely counteracted any bacterial shedding. Ten years later, however, a conflicting study showed a 2- to 5-fold increase in bacterial contamination at random sites throughout the room when headgear was not worn, and a 60-fold increase in contamination in the wound bed.[7] This study prompted operating room leaders to investigate hats more closely.

The 2016 edition of the Association of periOperative Registered Nurses Procedure Manual suggested that all operating room personnel wear disposable bouffant type hats.[8] Cited studies have suggested that the hair is a potential vehicle for bacterial dispersal, and that it can carry various core and transient bacteria including, but not limited to, *Staphlococcus, Streptococcus,* and *Corynebacterium.*[5,9] However, there has been no definitive evidence that links bacteria in the hair to surgical site infections. Additional studies suggested that more bacteria could be found in the ears of surgical staff as compared with the forehead or eyebrows.[10] Therefore, the intent of the bouffant hat was to "cover the head, hair, ears, and facial hair."[8]

The debate on hats further came into question in September 2016, when *The Boston Globe* published an article citing discord between members of the American College of Surgeons and the Association of periOperative Registered Nurses.[11] In this article, surgeons did not believe that they should be mandated to wear a bouffant type hat because there was no evidence to suggest that these hats were superior, nor did they feel that they represent the symbolic nature of the surgeon. Given that there were very few scientific studies supporting optimal headgear in the operating room, we set out to investigate the degree of airborne contaminants with different head covers in an operating room environment, using a previously validated test of Environmental Quality Indicators.[12] We hypothesized that bouffant style hats would be as effective in preventing bacterial and particulate contamination in the operating room compared with disposable or cloth skull caps, and bouffant style hats would have similar permeability, particle penetration, and porosity compared with skull caps.

## METHODS

### Location

One operating room from each of 2 different hospital systems were chosen for experimentation. Both were associated with academic medical schools. Both had High Efficiency Particulate Air Filter air supplies to the rooms and were 638 and 554 square feet, respectively. Studies took place from February to April 2017.

### Personnel and mock surgical procedure

The study team consisted of a surgeon, a microbiologist, 2 engineers specializing in heating, ventilation, and air conditioning, and an industrial air hygienist. These 5 people, in addition to a scrub nurse and medical student from each individual facility, performed 1-hour-long mock surgical experimental procedures, as previously validated and described.[11] Study personnel wore standard hospital issued clean scrubs, masks, and shoe covers.

In order to provide consistent execution of the procedure and to ensure unbiased repeatability, a detailed timed process was developed and displayed on the computer monitors within the operating room. This "script" defined the physical actions for each of the research team members to perform in 4-minute increments during the procedure to simulate actual operating room conditions. The script simulated the actual steps undertaken by operating room staff and included gowning and gloving, passing instruments, personnel entering and leaving the room, and use of electrocautery on an uncooked steak to generate particulate tissue matter.

### Hats

Disposable bouffant and skull cap headgear from each of the 2 institutions were used for experimentation. Cloth skull caps were provided by the surgeon leading the procedure and were laundered in hot water with detergent at home the evening before the study. Disposable bouffant style caps were worn with all hair and ears within the garment (Fig. 1A). Disposable and cloth skull caps were worn similarly, with the ears exposed and a small amount of hair protruding at the sides and base (Figs. 1B, C).


**Figure 1.** Styles of hats. All hats were worn in the manner that they were intended. (A) Bouffant hats covered all hair and were worn over the ears. (B) Disposable skull and (C) cloth skull hats were worn with some hair and the ears exposed. (Reprinted with permission from Troy A Markel, MD, FACS.)

Hats were changed and alternated between each experiment so that all participants were wearing the same style of hat for each separate experiment. Each hat was evaluated twice at each institution for a total of 4 1-hour-long experiments for each hat (4 hours of experimentation for bouffant, 4 hours for disposable skull caps, and 4 hours for cloth skull cap). Similar hats then underwent permeability and porosity testing.

## Environmental quality indicators

Assessment of airborne contamination and Environmental Quality Indicators was performed as previously described.[12] Air velocity measurements at key locations in the rooms were measured using a calibrated air velocity meter (Model 9565; TSI Velocicalc). The velocities were measured every 2 minutes during the 1-hour mock procedure at the operating room table (sterile field-SF, n = 108 data points per hat type) and at the back instrument table (back table-BT, n = 108 data points per hat type) and recorded in feet per minute.

Particle contamination was measured using a Climet Model CJ-750T 75 LPM counter. We used ISO 14644 standards, which required measuring the number of particles at 9 grid points throughout the room based on the size of the space (Fig. 2). This resulted in 3 complete passes through the 9-point grid during the 1-hour long mock procedure. The particle sizes recorded were 0.3, 0.5, 1.0, and 5.0 microns in particles per cubic meter (particles/$M^3$, n = 108 data points for each particle size per hat type).

Microbial contamination was measured by active assessment and by passive settle plate assessment. For active assessment, Bioscience viable surface air samplers (SAS180) were placed at both the sterile operating field and at the back instrument table to detect microbial contaminants (Fig. 2). Air samplers acquired 1,000 L of ambient air over a 5.5-minute period, and Petri plates with blood agar medium were used in the samplers to collect the microbes. The plates were changed in regular cycles to collect microbial data during the entire mock procedure (n = 96 agar plates assessed at sterile field and back table for each hat type). Passive settle plate assessment was achieved by placing 4 blood agar settle plates around the sterile field and allowing them to collect microbes and debris that dropped throughout the 1-hour mock procedures (Fig. 2; n = 16 agar plates assessed at sterile field for each hat type). The viable microbial samples were sent under chain of custody to a third-party microbiology laboratory for qualitative and quantitative analysis of bacteria. Bacterial genus were identified and quantified as colony forming units per cubic meter (CFU/$M^3$). Settle plates were analyzed by the team's microbiologist and quantified as colony forming units per plate (CFU/plate).

## Hat permeability, penetration, porosity, thickness, and fiber imaging

For hat fiber analysis, 3 samples of each type of hat from each institution were analyzed (n = 6 samples per hat type). Because the disposable skull cap was composed of

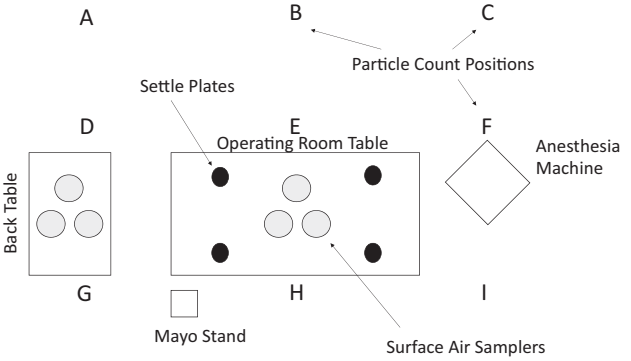


**Figure 2.** Room layout for measurement of environmental quality indicators. Representative layout of operating room table and back table along with key assay equipment. A-I points, placement of particle counter for 9-point assessment according to ISO 14644 standards.

a more porous appearing "crown" and a less porous appearing paper side, the materials from these hats were separated and assessed separately.

Hat permeability was analyzed using a TEXTEST model FX3300-II air permeability tester (TEXTEST Instruments). The TEXTEST uses a circular clamping mechanism that automatically creates a vacuum when the sample is clamped down, causing the air pressure to be different on 1 side of the sample. Air then flows from the side of higher pressure, through the sample to an area of lower pressure, creating the rate of flow, and determining the air permeability of the sample. The volume of air flow, in cubic feet per minute (CFM), at a resistance of 125 Pa, was then assessed for 6 samples of each hat type.

A TSI Automated Filter Tester 8130 (TSI Incorporated) was used to determine the penetration of a mono-dispersed, 0.3-micron sodium chloride aerosol. The aerosol particles were generated from a 15% by mass salt water solution. Penetration was tested at a 32-L per minute air flow, which is commonly used for standard air filtration tests.[13] Samples with an area of 100 $cm^2$ from each hat type were tested. Penetration was determined by 2 laser photometers measuring the aerosol concentration levels both upstream and downstream from the material. The resulting penetration value was a ratio of the 2 aerosol concentration measurements and represents the amount of particle that was transmitted through the hat. Values greater than 100% suggest that the hat shed material into the airstream.

Hat thickness was assessed with the use of an Ames gauge (B Ames Inc). The samples rested flat on a platform, while a circular pressure plate was lowered to rest on the surface of the sample. The pressure was manually maintained on the sample while a measurement of the distance between the platform and the pressure plate was calculated to the nearest 0.01 mm.

Pore size analysis was performed using a PMI Capillary Flow Porometer (model CFP1100-A, Porous Materials Inc). Samples of each hat (n = 6/group) were cut into approximately 2-inch squares and placed into the sample chamber. Each sample was fully hydrated with Galwick wetting solution (15.9 dynes/cm surface tension) before the chamber was sealed. Gas pressure was used to overcome the capillary action of the wetting fluid within the sample's pores under increasing pressure until all of the pores were empty and the sample was dry. The flow rate and pressure were used to calculate the diameter of the pores within the samples.

A Phenom ProX (Phenom-World BV) model desktop scanning electron microscope was used to image the fibers from each group of hats. A Cressington 108 Sputter Coater (Cressington Scientific Instruments) was used to coat the samples with a thin layer of gold to gain better image resolution.

### Statistics

All statistical analysis was done using GraphPad Prism 7 (GraphPad Software). Data were assessed for normalcy by the Shapiro-Wilk and the KS normality tests and reported as mean with standard error of the mean (parametric) or median with interquartile range (nonparametric). Parametric data were compared with 1-way ANOVA and post hoc Tukey's multiple comparisons test. Nonparametric data were compared with the Kruskal-Wallis test followed by post hoc Mann-Whitney comparison with Bonferroni correction. Values of $p < 0.05$ were considered statistically significant.

## RESULTS

### Particle shedding

Significant differences in airborne particles were observed in 0.5-μm and 1.0-μm particles based on the style of headgear worn. Post hoc analysis demonstrated that airborne particle contamination was significantly higher for disposable bouffant hats as compared with cloth hats at particle sizes of 0.5 μm ($p = 0.012$) and 1.0 μm ($p = 0.001$). There were no significant differences in other airborne particle sizes for these 2 hat types. In addition, there were no statistical differences in airborne particle counts when disposable skull caps and cloth hats were compared, or when disposable bouffants and disposable skull caps were compared (Table 1).

### Microbial shedding

Active microbial air sampling did not detect any differences in microbial shedding between any type of hat. Interestingly though, the amount of airborne microbes detected at the back instrument table was consistently and significantly higher than at the sterile field (Fig. 3A). This observation negatively correlated with air velocity within the room, which demonstrated that velocities at the back table were significantly lower than at the sterile field (Fig. 3B).

Passive settle plate microbial assessment did demonstrate a significant difference between hats (Fig. 4A). Bouffant hats yielded significantly higher levels of microbes (3, interquartile range [IQR] = 5) as compared with either disposable skull caps (1, IQR = 1) or cloth skull caps (1, IQR = 3; Fig. 4B). There was no difference in debris contamination (ie visible particulate matter, fiber contamination) between hat types (Fig. 4C). In

**Table 1.** Particle Counts with Different Operating Room Headgear

| | Bouffant | | Disposable skull | | Cloth skull | | KW |
|---|---|---|---|---|---|---|---|
| **Particle size, pass** | **Median** | **IQR** | **Median** | **IQR** | **Median** | **IQR** | **p Value** |
| 0.3 μm | | | | | | | |
| First pass | 48,775 | 33,181 | 46,795 | 20,193 | 50,544 | 27,546 | 0.67 |
| Second pass | 8,042,979 | 21,012,507 | 6,438,947 | 21,265,162 | 6,203,989 | 18,812,866 | 0.91 |
| Third pass | 6,445,975 | 22,055,148 | 2,837,841 | 21,623,512 | 100,358 | 18,188,184 | 0.38 |
| 0.5 μm | | | | | | | |
| First pass | 28,563 | 19,603 | 28,743 | 12,593 | 28,123 | 14,824 | 0.25 |
| Second pass | 776,787 | 866,690 | 538,342 | 2,059,248 | 325,052 | 530,541 | 0.03* |
| Third pass | 782,718 | 2,120,548 | 497,369 | 1,291,634 | 219,365 | 849,377 | 0.05 |
| 1.0 μm | | | | | | | |
| First pass | 14,523 | 9,043 | 13,957 | 6,618 | 13,100 | 7,147 | 0.24 |
| Second pass | 111,759 | 87,866 | 98,426 | 214,466 | 108,877 | 157,530 | 0.98 |
| Third pass | 129,648 | 238,011 | 83,749 | 144,434 | 54,706 | 111,927 | 0.03* |
| 5.0 μm | | | | | | | |
| First pass | 1,430 | 1,052 | 1,537 | 758 | 1,393 | 900 | 0.48 |
| Second pass | 1,620 | 1,248 | 1,560 | 738 | 1,713 | 761 | 0.63 |
| Third pass | 1,633 | 753 | 1,663 | 931 | 1,447 | 632 | 0.1 |

*Significant.
IQR, interquartile range; KW, Kruskal-Wallis.

addition, no human hairs were identified on any of the settle plates during experimentation.

### Permeability, penetration, and thickness

Bouffant hats and the disposable skull cap crowns had significantly higher permeability than the disposable skull cap sides or cloth skull caps (Fig. 5A). Three of the bouffant hats tested had permeability that was so high that it was not measureable by the machine. These 3 hats were arbitrarily given the highest value of measurable bouffants. Therefore, bouffants had a median permeability of 444.0 cubic feet per minute (CFM) (IQR 82.5 CFM). The disposable skull crown had a median permeability of 385.5 CFM (IQR 34.3 CFM), while the sides had a median permeability of 144.8 CFM (IQR 226.4 CFM). Cloth skull had the lowest median permeability, at 64.7 CFM (IQR 47.6 CFM).

Penetration of particulate matter was higher for bouffant hats (101.9% ± 1.1%) compared with either the disposable skull crown (94.6 ± 1.8%, $p < 0.05$) or the disposable skull sides (92.0 ± 0.6%, $p < 0.05$). Penetration of particulate matter was also higher for cloth skull

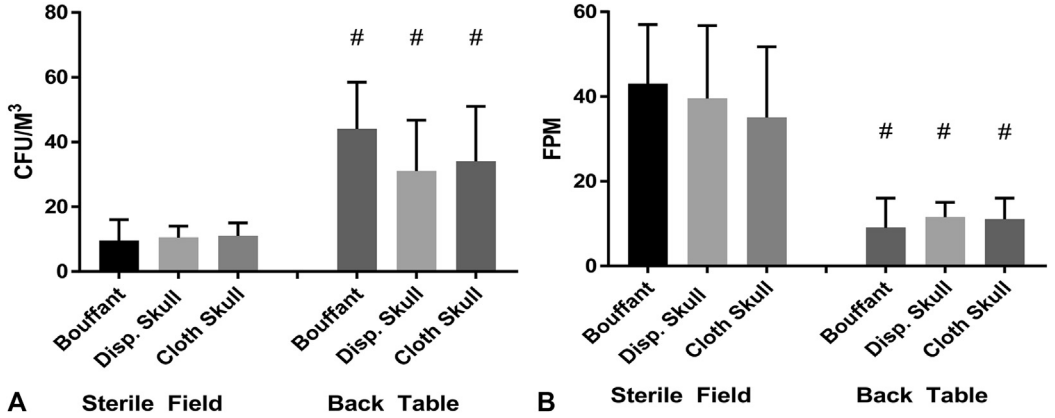


**Figure 3.** Active microbial assessment. (A) No differences were seen in airborne microbes at the sterile field or at the back table with regard to the type of hat worn. However, there was significantly higher microbial contamination at the back instrument table for all hat types when compared with the sterile operating field. (B) Air velocity at the sterile field was consistently higher in all conditions as compared with the back table. ($^{\#}p < 0.05$ vs respective sterile field value). CFU/M$^3$, colony-forming units per cubic meter; Disp., disposable; FPM, feet per minute.

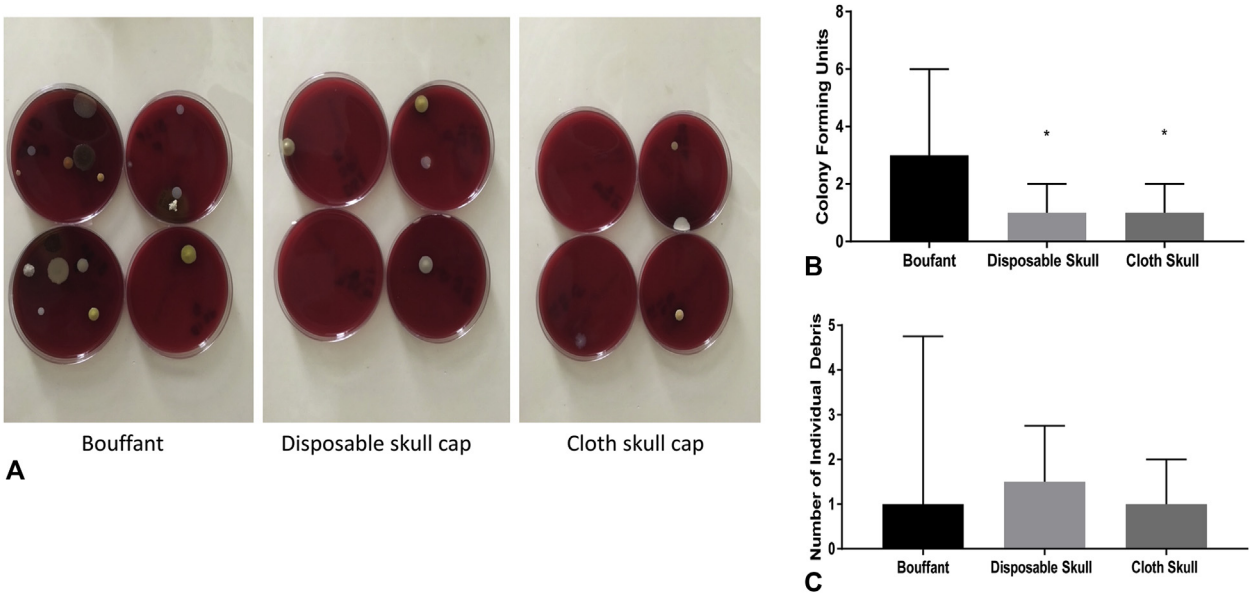


**Figure 4.** Passive microbial assessment. (A) Representative settle plates for bouffant, disposable skull, and cloth skull hats. (B) Higher numbers of colony-forming units were observed when bouffant style hats were worn compared to disposable skull or cloth hats. No significant difference was seen between disposable skull or cloth skull caps. (C) The level of debris detected was similar for each hat type.

hats (100.1 ± 0.84%) compared with either the disposable skull crown or the disposable skull sides ($p < 0.05$; Fig. 5B).

Cloth hats were significantly thicker than bouffants or the crowns and sides of disposable skull caps (Fig. 5C). There were no significant differences in hat thickness between bouffants and the crowns and sides of disposable skull caps.

## Porosity

Pore sizes were compared by maximum pore size, average pore size, and minimum pore size. There was no statistical difference between hats in minimum pore size (Fig. 6A). However, the average pore sizes (Fig. 6B) and the maximum pore sizes (Fig. 6C) in bouffant hats were significantly higher than those seen in cloth skull caps ($p < 0.05$). Bouffant hats had average and maximum pore sizes of 89.4 ± 30.68 μm and

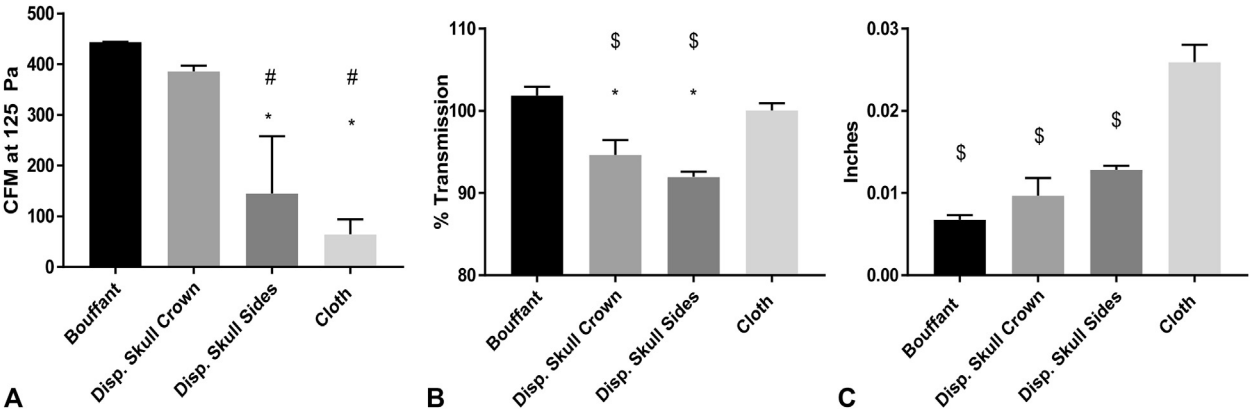


**Figure 5.** Hat permeability, penetration, and thickness. (A) The permeability of bouffant style hats was significantly higher than either the sides of the disposable skull cap or the cloth skull cap. The permeability of the crown of the disposable skull cap was also significantly higher than the sides of the disposable or cloth skull caps. No significant difference was seen in permeability between bouffants and the crown of skull caps. (B) Penetration of the bouffant hats and cloth skull caps was significantly higher than the disposable skull crown or sides. (C) Cloth skull hats were significantly thicker than bouffants or disposable skull cap sides or crowns. (*$p < 0.05$ vs bouffant hats, $^{\#}p < 0.05$ vs disposable skull cap crown, $^{\$}p < 0.05$ vs cloth skull cap). CFM, colony-forming units; Disp., disposable; Pa, Pascal.

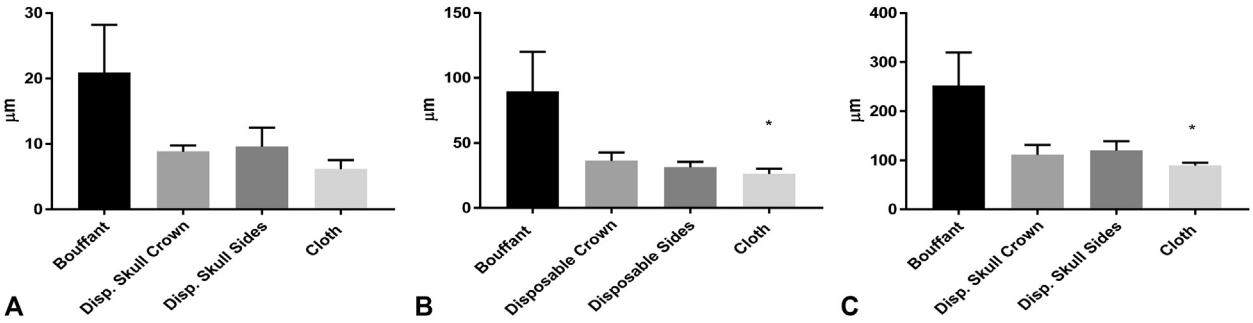


**Figure 6.** Hat pore size. No differences were seen between hats in terms of (A) minimum pore size. Bouffant hats did maintain significantly larger (B) average and (C) maximum pore sizes compared to cloth hats. No significant differences were seen in pore sizes between other groups ($p < 0.05$ vs bouffant). Disp., disposable.

251.8 ± 67.9 µm; those in the disposable skull cap crowns were 36.2 ± 6.6 µm and 111.0 ± 20.4 µm, disposable skull cap sides were 31.3 ± 4.1 µm and 119.8 ± 18.2 µm, and cloth skull caps were 26.1 ± 4.1 µm and 89.5 ± 5.7 µm. Representative scanning electron microscopy images of hat materials are depicted in Figure 7.

## DISCUSSION

Many policies that have been implemented in the operating room environment have been done so without rigorous scientific study. Most recently, the sterility of the surgical skull cap has been called into question, mostly because it exposes the hair around the nape of the neck and the sides of the head in addition to the ears. Some experts believe that a bouffant style hat is superior because these hats can be worn over the ears and hair, which are known sources of bacterial contaminants.[5,10] Here we report that bouffant hats are more permeable, have higher penetration of particles through the material, maintain a larger maximum pore size, and allow greater particle and microbial shed compared with certain types of skull caps.

The shedding of 0.5- and 1.0-µm particles was higher for bouffant hats as compared with cloth style skull

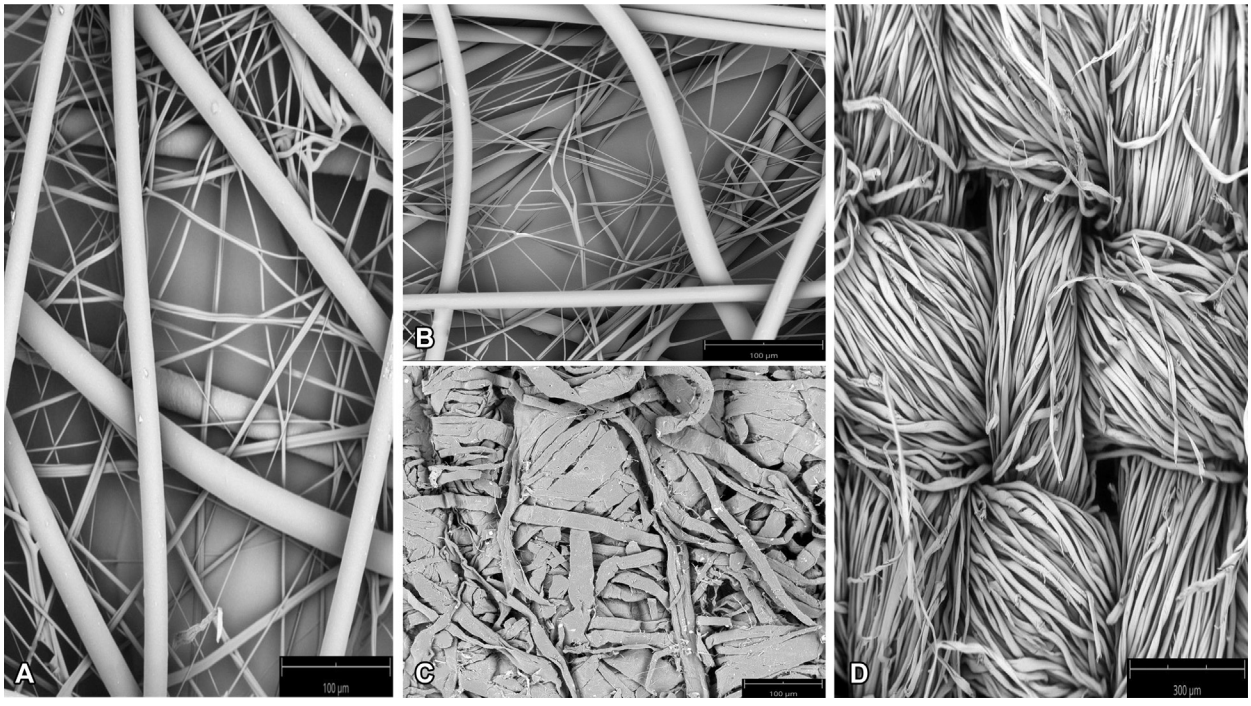


**Figure 7.** Electron microscopy. (A) Bouffant hats were visually identified with electron microscopy as having fairly porous material. (B) The crown of disposable skull caps also was made of a visually porous material. (C) The sides of the skull caps were visually less porous, as were (D) the cloth skull caps.

caps. No difference was seen in particulate airborne contamination between bouffant hats and disposable skull caps. This lack of difference may be due to the crown of the disposable skull caps being very similar to bouffant hats in terms of material composition. Therefore, particulate contamination may have been similar between these 2 hat types. It is interesting that only the 0.5- and 1.0-μm particles showed significant differences between cloth skull caps and bouffants. We observed a large variability in particle assessment throughout this study, and in our previous studies. We attributed this high variability to the use of electrocautery during the experiment. Electrocautery on a piece of steak, as is also seen on human flesh, generates a large amount of particles, and therefore the variation in numbers can be quite high.

Active assessment of airborne microbes yielded no significant differences between hat types at the sterile field or at the back instrument table. However, passive assessment with settle plates did reveal a significant decrease in microbial shed and deposition with the use of either a disposable skull cap or a cloth skull cap. The passive microbial assessment data are in line with other data in this study, which suggest that bouffant hats have higher porosity and permeability, and therefore, may contribute to higher levels of bacterial shed. The settle plates were set around the sterile field and were allowed to sit in place for the entire 1-hour mock surgical procedure. The Petri dishes in the active air samplers acquired 1,000 L of ambient air over 5.5 minutes and were changed regularly. Therefore, it is possible that having the settle plates out for the entire hour allowed for a better assessment of the ambient bacterial load.

The average and maximum pore sizes were observed to be larger in bouffant hats as compared with cloth skull hats. The median maximum pore size for bouffant hats was 247.9 μm and for cloth skull caps was 92.56 μm. It is generally thought that the average diameter of a single bacteria is between 0.2 and 0.3 μm, with lengths up to and slightly in excess of 1.0 μm.[14] In addition, the average diameter of a human hair ranges from 20 to 180 μm.[15] Therefore, the maximum pore diameters of both hats could allow bacteria and smaller diameter hair particles to escape, irrespective of the type of hat worn. The effects of pore size were seen in correlating with permeability and particle transmission. Bouffant style hats consistently had higher permeability. In fact, the bouffant hats at 1 institution were so porous that they were not able to effectively be measured by the permeability assessment machine.

Porosity also likely relates to higher transmission of particulate matter through the hat material. In this study, we saw that transmission of a small particle through bouffant hats was significantly higher than the crown or sides of disposable skull caps. We also saw that cloth skull caps had high particle penetration. Although not different from bouffants, cloth skull caps did have a higher transmission of particles than the crown or sides of disposable skull caps. Both bouffant hats and cloth hats had transmission numbers greater than 100%. This means that there were more particles noted on the downstream side of the tested material than on the incoming side. The explanation for this is that the fiber material actually added particles into the air stream during the assessment. This would suggest that bouffant hats and cloth hats may actually shed material during normal use in the operating room.

Another interesting finding was the consistent observation of higher microbial load at the back instrument table compared with the sterile field. This phenomenon likely relates to decreased air velocity over the back table as compared with the sterile field due to the placement of the diffusers in the ceiling and the air flow over the table. Despite these different conditions, the type of hat had no effect on microbial shed at these 2 sites with active assessment. These data are in line with previous studies that suggested that the location of the grilles providing ventilation, rather than the hat itself, make the most difference in terms of airborne contamination in the operating room.[4]

Limiting infectious complications in an operating room environment is of utmost importance. In this study, we observed that disposable bouffant hats had higher microbial shed compared with disposable skull caps, as assessed by passive settle plate analysis. In addition, bouffant hats had similar permeability and pore sizes, but higher particle penetration compared with disposable skull caps. Therefore, we concluded that disposable bouffant hats are not superior to disposable skull caps in terms of limiting airborne contamination in an operating room environment.

When assessing cloth skull caps, there appeared to be no differences in terms of microbial or particulate shed compared with disposable skull caps. Cloth skull caps had a lower permeability compared with the crown of a disposable hat, but no difference compared to the material that made up the sides. Furthermore, cloth skull caps had a higher transmission of particles through the material compared to disposable skull caps, suggesting that some of the cloth may shed with active wear. When comparing cloth skull caps to disposable bouffant hats, the cloth skull caps had lower particulate shed, and lower settle plate shed. In addition, cloth skull caps had a lower permeability, lower average and maximum pore sizes, and similar penetration compared with bouffants. These data might suggest that cloth skull caps are superior to disposable bouffant hats.

## Limitations

There were several limitations in this study that should be noted. First, our experiments were performed during a

mock procedure rather than during real operations with patients. Due to health privacy laws and ethical considerations, we were not able to perform these experiments during patient operations. However, the conditions of the mock procedure were very similar to those of a real operation, and therefore, the data are likely able to be extrapolated. In this regard, we believe that this study represents the best scientific attempt to assess operating room headgear in a dynamic, microbial loaded operating room.

An additional limiting factor to this study was that it was not blinded or randomized. The study personnel wearing the hats were also performing data acquisition as part of their scripted mock procedure. Therefore, they could not be blinded by the hat type. Study bias could therefore be a criticism, but we felt that careful adherence to the scripted mock procedure would eliminate that bias.

We also realize that there are likely numerous brands of disposable skull, cloth, and bouffant style hats on the market that are made of different materials. Some of these may be perform better than others in alleviating microbial and particulate airborne contamination. Comparing specific brands of hats was beyond the scope of this study and could be considered for additional studies. Furthermore, it is unclear how the laundering process of the cloth hats affected the outcomes. Given that the disposable hats were clean, we believed that testing a clean cloth hat would be prudent. However, it is common knowledge that surgeons don't always launder their cloth hats daily, and therefore, a dirtier, unwashed hat could possibly lead to different penetration, transmission, and airborne contaminant results.

## CONCLUSIONS

The topic of operating room headgear has been very controversial, and the quality of data used to support operating room policy surrounding this topic is marginal. In this study, we observed that bouffant style hats had high permeability, particle penetration, and porosity, and also had higher levels of bacterial and particulate contamination in a dynamic operating room environment. When compared with disposable skull caps, bouffant hats cannot be considered superior. Furthermore, if properly laundered the use of cloth skull caps may yield better sterility compared with standard disposable bouffants.

### Author Contributions

Study conception and design: Markel, Gormley, Greeley, Wagner

Acquisition of data: Markel, Gormley, Greeley, Ostojic, Wise, Rajala, Bharadwaj, Wagner

Analysis and interpretation of data: Markel, Gormley, Greeley, Ostojic, Wagner

Drafting of manuscript: Markel

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