

dificuldade cirúrgica em 9 de 20 pacientes (redução de  $47,8 \pm 17,2\%$ ), enquanto não houve qualquer reclamação dos cirurgiões nos outros dois grupos: dose baixa de 150 µg e placebo ( $p < 0,01$ ), questionando-se aquela dose para medicação pré-anestésica<sup>8</sup>. No presente estudo, não houve relato por parte dos cirurgiões de dificuldade técnica.

A avaliação de medicação pré-anestésica deve considerar, obviamente, efeitos desejados e incidência de complicações<sup>21,24,25</sup>. A dose de 150 µg por via oral, por exemplo, foi considerada dose baixa, com alguns autores relatando alterações hemodinâmicas associadas<sup>7,8,16</sup> e outros não<sup>17</sup>. O efeito da clonidina nas variáveis hemodinâmicas é controverso, com alguns autores sugerindo que não há alterações hemodinâmicas importantes em pacientes jovens e hígidos, enquanto outros relatam diminuição da pressão arterial sistêmica e bradicardia, mesmo nesse grupo. Outros, ainda, relatam maior estabilidade hemodinâmica em comparação a pacientes sem uso de clonidina pré-operatória. No presente estudo, não houve casos de bradicardia ou hipotensão arterial nos pacientes tratados com 100 µg de clonidina. Em contrapartida, houve um caso de hipotensão arterial grave (PAS menor que 80 mm Hg) no grupo de pacientes que recebeu a dose de 200 µg. Filos e col., utilizando dose de 300 µg de clonidina por via oral como medicação pré-anestésica, relataram 50% de bradicardia e 40% de hipotensão arterial em pacientes idosos submetidos a tratamento cirúrgico de catarata. Com a dose de 150 µg, encontrou 10% de bradicardia, havendo diferença estatística significativa entre os valores de bradicardia no grupo de dose alta e no de placebo. Em relação à pressão arterial, houve diferença significativa entre os dois grupos de clonidina e placebo, com diminuição das pressões arteriais sistólica, diastólica e média. Foi encontrada diferença estatística significativa também entre os dois grupos de clonidina ( $p < 0,001$ )<sup>8</sup>. Ghignone e col. registraram 35% de casos de bradicardia com a dose de 300 µg e não encontraram complicações com a dose de 150 µg em pacientes geriátricos submetidos a operações oftálmicas<sup>17</sup>. Stocche e col., estudando 60 pacientes submetidos ao tratamento cirúrgico de catarata com bloqueio peribulbar e dose de 150 µg de clonidina como medicação pré-anestésica em pacientes idosos, encontraram um caso de bradicardia (FC = 39 bpm) e nenhum no grupo controle<sup>16</sup>. Outro estudo, com a clonidina por via oral como pré-medicação na dose de 300 µg, encontrou vários casos de hipotensão arterial no período intra e pós-operatório<sup>26</sup>. Já outro com a clonidina por via oral na dose de 300 µg como medicação pré-anestésica não encontrou alteração hemodinâmica significante em relação ao grupo placebo<sup>27</sup>.

Ferreira e col., utilizando clonidina 100 µg via oral como pré-medicação em operações oftálmicas em 30 pacientes, encontraram 33% de bradicardia e 30% de hipotensão arterial em pacientes submetidos à anestesia geral, sendo que nos pacientes submetidos à anestesia locoregional não houve bradicardia nem hipotensão arterial<sup>28</sup>. Stocche e col. obtiveram

60% de pacientes "calmos ou dormindo" quando tratados com clonidina 150 µg via oral após 30 minutos como medicação pré-anestésica<sup>16</sup>. Esses resultados são semelhantes aos do presente estudo, porém neste com a dose de 100 µg de clonidina.

As operações intraoculares com anestesia regional demandam um paciente calmo, quieto e cooperativo<sup>19,21,24,25,29</sup>. Noventa minutos após utilizar-se a clonidina nas doses de 100 e 200 µg, 60% e 80% dos pacientes estavam sedados em Ramsay 3 e 4, respectivamente, enquanto 25% dos que utilizaram placebo apresentavam-se naqueles níveis de sedação. Nenhum paciente necessitou de complementação na sedação, teve agitação ou mesmo sedação excessiva. Concluindo, a clonidina na dose de 100 µg pode ser indicada como medicação pré-anestésica para facectomia por seu efeito na sedação, na diminuição da pressão intraocular e pela ausência de efeitos adversos na pressão arterial sistêmica e na frequência cardíaca.

### ***Clonidine as Pre-Anesthetic Medication in Cataract Extration: Comparison between 100 µg and 200 µg***

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#### **INTRODUCTION**

The objectives of premedication include: reduction of anxiety, sedation, amnesia, analgesia, reduction of airways secretion, prevention of the response to autonomous reflexes, reduction of the gastric volume and/or increase in pH, antiemetic action, facilitate anesthetic induction, reduction in the need of anesthetics, prophylaxis of allergic reactions, and prevention of myocardial ischemia<sup>1-5</sup>. Some of those objectives such as anxiety relief and sedation apply to virtually all patients while others only occasionally<sup>6</sup>.

Clonidine is the prototype of  $\alpha_2$ -adrenergic agonists. It has antihypertensive and sedative properties, inhibits adrenergic hyperactivity, it has potent analgesic properties, antisialagogue, and decreases intraocular pressure<sup>7,8</sup>. Premedication with clonidine reduces the incidence of intraoperative myocardial ischemia<sup>1,9,10</sup>, improves metabolic control in diabetics<sup>11,12</sup>, reduces the incidence of postoperative nausea and vomiting<sup>13,14</sup>, and reduces or abolishes postoperative tremors<sup>9,15</sup>. The effects of clonidine on hemodynamic parameters are controversial. In cataract surgeries, 150 µg of clonidine can have undesirable effects<sup>7,8,16</sup>. But this dose is also associated with hemodynamic stability, even in the geriatric population<sup>17</sup>. Higher doses are associated with excessive reduction in intraocular pressure<sup>17</sup>.

The results of studies published so far are not enough to define the best strategy when conducting anesthesia for the surgical treatment of cataracts<sup>18,19</sup>. The majority of the studies on premedication with clonidine in ophthalmologic surgeries compared doses of 150 and 300 µg. With the hypothesis of obtaining the desirable effects of sedation and reduction in intraocular pressure with hemodynamic stability using lower doses of clonidine, this study evaluated sedation, intraocular pressure, and hemodynamic changes associated with premedication with 100 µg and 200 µg of oral clonidine in outpatient cataract surgeries and compared them with placebo.

## METHODS

This study was approved by the Ethics on Research Committee of the Escola Paulista de Medicina, Universidade Federal de São Paulo. A randomized double-blind clinical study was conducted with 60 patients of both genders, physical status ASA I and II, 18 to 80 years old, undergoing extracapsular fasciectomy with or without phacoemulsifier. All patients signed an informed consent after being informed of the objectives and risks of oral clonidine. Data were gathered by the same anesthesiologist and ophthalmologist.

Patients with acute myocardial infarction during the 12-month period before surgery, angina, uncontrolled hypertension, uveitis, glaucoma prior ophthalmologic surgery or chronic use of topical drugs were excluded. Weight, height, physical status ASA, associated diseases, and surgical procedure performed were recorded.

Sixty white envelopes previously sealed identifying the premedication were used for randomization. Those envelopes contained 20 cards for each group: placebo, 100 µg of clonidine, and 200 µg of clonidine. The person who opened the envelope and administered the premedication did not tell the patients and physicians which drug was administered: group 1 - placebo; group 2 - clonidine 100 µg; and group 3 - clonidine 200 µg.

Two drops of 10% phenylephrine and 2 drops of 1% tropicamide were used to dilate the pupils of all patients after

determination of the blood pressure and heart rate. Intraocular pressure was measured in both eyes with the Perkins applanation tonometer.

Ninety minutes after the administration of oral clonidine, intraocular pressure, heart rate, and blood pressure were measured again. This was followed by the peribulbar block. After instillation of proximetacaine and antisepsis with topical povidone-iodine, peribulbar block with the two-puncture technique (superior and inferior) with a 30 x 7 mm needle was performed. Fifteen minutes after the blockade, and approximately 105 minutes after the administration of clonidine, sedation was evaluated once more.

The levels of sedation were evaluated before and after the oral administration of clonidine, according to the Ramsay sedation scale<sup>20</sup>: 1 – anxious; 2 – calm, awake; 3 – sleepy, but opens eyes to verbal commands; 4 – sleeping, only answers to vigorous verbal commands; 5 – sleeping, responding to painful stimulus of glabellar compression; and 6 – absence of answer to painful stimuli.

Results were analyzed as mean ± standard deviation (SD). The parametric Student *t* test was used to compare intraocular pressure, heart rate, and blood pressure among the groups. The Kruskal-Wallis test was used for ordinal data, such as sedation. Data were considered significant when  $p < 0.05$ .

## RESULTS

Significant statistical differences in gender, age, height, and weight were not observed among the groups (Table I). Twenty-three females (38%) and 37 males (62%) were evaluated. Patients in groups 1, 2, and 3 had a mean weight of  $63.7 \pm 9.5$ ,  $69.5 \pm 9.3$ , and  $67.9 \pm 12$  kg, respectively.

Thirty-six (60%) of those patients were healthy and 24 (40%) had associated diseases, being classified as ASA I and II, respectively. Phacoemulsification was the technique used more often (73%).

Hypertension (11) and diabetes mellitus (5) were the disorders observed more often. One case of rheumatoid arthritis, one of epilepsy, and one of allergic rhinitis were also observed.

Table I – Demographic Data

	Group 1	Group 2	Group 3
Gender			
Male	12 (60%)	13 (65%)	12 (60%)
Female	8 (40%)	7 (35%)	8 (40%)
Age (years) *	$64 \pm 10.5$	$61.5 \pm 16.4$	$61.8 \pm 2.6$
Weight (kg) *	$63.7 \pm 9.5$	$69.5 \pm 9.3$	$67.9 \pm 12$
Height (cm) *	$162 \pm 7.4$	$163 \pm 8.6$	$162 \pm 6.3$

Data expressed as Mean ± SD

Group 1 – placebo; Group 2 – clonidine, 100 µg; Group 3 – clonidine, 200 µg

Patients who received placebo and 100 µg of clonidine did not have significant reductions in heart rate, while patients who received 200 µg had significant reduction in heart rate (Table II).

Table II shows the mean systolic blood pressure in the study groups. A statistically significant reduction in systolic blood pressure was observed in patients who received 200 µg of clonidine (group 3).

A significant reduction in diastolic blood pressure was also observed in patients in group 3 (200 µg of clonidine) (Table II). One patient in this group developed severe hypotension with systolic blood pressure lower than 80 mmHg treated with rapid infusion of Ringer's lactate.

Patients who received clonidine and pupillary dilation had a significant reduction in intraocular pressure (Table II). In

the placebo group, a tendency for the reduction of intraocular pressure was observed, but it was not statistically significant.

A significant reduction in intraocular pressure was observed in patients who received clonidine but not pupillary dilation. In the placebo group, a tendency for the reduction of the intraocular pressure was observed, but it was not statistically significant (Table II).

As for the level of sedation, 90 minutes after the oral administration of clonidine, 60% of the patients in groups 2 and 80% of the patients in group 3 presented Ramsay 3 or 4 versus 25% of the patients in groups 1. After peribulbar block with bupivacaine 55%, 70%, and 95% of the patients in groups 1, 2, and 3 respectively presented Ramsay 3 or 4 (Table III).

Table II – Influence of Premedication with Clonidine

	Control	After 90 min	p
Heart rate			
Group 1	77.25 ± 11.2	76.2 ± 11.8	0.55
Group 2	75.6 ± 9.3	72.35 ± 12.7	0.16
Group 3	79.75 ± 16.95	68.35 ± 10.3	0.004 *
Systolic blood pressure			
Group 1	140 ± 19	142 ± 17	0.57
Group 2	132 ± 16	130 ± 17	0.88
Group 3	140 ± 19	126 ± 19	0.006 *
Diastolic blood pressure			
Group 1	84 ± 9	85 ± 11	0.82
Group 2	83 ± 8,6	81 ± 8,5	0.37
Group 3	87 ± 10	76.5 ± 13	0.0006 **
Intraocular pressure without pupillary dilation			
Group 1	12.5 ± 3	12.3 ± 2.8	0.1
Group 2	12.3 ± 2.8	10.2 ± 2.4	0.001 *
Group 3	14.6 ± 3.8	10.9 ± 3.3	0.0002 **
Intraocular pressure with phenylephrine and tropicamide-induced pupillary dilation			
Group 1	11.9 ± 3	10.9 ± 3	0.07
Group 2	12.3 ± 2.6	10.6 ± 2.5	0.003 *
Group 3	14.6 ± 3.9	11 ± 5.6	0.0002 **

Data expressed as Mean ± SD

Group 1 – placebo; Group 2 – clonidine, 100 µg; Group 3 – clonidine, 200 µg

\* p < 0.05; \*\* p < 0.001

Table III – Evaluation of Clonidine-Induced Sedation According to the Ramsay Sedation Scale

Time	Ramsay	Group 1	Group 2	Group 3	p
M <sub>0</sub>	1	-	-	-	0,95
	2	19 (95%)	20 (100%)	20 (100%)	
	3	1 (5%)	-	-	
	4	-	-	-	
M <sub>1</sub>	1	-	-	-	0,0001 **
	2	15 (75%)	8 (40%)	4 (20%)	
	3	5 (25%)	10 (50%)	10 (50%)	
	4	-	2 (10%)	6 (30%)	
M <sub>2</sub>	1	-	-	-	0,004 *
	2	9 (45%)	6 (30%)	1 (5%)	
	3	10 (50%)	9 (45%)	11 (55%)	
	4	1 (5%)	5 (25%)	8 (40%)	
p		0.015 *	0.0001 **	0.0001 **	

M<sub>0</sub> – control; M<sub>1</sub> – 90 min after clonidine; M<sub>2</sub> – 105 min after clonidine  
 \* p < 0.05; \*\* p < 0.001

## DISCUSSION

The doses of clonidine used in the present controlled double-blind clinical study presents results not tested yet on premedication with 100 µg of oral clonidine compared to 200 µg. The present study showed that it is possible to achieve sedation and a reduction in intraocular pressure without significant hemodynamic changes with 100 µg of clonidine.

In this study, 60% of the patients were classified as ASA I and 40% ASA II. Hamilton et al. detected a predominance of patients ASA 2 and 3 in 12,000 consecutive fasciectomy with intraocular lens implantation. Schein et al., evaluating 20,000 patients with cataract also observed that the majority was classified as ASA 2, but this study had a lower number of patients with comorbidities<sup>21-23</sup>.

Premedication with oral clonidine, 100 µg and 200 µg, in patients with pupillary dilation with tropicamide and phenylephrine caused a 13 and 24% reduction in intraocular pressure respectively. Using oral clonidine, 100 µg and 200 µg, a 17 and 25% reduction in intraocular pressure without pupillary dilation, respectively, was observed. Evaluation of the contralateral eye showed that the reduction in intraocular pressure was not secondary to the use of tropicamide and phenylephrine.

Comparisons between low doses of clonidine such as the ones used in this study were not found in the literature. Ghignone et al. reported a 35% reduction in intraocular pressure (IOP) 90 to 120 minutes after premedication with 5 µg.kg<sup>-1</sup> of oral clonidine, which lasted for at least six hours<sup>17</sup>.

Filos et al. observed an even greater reduction in IOP (47.8%) after similar oral dose, and a 32.1% reduction with 150 µg (2 to 2.5 µg.kg<sup>-1</sup>) of clonidine, which was significantly different that the control group<sup>8</sup>. Although reduction in IOP is a de-

sirable effect in cataract extraction, an exaggerated reduction can result in technical difficulties for the surgeons. Filos et al., using 4 to 4.5 µg.kg<sup>-1</sup> of oral clonidine (300 µg) as premedication, met with surgical difficulties in nine out of 20 patients (reduction of 47.8 ± 17.2%), while the surgeons of the other two groups, 150 µg and placebo, did not have any complaints (p < 0.01), raising the question of whether that dose should be used as premedication<sup>8</sup>. In the present study, the surgeons did not report technical difficulties.

Evaluation of premedication should obviously consider undesirable effects and the incidence of complications<sup>21,24,25</sup>. The oral dose of 150 µg, for example, was considered low, with some authors reporting associated hemodynamic changes<sup>7,8,16</sup> while others did not<sup>17</sup>. The effects of clonidine on hemodynamic parameters is controversial, with some authors suggesting that young and healthy patients do not develop hemodynamic changes, while others reported a reduction in systolic blood pressure and bradycardia in the same group of patients. Others have reported greater hemodynamic stability when compared to patients who were not premedicated with clonidine. In the present study, bradycardia and hypotension were not observed in patients who received 100 µg of clonidine. On the other hand, one case of severe hypotension (SBP < 80 mmHg) was observed in the group of patients premedicated with 200 µg of clonidine. Filos et al, using 300 µg of oral clonidine as premedication, observed and incidence of 50% of bradycardia and 40% of hypotension in elderly patients undergoing surgical treatment of cataracts. With 150 µg they observed a 10% incidence of bradycardia, and a statistically significant difference was observed in the levels of bradycardia between the high dose and placebo groups. As for blood pressure, a significant difference was observed between the two clonidine groups

and the placebo group, with a reduction in systolic and diastolic blood pressure and mean arterial pressure. A statistically significant difference was also observed between the two clonidine groups ( $p < 0.001$ )<sup>8</sup>. Ghignone et al. recorded and incidence of 35% of bradycardia with the dose of 300 µg, but they did not observe complications with the 150 µg dose in elderly patients undergoing ophthalmologic surgeries<sup>17</sup>. Stocche et al., studying 60 elderly patients undergoing surgical treatment of cataract with peribulbar block and premedication with 150 µg of clonidine, observed one case of bradycardia (HR = 39 bpm) and none in the control group<sup>16</sup>. Another study with premedication with 300 µg of oral clonidine observed several cases of intra- and postoperative hypotension<sup>26</sup>. On the other hand, in another study with 300 µg of oral clonidine as premedication, significant hemodynamic changes were not observed when compared with the placebo group<sup>27</sup>.

Ferreira et al., in a study with 30 patients, administered 100 µg of clonidine as premedication for ophthalmologic surgeries and observed 33% of bradycardia and 30% of hypotension in patients who underwent general anesthesia, but patients who underwent regional blocks did not develop bradycardia or hypotension<sup>28</sup>. Stocche et al. observed that, 30 minutes after receiving 150 µg of oral clonidine, 60% of the patients were "calm or sleeping"<sup>16</sup>. Those results are similar to the present study, except for the dose of clonidine, 100 µg.

Intraocular surgeries with regional blocks require patients to be calm and cooperative<sup>19,21,24,25,29</sup>. Ninety minutes after the administration of 100 and 200 µg of clonidine, 60% and 80% of the patients were sedate presenting Ramsay scores of 3 and 4 respectively while only 25% of the patients in the placebo group presented the same levels of sedation. Patients did not require supplementation of sedation, and agitation or excessive sedation was not observed.

To conclude, 100 µg of clonidine can be indicated as premedication in fasciectomy due to the sedative effect, reduction in intraocular pressure, and absence of adverse effects on blood pressure and heart rate.

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#### RESUMEN

Cruz JRS, Cruz DFBM, Branco BC, Santiago AEQ, Amaral JLG – La Clonidina Como Medicación Preanestésica en Facectomías: Comparación entre las Dosis de 100 µg y 200 µg.

**JUSTIFICATIVA Y OBJETIVOS:** *Evaluar la sedación, la presión intraocular y las alteraciones hemodinámicas con el uso de bajas dosis de clonidina, 100 µg y 200 µg por vía oral, como medicación preanestésica para operaciones de catarata en el ambulatorio.*

**MÉTODO:** *El trabajo fue realizado por la Universidad Federal de São Paulo, siendo un estudio clínico aleatorio y doble ciego en 60 pacientes de los dos sexos, estado físico ASA 1 y 2, con edad mínima de 18 años y máxima de 80 años. Los pacientes fueron divi-*

*dados en tres grupos: placebo, clonidina 100 µg y 200 µg. Las medidas de presión intraocular, frecuencia cardíaca y presión arterial, además de la evaluación de sedación, fueron hechas antes y después de los 90 minutos iniciales en que se administró la clonidina. Los niveles de sedación se clasificaron de acuerdo con la escala de sedación de Ramsay.*

**RESULTADOS:** *Los pacientes que recibieron placebo y 100 µg de clonidina, no presentaron una reducción de la frecuencia cardíaca con diferencia estadística significativa, mientras que los que recibieron 200 µg de clonidina, sí la presentaron. Los que recibieron clonidina en dosis de 200 µg presentaron una reducción en la presión arterial sistólica y diastólica ( $p < 0,05$ ). Un paciente que utilizó 200 µg de clonidina, debutó con hipotensión arterial grave y presión sistólica  $< 80$  mm Hg. Los pacientes tratados con clonidina, presentaron una reducción de la presión intraocular ( $p < 0,05$ ). En cuanto a la sedación, 90 minutos después de la administración del placebo y la clonidina 100 µg y 200 µg por vía oral, 25%, 60% y 80% de los pacientes estaba respectivamente en Ramsay 3 ó 4.*

**CONCLUSIONES:** *La dosis de 100 µg de clonidina puede ser indicada como una medicación preanestésica para facectomía, con efecto en la sedación, reducción de la presión intraocular y ausencia de efectos adversos en la presión arterial sistémica y en la frecuencia cardíaca.*