Effectiveness of Oxygenation under the Drape in Phacoemulsification with Intraocular Lens Implantation: A Randomized Clinical Trial

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Objective: *To compare the oxygen saturation and comfort of the patients undergoing phacoemulsification with intraocular lens implantation (PE/IOL) between the patients with and without oxygenation under the linen drape.*
Setting: *Institutional practice.*
Material and Method: *A randomized, triple-blind, clinical equivalence trial was conducted. Eighty consecutive patients, scheduled for PE/IOL under topical or subconjunctival anesthesia, were randomized. The patients in group 1 received 5 liters/minute flow of 100% oxygen via tubes attached to the upper chest walls. Sham oxygenation was given to the patients in group 2. Patients, surgeons and investigators were masked. The oxygen saturation was recorded every 10 minutes. The patients rated the comfort score within 15 minutes after operation.*
Results: *In group 1 (n = 37), mean age was 68.2 10.5 years and mean operative time was 29.4 7.2 minutes. In group 2 (n = 43), mean age was 66.9 10.6 years and mean operative time was 27.2 6.3 minutes. In both groups, the oxygen saturation ranged from the mean of 97.3 to 100% throughout the present study. The 99% confidence intervals of the mean differences of the oxygen saturation at 10, 20, and 30 minutes after draping were -1.60 to 0.17%, -1.63 to 0.05%, and -2.37 to 0.74%, respectively. The comfort score was 84.9% in group 1 and 89.8% in group 2 (p = 0.61).*
Conclusion: *With or without oxygen flow under the drape with the tip of the oxygen tube 1.5 cm away from the chin during PE/IOL, the patients' oxygen saturation is equivalent. The patients' comfort is not statistically different. Oxygenation under the linen drape seems to be unnecessary in uncomplicated cases.*

Keywords: *Linen drape, Oxygenation, Phacoemulsification, Cataract*

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Cataract is the leading cause of blindness in developing countries[1]. Surgical intervention is routinely used to treat the disease. Most cataract operations are performed under local anesthesia. Under the surgical drape which covers the patient's face, hypoxia and carbon dioxide accumulation are considered as potential problems, especially in senile patients that frequently have coexisting cardiac, pulmonary or neurological diseases. Hypoxia and hypercapnia may cause hemodynamic and neurological adverse events[2] as well as local ocular effects such as increased intraocular pressure[3], which could inadvertently complicate the operations.

Oxygen administration via a nasal probe increased oxygen saturation in patients undergoing cataract surgery under retrobulbar anesthesia[4] and other elective intraocular surgeries under peribulbar

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block[5]. A study recommended air flow rather than oxygen flow since more patients with acidosis were found in the oxygen-administered group[6]. Suction of the re-breathing air under the drape in order to alleviate the carbon dioxide accumulation was also another area of interest. Numerous instruments have been invented to support both the oxygen tube and the suction[7-10]. These instruments are not readily available in most parts of the world, however.

Currently, most immature cataracts are removed by phacoemulsification under local anesthesia. Topical and subconjunctival anesthesia have almost replaced the injection anesthesia in these cases. The necessity of the oxygen flow under the drape is now questionable since the operating time is shorter and the anesthesia practice has been modified. The authors therefore conducted a study to assess the effectiveness of the oxygenation under the drape in terms of oxygen saturation and the comfort of the patients undergoing phacoemulsification and intraocular lens implantation under topical or subconjunctival anesthesia.

Design

A prospective, randomized, patient-, investigator- and physician-masked, clinical equivalence trial.

Material and Method

The study complied with the Declaration of Helsinki and was conducted in accordance with the Guidelines for Good Clinical Practice. The study protocol was approved by the Ethics Committee of the Faculty. Written informed consent was obtained in all subjects prior to trial entry.

Consecutive cataract patients, planned for phacoemulsification and intraocular lens implantation under topical or subconjunctival anesthesia, were enrolled. Exclusion criteria included the patients with pre-existing respiratory tract diseases and/or cardiovascular diseases and the patients with ocular diseases that might prolong the surgical time such as cases with corneal scar, very shallow anterior chamber, chronic uveitis with poor pupillary dilatation, and pseudoexfoliation syndrome. The patients with pre-existing oxygen saturation of lower than 90% were also excluded. For statistical reasons, the second eye of the patients who had already participated in the same study was excluded. A sample size of eighty subjects was estimated from an alpha error of 0.025 (2-tailed), 90% power, the equivalence range of $\pm$ 5% of the oxygen saturation, the standard deviation from internal pilot data of 5.9%, and a 10% anticipated dropout rate.

The subjects were randomly allocated by simple randomization. The sequence was generated by random number table. The allocation codes were separately kept concealed in stapled opaque paper packets.

The standard method of draping was used in every case (Fig. 1). Four linen clothes were used to make a full surgical drape. A piece of 90 x 90 cm cloth was initially placed to wrap the patient's hair. Simultaneously, another piece of the same size was placed under the patient's head. A 200 x 200 cm cloth was used to cover the patient's body, from chin to feet. A silicone oxygen tube of 7/10 mm size (inner diameter/outer diameter) was placed on the upper chest wall. The tube was taped to the linen cloth with the tube end at 1.5 cm away from the patient's chin. Another piece of 90 x 90 cm cloth with a central hole was then placed on the patient's face. With the vertical height of the Mayo stand from the patient's chest wall of 15 cm, one rim of the linen covering the patient's face was pulled up as a small tent to attach to the Mayo stand and thus make a 30 degree angle between the patient's chest wall and the drape. The length of linen from the patient's nose to the Mayo stand was around 40 cm. An ophthalmic drape (OpSite, Smith and Nephew Medical Limited, Hull, UK) of 15 cm x 28 cm size was placed on the linen drape afterwards.

Immediately after the patient's face was covered, the codes were opened by a research assistant who was not the generator of the allocation sequence. In group 1, the patients received 5 liters per minute (lpm) flow of 100% oxygen passing through a wall-mounted bubble humidifier. In group 2, no oxygen was given. Since the humidifier produced some bubbling sound and was rather close to the operating table, therefore, in an attempt to mask all the other personnel in the operating room, the research assistant, the only person who was aware of the code, would cover the oxygen outlet area with a dark green cloth. Under the cloth, the tubes were connected to the humidifier outlet in group 1, but not in group 2.

The operating room temperature was controlled between 24-26 degrees Celsius. All patients received 1000 mg acetaminophen orally before the operation. No sedatives were given. Phacoemulsification with intraocular lens implantation was performed under topical or subconjunctival anesthesia by 5 experienced surgeons using temporal, clear corneal incision and a standard phacoemulsification technique[11]. Oxygen saturation and pulse rate were continuously monitored with a pulse oximeter (Nellcor Ultracap N6000B, Pryon Corporation, Menomonee

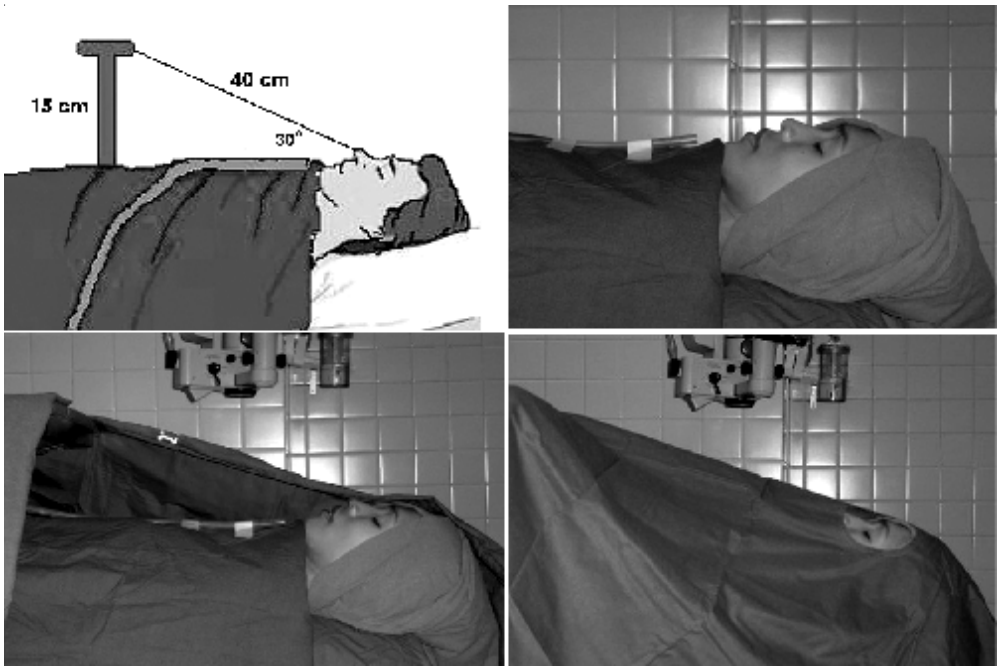

Fig. 1 The surgical draping method. (Top left) The schematic diagram shows the linen surgical draping. (Top right) The patient's head and trunk was covered with three pieces of linen cloth. The silicone oxygen tube was placed at 1.5 cm from patient's chin. (Bottom left) A tent was made by inserting the inferior rim of the linen drape under the Mayo stand. (Bottom right) The linen drape with a central hole completely covered the patient's face

Falls, Wisconsin, USA) via a finger probe. The oxygen saturation and pulse rate were recorded at time 0 and then every 10 minutes by a masked research assistant until the end of the operation. During the surgery, if the saturation was 90% or lower, the codes would be broken. In that case, 5 lpm oxygen flow would be given to the patients in group 1, and the oxygen flow would be raised to 10 lpm for the patients in group 2.

Within 15 minutes after the end of the surgery, the patients were asked to rate the comfort score in terms of the difficulty in breathing using visual analogue scale (VAS). Since most cataract patients were elderly and some of whom had poor vision in the other eye, a 30-cm ruler was used to facilitate the scale rating. The ruler was covered with a grayscale, without any numbers on its surface. The dark end of the ruler represented zero score (least comfortable), and the white end represented 100% (most comfortable). Aided by a masked research assistant, the patients were asked to look at or palpate the whole length of the ruler to approximate the 100% value and then assess the comfort score by pointing on the ruler at one point. The comfort score was the length measured from the dark end to that point, which was subsequently converted to a percentage.

The primary outcome, the oxygen saturation, was analyzed by confidence interval approach. Comfort score was compared by Student's t-test. Correlation between surgical time and comfort score was assessed by Pearson correlation. All statistical analyses were performed under SPSS version 11.0.1 for Windows (SPSS Incorporation, Chicago, IL). A p-value of less than 0.05 was considered statistical significant.

Results

A total of 80 eyes from 80 patients were enrolled and all of them completed the study. The demographic data and the baseline characteristics of the patients are shown in Table 1. Two patients (one from each group) were converted to extracapsular cataract extraction due to incomplete curvilinear anterior capsulorhexis. In both groups, the operation started at a median time of 3 minutes after the surgical draping (interquartile range; 2, 4 in group 1, and 2, 5 in group 2). The mean operating time was less than 30 minutes in both groups.

No codes were broken before the end of the study since the oxygen saturation was stably high, ranging from the mean of 97.3 to 99.5% in group 1 and 98 to 100% in group 2 throughout the study (Fig. 2).

Table 1. Demographic data and baseline characteristics of the patients

	Group 1 with oxygenation (n = 37)	Group 2 without oxygenation (n = 43)
Male: Female	16:21	18:25
Right: Left eye	19:18	26:17
First: Second eye	17:20	31:12
Subconjunctival: Topical anesthesia	29:8	37:6
Age in years*	68.2 ± 10.5	66.9 ± 10.6
Oxygen saturation at time 0* (%)	98.6 ± 2.0	98.7 ± 1.5
Pulse rate at time 0* (beats/min)	71.0 ± 13.0	71.0 ± 12.5
Operative time in minutes*	29.4 ± 7.2	27.2 ± 6.3

* baseline values expressed in mean ± SD

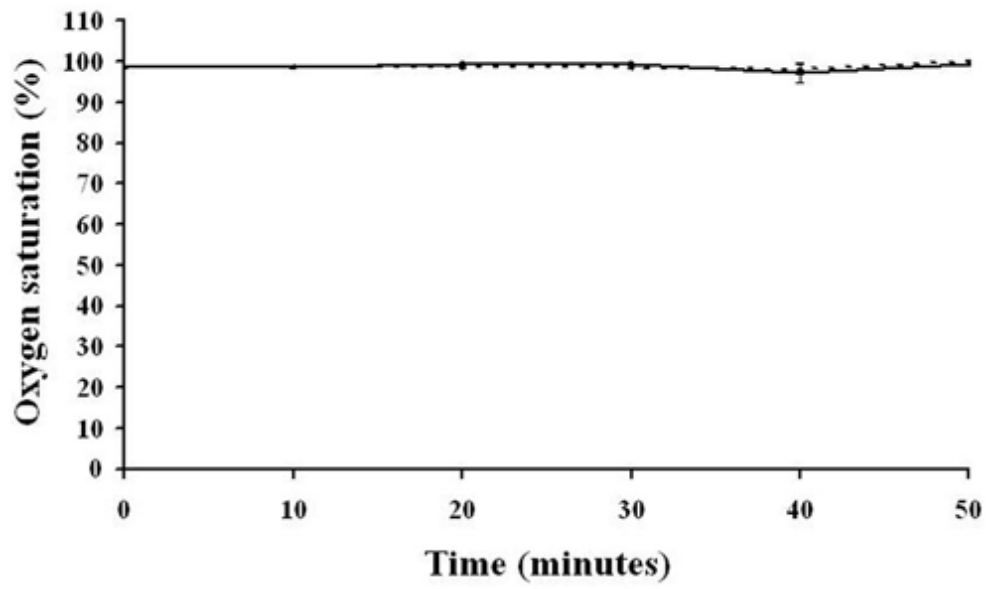

Fig. 2 The oxygen saturation in percentage (mean ± standard error of mean) at different time points, comparing oxygenation group (dark line) with no oxygenation group (dotted line)

The 99% confidence intervals of the mean differences of the oxygen saturation at 10, 20, and 30 minutes after draping were -1.60 to 0.17%, -1.63 to 0.05%, and -2.37 to 0.74%, respectively. The mean pulse rate ranged from 64 to 72 beats per minute (bpm) in group 1, and 69 to 88 bpm in group 2 (Fig. 3). Since most operations were completed within 30 minutes, the data at 40 minutes after draping were calculated from only 4 patients in each group. Similarly, at 50 minutes after draping, there were only 2 patients in group 1 and 1 in group 2. This patient in group 2 had the pulse rate of 103 bpm at time 0, 96 bpm at 40 minutes, and 88 bpm at 50 minutes and thus had made the mean pulse rate at 40 and 50 minutes higher than at the earlier time.

The mean VAS comfort score was 84.9% ± 14.1 (SD) in group 1 and 89.8% ± 7.5 (SD) in group 2 ($p = 0.61$). There was no significant correlation between the surgical time and comfort score in both groups ($r = 0.064$, $p = 0.708$ in group 1, and $r = -0.148$, $p = 0.342$ in group 2).

Discussion

Cataract extraction remains the most common intraocular surgery. The linen drapes are used to keep the surgical field sterile but may alternatively lead to hypoxia, hypercapnia, or patient discomfort. Studies have shown the advantages of oxygen supplementation in cases undergoing cataract extraction under

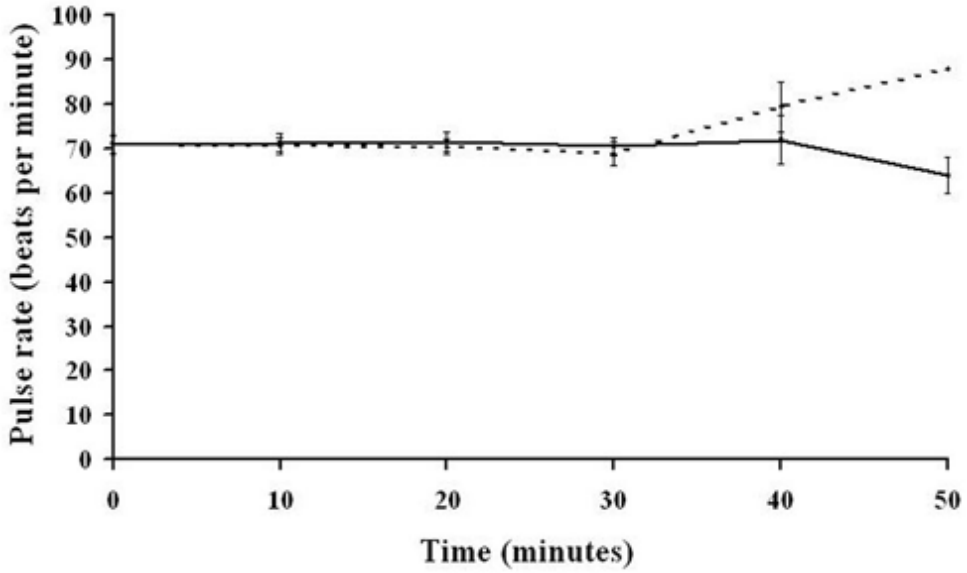

Fig. 3 The pulse rate in beats per minute (mean ± standard error of mean) at different time points, comparing oxygenation group (dark line) with no oxygenation group (dotted line)

retrobulbar or peribulbar anesthesia[4,5]. Due to the conversion of the cataract extraction techniques to phacoemulsification in most clinical settings, the shorter surgical time as well as the lower anesthetics amount and change of anesthetic techniques given to the patients, the question was raised whether the oxygenation is still needed.

The present findings have shown that even without the oxygenation, the oxygen saturation and comfort were similar to the patients with oxygenation. Nonetheless, the surgical draping method may vary from one institution to another which may alter the results of the oxygen saturation and patient comfort. The surgical time in the present study was approximately within 30 minutes. The findings might have limited generalization if the surgical time is much longer.

The oxygen saturation was selected as the primary outcome even though it might not exactly represent the intra-arterial partial pressure of the oxygen. Since the blood gas examination is an invasive procedure and is not routinely employed in cataract surgeries, a less invasive method, the pulse oximeter with a finger probe, was preferred in the present study.

The pre-specified equivalence limit of ± 5% was determined to compare with the mean difference between groups. Due to the stability of the oxygen saturation throughout the study, the authors have demonstrated that even with the 99% confidence intervals of the mean difference, the precision estimation intervals still located within the range of equivalence. The authors did not try to demonstrate the confidence interval or make any inference after the time point of 30 minutes since there were too few patients and the results would be misleading.

Surprisingly, in both groups, the comfort of the patients was not different and the authors did not find the correlation between surgical time and comfort score. The patient's discomfort may depend on other factors including the room temperature, previous surgical experience or the doctor-patient relationship, but with a randomized and masked fashion of the study, the selection and measurement biases are considered minimal.

In conclusion, with or without oxygen flow under the linen drape during the surgery, the oxygen saturation of the patient is equivalent. The patients' comfort was not different between the two groups. Providing oxygenation flow under the linen drapes in uncomplicated cases of phacoemulsification with implantation of the intraocular lens under topical or subconjunctival anesthesia is not necessary.

Acknowledgment

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Conflicts of interest

None declared.

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การเปรียบเทียบผลของการให้ออกซิเจนแก่ผู้ป่วยระหว่างการทำผ่าตัดสลายต้อกระจกด้วยคลื่นความถี่สูงและใส่เลนส์ตาเทียม: การทดลองทางคลินิกแบบสุ่ม

มาเรียม เอี่ยมสุคนธ์, ปิยะวรรณ กุลปภังกร, พริมา หิรัญวิวัฒน์กุล, วสี ตุลวรรธนะ

วัตถุประสงค์: *เพื่อศึกษาระดับความอิ่มตัวของออกซิเจนในเลือดและความสบายของผู้ป่วยที่ได้รับการผ่าตัดสลายต้อกระจกด้วยคลื่นความถี่สูงและใส่เลนส์ตาเทียม เปรียบเทียบระหว่างผู้ป่วยที่ได้รับและไม่ได้รับออกซิเจนภายใต้ผ้าคลุมผ่าตัด*

สถานที่ศึกษา: *โรงเรียนแพทย์*

วัสดุและวิธีการ: *การศึกษาทดลองทางคลินิกแบบสุ่ม มีการปกปิดทั้งผู้ป่วย ผู้ทำการศึกษา และผู้วัดผล โดยมีผู้ป่วยเข้าร่วมการศึกษา 80 คนที่ได้นัดผ่าตัดสลายต้อกระจกด้วยคลื่นความถี่สูงและใส่เลนส์ตาเทียม ภายใต้การระงับความรู้สึกโดยหยอดยาชาหรือฉีดยาชาใต้เยื่อบุตา แบ่งผู้ป่วยเป็น 2 กลุ่มโดยการสุ่ม กลุ่มที่ 1 ได้รับออกซิเจน 100% 5 ลิตร ต่อนาที ผ่านท่อที่ติดกับหน้าอกของผู้ป่วย กลุ่มที่ 2 มีท่อออกซิเจนติดที่หน้าอกแต่ไม่ได้รับออกซิเจน การจัดกลุ่มของผู้ป่วยจะถูกปกปิดไม่ให้ผู้ป่วย แพทย์ผู้ผ่าตัด และผู้ประเมินผลทราบ บันทึกความอิ่มตัวของออกซิเจนในเลือดทุก 10 นาที และผู้ป่วยจะประเมินความสบายภายใน 15 นาทีหลังผ่าตัดเสร็จ*

ผลการศึกษา: *ในกลุ่ม 1 (จำนวน 37 คน) อายุเฉลี่ย 68.2 $\pm$ 10.5 ปี และ เวลาการผ่าตัดเฉลี่ย 29.4 $\pm$ 7.2 นาที ในกลุ่ม 2 (จำนวน 43 คน) อายุเฉลี่ย 66.9 $\pm$ 10.6 ปี และ เวลาการผ่าตัดเฉลี่ย 27.2 $\pm$ 6.3 นาที ผู้ป่วยทั้งหมดมีระดับความอิ่มตัว 97.3-100% ตลอดการศึกษา ความแตกต่างของระดับความอิ่มตัวของออกซิเจนในเลือดเฉลี่ยในทั้งสองกลุ่ม มีค่าความเชื่อมั่นที่ระดับ 99% ณ เวลา 10, 20 และ 30 นาทีหลังการคลุมผ้าอยู่ระหว่าง -1.60 ถึง 0.17%, -1.63 ถึง 0.05% และ -2.37 ถึง 0.74% ตามลำดับ คะแนนของความสบายอยู่ในระดับ 84.9% ในกลุ่ม 1 และ 89.8% ในกลุ่ม 2*

สรุป: *ระดับความอิ่มตัวของออกซิเจนในเลือดของผู้ป่วยขณะที่ได้รับการผ่าตัดสลายต้อกระจกด้วยคลื่นความถี่สูงและใส่เลนส์ตาเทียมในกลุ่มที่ได้รับ หรือไม่ได้รับออกซิเจนใต้ผ้าคลุม ไม่มีความแตกต่างกัน ความสบายของผู้ป่วยทั้งสองกลุ่มไม่ต่างกันอย่างมีนัยสำคัญทางสถิติ ดังนั้นการให้ออกซิเจนใต้ผ้าคลุมด้วยวิธีที่ปฏิบัติอาจไม่มีความจำเป็นในระหว่างผ่าตัดชนิดนี้ในกรณีที่ไม่มีภาวะแทรกซ้อน*