The use of a new viscoelastic substance combined with anaesthetic in cataract surgery by phacoemulsification

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AIM OF THE STUDY: *To compare and estimate the safety and efficacy of a new viscoelastic substance combined with anaesthetic used in phacoemulsification surgery.*
METHOD: *Eight hundred seventyfour patients observed at the Department of Optlamology and the Department of Family Medicine of the General State Hospital of Nikea-Piraeus (Greece) submitted to a phacoemulsification surgery for cataract during a six-month period were randomly divided into two groups of 437 patients each. All patients were operated using the same scheme of anesthesia, consisting of ropivacaine drops 0.75% and lidocaine gel 2% immediately before surgery. Viscoelastic without anesthetic was used during the operation of the patients of group 1, while the new viscoelastic with anesthetic (sodium hyaluronate 1.5% and lidocaine 1%) (viscoanesthetic) was used in group 2. No intravenous sedation was given to either group. Patients were asked to complete a questionnaire including irritation or pain sensation during various phases of the operation, after the operation, as well as the degree of satisfaction from the anesthesia scheme. The participating surgeons were called to estimate post-operative corneal edema.*
RESULTS: *In the first group of patients (viscoelastic without anesthetic) 15.6% of them reported pain during intraocular lens insertion, 24.6% reported burning sensation during acetylcholine injection, 17.4% reported pain during placement of the corneal suture, 4.1% immediate postoperative pain and 1.8% night pain. In the second group of patients (viscoelastic with anesthetic) the percentages were 1.8%, 3.2%, 4.3%, 3.6% and 1.4% respectively. 78.9% of the first group and 82.1% of the second group had no corneal edema on the first postoperative day. 91.1% of the patients of the first group and 97.3% of the second group were satisfied.*
CONCLUSION: *The new combination of viscoelastic and anesthetic is a safe and efficient choice for the cataract surgeon who uses only anesthetic drops for cataract operations. It minimizes patients' complaints and helps in achieving better cooperation during cataract surgery.*

KEY WORDS: Anesthetic, Cataract surgery, Phacoemulsification, Viscoelastic substance.

Introduction

The new techniques of cataract extraction, like phacoemulcification with folded lens insertion, would be impossible to develop without the use of viscoelastic substances. These substances allow the creation and maintenance of adequate space into the eyeball, while they simultaneously protect sensitive structures of the area (corneal endothelium).
The development of these atraumatic techniques leaded to the simplification of topical anesthesia, concerning mainly the globe movements, which are not necessary. The regional anesthesia by injection (retrobulbar, peribulbar and sub-Tenon's) has already been replaced by local anesthesia by drops [1]. This kind of anesthesia however, sometimes, has turned out to be inadequate and this fact led to its completion with the intracameral anesthesia, e.g. the infusion of anesthetic solution into the anterior chamber.
In this essay, we present the safety and efficacy of a new method of topical anesthesia using a new substance which combines both properties of the anesthetic and the viscoelastic. This new method is internationally known as VISCOANESTHESIA.
In recent years more and more ophthalmologists give up

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on regional anesthesia by injection (retrobulbar, peribulbar and sub-Tenon's) in cataract surgery by phacoemulsification and prefer true local anesthesia by drops [1], mainly due to its many advantages. The most important of them include less pain than with the injection and immediate recovery of the eye after surgery.

Major disadvantages of retrobulbar and peribulbar anesthesia are [2]: subconjuctival or lid hemorrhage, diplopia, damage to extraocular muscles (lid ptosis), peribulbar or retrobulbar hemmorhage [3], apnea, hypesthesia of the face [4], central nervous system disturbances [5], cardiac and respiratory problems [6], damage to the optic nerve and globe perforation.

The greatest disadvantages of local anesthesia by drops include: considerable residual motion of the globe and less deep level of anesthesia than retrobulbar and peribulbar injection. The combination of local anesthetic with drops and intravenous suppression offers deeper levels of anesthesia, there are however side effects of the anesthetic drugs, while the presence of an anesthetist is mandatory. Relative contra-indications for the application of local anesthetic by drops include: difficulty in communication between surgeon and patient (language), demanding operation, time-consuming operation, non co-operative patient and deafness. Absolute contra-indications are allergy to local anesthetic drops and nystagmus [2].

The use of local anesthetic drops goes back to 1884 when Karl Koller used cocaine dilution during eye operations [7]. Many years later in 1996, R.A. Fichman reported the application of local anesthesia using only tetracaine 0.5% drops in cataract surgery [8]. Later marcaine 0.75% and lidocaine 1-2% drops were also added; some ophthalmologists apply intravenous sedation along with the use of local drops [9,10]. In 1995 J.P. Gills introduces the combination of local tetracaine 0.5% drops and infusion of preservative-free lidocaine 1% solution into the anterior chamber (intracameral anesthesia) [11]. In the following years lidocaine gel 2% is used more often, either alone, or in combination with drops; its advantage over drops lies with the fact that the gel form has longer contact time with the ophthalmic tissues [12]. I.S. Barequet in one study published in 1999 in the Journal of Cataract and Refractive Surgery supports the idea that one application of lidocaine gel 2% preoperatively offers the patient anesthesia during cataract operation similar to that achieved by three consecutive applications of tetracaine 0.5% drops [13]. Finally, the use of cryoanalgesia was proposed by Fr. Gutierrez-Carmona (2003), during which no analgesic medication is applied and analgesia is achieved by freezing the eye with frozen BSS drops, frozen methylcellulose gel and frozen (at 4° C) BSS for anterior chamber maintenance [14].

Patients and methods

This is a double blind randomized combined parallel study. Our aim was to study and estimate the safety and effectiveness of a new viscoelastic substance combined with anesthetic. 874 patients participated in the study. They were randomly divided into two groups: Group 1 included 437 patients (mean age 69 years), of which 235 women and 202 men). Group 2 included also 437 patients (mean age 68 years), of which 227 women and 210 men. All patients were operated using the same scheme of anesthesia: use of ropivacaine 0.75% drops 7 and 5 minutes before the onset of surgery and lidocaine gel 2% 3 minutes before surgery. In group 1 the surgeons used viscoelastic without anesthetic in the anterior chamber at the beginning of operation and at any other stage considered necessary, while in group 2, the new viscoelastic with anesthetic (sodium hyaluronate 1.5% and lidocaine 1%) (viscoanesthetic) was used in the same way. No intravenous sedation was used in any of the above schemes.

Patients were asked to answer, according to our protocol, whether they felt uncomfortable and how much during various stages of the operation, as well as after surgery. The basic parameter we wanted to estimate was any pain or burning sensation of the patients during operation. The following protocol was applied: patients were asked whether they felt pain or burning during intraocular lens insertion, during acetylcholine infusion and during suture placement, wherever this took place. They could choose from three answers: not at all, slightly and intensely. Patients were asked whether they had any pain immediately after the operation.

If the answer was positive they were given one oral paracetamol tablet 500 mg. Next day patients were also asked if they had any pain during the previous night. Finally, they were also asked whether they were happy with the anesthetic scheme applied to them. If they had undergone peribulbar anesthesia in their first eye they were asked to compare the two methods by stating whether the first one or the second one were better or similar. If they underwent surgery of the first eye without the application of viscoanesthetic and in the second eye with viscoanesthetic, they were asked to compare the two methods.

Patients who referred allergy to any of the used medication as well as those requiring general anesthesia were not included in the study. One-eyed patients and patients with hearing problems were also excluded.

Surgeons were asked to confirm the hardness of the lens that had been estimated during preoperative assessment and ascribe it into one of four categories. They were also asked to estimate pupil's size at the beginning of operation. They reported the use of blue dye for capsulorhexis, any rupture of the posterior capsule with or without vitreous prolapse, the performance of anterior vitrectomy, the kind of intraocular lens used, whether it was placed in the bag or in the sulcus, the use of acetylcholine, as well as any placement of suture/s. Postoperative corneal edema was also reported and esti-

mated as well as patients' satisfaction from the method applied to them. On the first postoperative day the presence of corneal edema is confirmed and allocated into one of six categories: 1: slight localized edema, 2: slight diffuse edema, 3: moderate localized edema, 4: moderate diffuse edema, 5: serious localized edema and 6: serious diffuse edema. On the following days the clinical course of corneal edema was reported, until it completely subsided. In cases where no problem was noted patients were examined on the first, the third and seventh postoperative day.

In the 437 cases of group 1 nucleus hardness was rated as follows: 114 (26.1%) were rated stage +1, 126 (28.8%) were stage +2, 129 (29.5%) were stage +3, while 68 (15.6%) were rated as stage +4 (following the Wilmer classification [15]). In 53 patients (12.1%) blue dye was used during capsulorhexis. 21 patients (4.8%) had a pupil size smaller than 6 mm and in 6 of them (1.4%) pupil size was smaller than 4 mm. In 27 patients (6.1%) posterior capsule rupture was reported and in 23 patients (5.3%) vitreous prolapse happened as well and anterior vitrectomy was performed. Of those cases, the foldable intraocular lens was placed in the bag in 4 patients (0.9%), in 17 patients (3.9%) it was placed in the sulcus, while in 6 cases (1.4%) an anterior chamber lens was placed.

In group 2 which included 437 patients, nucleus hardness was rated as follows: 117 (26.8%) were stage +1, 123 (28.1%) were stage +2, 132 (30.2%) were stage +3 and 65 (14.9%) were stage +4 (according to Wilmer classification [16]). In 49 patients (10.8%) blue dye was used during capsulorhexis. In 22 patients (5%) pupil size was smaller than 6 mm, while in 7 (1.6%) it was smaller than 4 mm. Posterior capsule rupture was reported in 24 patients (5.5%) and vitreous prolapse took place in 19 (4.3%) patients. In these cases the foldable intraocular lens was placed in the bag in 6 patients (1.4%), in the sulcus in 13 patients (2.9%), while in 5 cases (1.2%) an anterior chamber lens was used.

Participating surgeons operated on all patients with their own way and used the same phacoemulsification machine (Legacy 2000 by Alcon).

Results

In the group following the first scheme (viscoelastic without anesthetic) 68 patients (15.6%) sensed pain during intraocular lens insertion. Of them 54 (12.4%) referred to it as mild, while 14 patients (3.2%) referred to it as intense. Acetylcholine was used in 362 patients. Of them 89 (24.6%) complained of burning sensation; 73 patients (20.2%) of the above group referred to burning as mild, while 16 of them (4.4%) referred to it as intense. Suture placement was performed in 109 patients and from them 19 patients complained about pain (17.4%). Of them 8 patients (7.3%) referred to it as mild, 11 patients (10.1%) referred to it as intense. 18 patients (4.1%) complained of immediate postoperative pain. On the first postoperative day, night pain was reported by 8 patients (1.8%).

The results in group 2 (viscoelastic combined to anesthetic) were as follows: 8 patients (1.8%) complained for pain during intraocular lens insertion; they all rated the pain as mild (1.8%). Acetylcholine was infused in 351 patients; of them, 11 patients (3.2%) reported burning during infusion. From them 10 patients (2.8%) rated the burning as mild, one patient (0.4%) rated it as intense. Suture was placed in 93 patients. 4 patients (4.3%) reported pain at this stage. From them, 3 patients (3.2%) complained of mild pain, one patient (1.1%) rated pain as intense, while 16 patients (3.6%) complained of immediate postoperative pain. On the first postoperative day 6 patients (1.4%) reported pain during the previous night.

In Fig. 1 we can see the percentages of pain and burning sensation during the different phases of phacoemulsification and after it, in both groups.

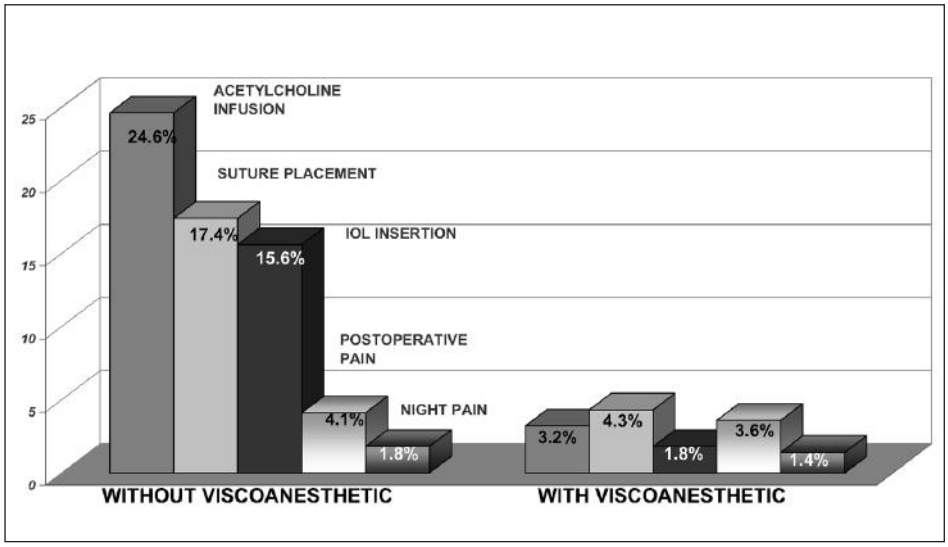

Fig. 1: Pain and burning sensation during the different stages of phacoemulsion and after it, with and without the use of viscoanesthetic.

The statistic analysis (x^2), with or without Yates' correction, shows that the difference between the two groups as concerning the pain and burning sensation during the infusion of acetylcholine, the placement of the suture(s) and the intraocular lens insertion is statistically important ($p < 0.01$). There is no statistical difference as concerning the immediate postoperative and the night pain.

In group 1 corneal edema was absent in 345 patients (78.9%) on the first postoperative day. Mild localized edema (mainly at the site of entry) was noted in 59 patients (13.5%), mild diffuse edema was reported in 9 patients (2.1%), moderate localized edema was present in 18 patients (4.1%), moderate diffuse edema was present in 4 patients (0.9%), intense localized edema was evident in 2 patients (0.5%), while no patient (0%) presented intense diffuse edema.

In group 2 no corneal edema was noted in 359 patients (82.1%), mild localized edema (at the entry site) existed in 51 patients (11.6%), mild diffuse edema was present in 10 patients (2.3%), moderate localized edema was present in 13 patients (3%), moderate diffuse edema was noted in 3 patients (0.7%). Intense localized edema was reported in one patient (0.2%) while no patient presented with intense diffuse edema.

On the third postoperative day following the standard postoperative treatment the results in group 1 were as follows: no corneal edema in 408 patients (93.3%), mild localized edema in 18 patients (4.1%), mild diffuse edema in 6 patients (1.4%), moderate localized edema in 2 patients (0.5%), moderate diffuse edema in 2 patients (0.4%), intense localized edema in one patient (0.2%) and intense diffuse edema in no patient.

On the third postoperative day, following the standard postoperative treatment the results in group 2 were as follows: no edema in 411 patients (94.1%), mild localized edema (at the entry site) in 14 patients (3.2%), mild diffuse edema in 7 patients (1.6%), moderate localized edema in 2 patients (0.5%), moderate diffuse edema in 2 patients (0.4%), intense localized edema in one patient (0.2%) and intense diffuse edema in no patient.

On the seventh postoperative day, following the standard postoperative treatment, results in group 1 were as follows: 436 patients (99.8%) had no edema at all and only one patient (0.2%) presented mild diffuse edema.

In group 2 (following the standard postoperative treatment) 436 patients (99.8%) had no edema at all, while only one patient (0.2%) presented mild diffuse edema.

The standard postoperative treatment included 250 mg acetazolamide orally in the afternoon of the operation day and another 250 mg on the following day. Local drops included antibiotic combined to steroid five times daily and non-steroid anti-inflammatory drops three times daily for the first two postoperative days. Then, both preparations were applied three times daily.

As far as patients' satisfaction was concerned, in group 1, 398 patients (91.1%) were happy with the anesthetic scheme and 39 patients (8.9%) were not. In group 2, 425 patients (97.2%) were happy, while 12 (2.7%) were not.

From the 87 patients who had been previously operated on the other eye with peribulbar anesthesia, 84 (96.6%) claimed that the new method with the drops was better than the previous one. 3 patients claimed that the two methods were equally good, while no patient suggested that peribulbar anesthesia was a better method.

94 patients were operated on the one eye following scheme 1 and on the fellow eye following scheme 2. From them 68 (72%) considered both schemes as equally good, 23 (24.5%) thought the second scheme was better, while only 3 patients (3.2%) said the first scheme was better than the second.

Discussion

Patient's comfort during cataract surgery is very important. Any reaction to pain or burning may cause problems to the surgeon at the time of surgery. The main reactions include firm squinting of the eyelids and abrupt upward movement of the eyes. In those patients operated on with anesthetic scheme 1 (ropivacaine drops 0.75%, lidocaine gel 2% before surgery and viscoelastic without anesthetic during the operation), the previously mentioned problems were limited by informing the patient in time at the stage of intraocular lens insertion, at the acetylcholine infusion and at the placement of suture about the forthcoming pain, in order to eliminate possible reactions. At the stage of intraocular lens insertion the use of manipulator from the side-port entry further limited the upward movement of the globe. At the stage of acetylcholine infusion we first sealed the wound by inducing corneal edema, or by placing a nylon 10-0 suture. If this was not achieved, abrupt squinting due to burning might cause anterior chamber to collapse, inducing endothelial cell damage, intraocular lens dislocation or even iris prolapse. In six cases (operated on after the completion of this study) that got started on ropivacaine drops, lidocaine gel and viscoelastic without anesthetic and complained of pain at some stage, we decided to use the new viscoelastic combined with anesthetic at the time of discomfort. However, the results were not satisfactory; all patients continued to be in pain for some more minutes after the infusion and never reached the ideal level of anesthesia achieved in similar cases, where the new viscoelastic had been used from the beginning. Probably the simple viscoelastic had covered the tissues and this reduced the effectiveness of the new viscoelastic by limiting its contact with the eye tissues. We did not face similar problems in those cases where the new viscoelastic had been used right from the start even though we faced pain-inducing situations. Our experience with intracameral anesthesia showed that the

anesthetic effect of liquid lidocaine lasts for about 25 minutes after its infusion in the anterior chamber; the anesthetic effect of the new viscoelastic with anesthetic however lasts longer. This may be due to the mixture of lidocaine with sodium hyaluronate, which allows for longer lasting contact with the tissues of the anterior chamber. Repeated application of the new viscoelastic with anesthetic in the anterior chamber further prolongs globe anesthesia.

Apple D., Werner L. et al reported at the American Society of Cataract and Refractive Surgeons in Philadelphia, USA, in June 2002 that the new combination of viscoelastic with anesthetic is non toxic to endothelial cells and to the retina in case there is posterior capsule rupture (this study was performed on rabbits) [14]. The participating researchers in the multi-center study presented at the 7th ESCRS Winter Refractive Surgery Meeting reported that there was no significant endothelial cell loss compared to the previous viscoelastics.

At the present study, the surgeons did not notice any differentiation between the two groups as concerning the postoperative edema and the degree of its retreat during the next days, while the attributes of the new viscoanesthetic, beyond its anesthetic action (elasticity, viscosity, pseudoplasticity, clearness), were satisfactory. There are no studies so far as to possible side effects of lidocaine on the natural lens of the eye over a long period of time. Until there are, we must be cautious with the use of intracameral lidocaine 1% as well as the use of the new viscoelastic with lidocaine 1%, in ophthalmic operations where no lens removal is involved, like trabeculectomy (in case viscoelastic is used), phakic intraocular lens insertion for the correction of high myopia, penetrating corneal wound management, etc.

Conclusion

The new viscoelastic combined with anesthetic is a safe and effective choice for the surgeon performing phacoemulsification on anesthetic drops only for cataract removal. It minimizes patient's discomfort and pain, thus achieving better cooperation during cataract surgery.

Riassunto

OBIETTIVO: Lo scopo di questa ricerca era quello di valutare la sicurezza e l'efficienza di un nuovo materiale viscoelastico con aggiunta di anestetico, comparando due schemi d'applicazione.

MATERIALE E METODO: Abbiamo utilizzato parallellamente in due diversi campioni di 437 pazienti ciascuno, per un totale di 874 pazienti operati di cataratta col metodo della lentemulsificazione, in un intervallo di tempo di sei mesi. Lo studio è stato comparativo, parallelo, doppio e randomizzato.

CONCLUSIONI: Dallo studio effettuato si conclude sulla efficienza e la sicurezza che deriva dall'uso del nuovo preparato viscoelastico con aggiunta di anestetico, sia per il chirurgo che ne usa solo poche gocce per effettuare l'intervento, ma anche per il paziente, di cui il detto preparato diminuisce i possibili fastidi nel postoperatorio e permette di ottenere una migliore sua collaborazione durante l'intervento. Bisogna tenere conto che durante l'operazione, non si è somministrato dell'anestetico per via endovenosa a nessuno dei pazienti dei due campioni. Dopo l'intervento i pazienti sono stati convogliati a rispondere su delle domande riguardanti la loro soddisfazione dall'utilizzo del preparato viscoelastico con aggiunta di anestetico, l'efficacia del metodo e lo sviluppo o meno di fastidi durante oppure dopo l'intervento. I chirurghi d'altra parte sono stati portati a valutare nel postoperatorio, in base alle norme del protocollo usato per la ricerca, l'entità dell'edema sclerale, dei pazienti da loro operati.

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Commento Commentary

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Lavoro comparativo, randomizzato in doppio cieco di valutazione dell'effetti anestetico in chirurgia della cataratta con anestesia topica senza sedazione endovenosa, per l'uso di un viscoelastico-anestetico (jaluronato di sodio 1,5% con aggiunta di lidocaina 1%), usato fino dall'inizio dell'intervento di facoemulsificazione per il mantenimento degli spazi chirurgici e per la protezione delle strutture sensibili (endotelio corneale) e per il blocco dei recettori iridei, stimolati in particolar e da manovre di sfregamento chirurgico intraoperatorio con rilascio di prostaglandine miosizzanti [1] o per azione dell'acetilcolina iniettata in Camera Anteriore (CA) al termine dell'intervento per ottenere la miosi, desiderabile peraltro soltanto in questo ultimo tempo chirurgico.
I pazienti che vengono preparati in anestesia topica (ropivacaina 0,75% e lidocaina gel 2% applicati esternamente su cornea e congiuntiva e divisi in due gruppi: senza (gruppo 1) e con aggiunta di viscoanestesia intracamerulare (gruppo 2).
Non vi sono differenze statisticamente significative fra i due gruppi per età, sesso, popolazione né per caratteristiche della cataratta, valutabile per durezza del nucleo (che può implicare manovre più complesse e maggior durata dell'intervento correlabile al maggior sonicazione, cavitazione e riscaldamento della CA e conseguente maggiore edema corneale postoperatorio) e per uso del colorante capsulare, percentualmente similare nei due gruppi, se assumiamo l'uso del colorante come un plus per facilitare la visibilità della capsula anteriore in casi complessi o in carenza di riflesso rosso e, dunque, per maggiore densità dell'opacità catarattosa [2,3]. Non vi è differenza statistica nemmeno per le rotture capsulari, incidente intraoperatorio che peraltro presenta nella somma dei due gruppi un totale relativamente elevato (5,8% [51/874]) [4].
L'analisi statistica rileva differenze significative soltanto nella percezione soggettiva del dolore intraoperatorio ($p < 0.01$), ridotto dalla viscoanestesia; non c'è, invece, differenza nel controllo del dolore postoperatorio notturno (1,8% gruppo 1; 1,4% gruppo 2). Questo vale anche per l'edema corneale postoperatorio sino al 3° controllo del 7° giorno.
Dunque il metodo si applica con vantaggio al solo tempo intraoperatorio perché consente una migliore compliance del paziente, fattore importante per il buon esito della chirurgia.
Interessante la nota, fuori protocollo, che l'aggiunta di viscoanestesia a chirurgia già iniziata per meglio dominare in anestesia topica insufficiente (quindi con viscoelastico non anestetico già iniettato in CA) non raggiunge gli stessi effetti di controllo del dolore : "probably the simple viscoelastic had covered the tissues and this reduces the effectiveness of the new viscoelastic by limiting its contact with the eye tissue".
In conclusione, per la numerosità campionaria e per la semplicità dell'end-point, si tratta di uno studio confermativo di utilità pratica per il chirurgo della cataratta.

The present comparative, randomized, double-blind study involves assessment of the increased anaesthetic effect of topical anaesthesia without intravenous sedation in cataract surgery. A viscoelastic-anesthetic (sodium hyalodurate 1.5% and lidocaine 1% was used right form the beginning of phacoemulsification surgery. This is important for maintaining surgical spaces and for protecting the sensitive structures (corneal endothelium). Furthermore, iris receptor are blocked, which are stimulated by particular intraoperative surgical friction maneuvers with release of myotic prostaglandins [1] or by the action of acetylcholine injected in the anterior placed zonules (CA) at the end of the operation so to obtain myosis, which is desirable only during this last surgical phase.
Patients were prepared under topical anaesthesia (ropivacaine 0.75% and lidocaine 2% applied externally on the cornea and conjunctiva). Patients were divided into two groups : without (group 1) and with intracamerular viscoanasthesia (group 2).
No statistical significant differences could be evidenced in the two group in terms of age, sex, race and for cataract characteristics. This latter could evaluated for nucleus hardness (which could imply more complex maneuvers and longer operations that can be correlated with greater sonication, cavitation, and warming up of CA and consequent greater postoperative corneal edema) and for the use of a staining as an addition to facilitate CA visibility in complex cases or when

lacking red reflex and thus for higher density of catarct opacity [2,3]. No statistical differences could be observed neither in terms of capsule rupture, which is an intraoperative accident showing a relatively high totale (5.8% [51/874]) in both groups [4]. The statistical analysis reveals significant differences only in the subjective perception of intraoperative pain ($p < 0.01$), whis is reduced by viscoansthesia. While no differences could be found in terms of relief of night postoperative pain (1.8% group 1; 1.4% group 2). This is also true for postoperative corneal edema, up to the 3rd check up at the 7th day after operation.

Out of the experiment protocol, it is noteworthy that the addition of viscoanasthesia, when the operation was already started to better dominate an insufficient topical anesthesia (thus with non-anesthesic viscolelastic already injected in CA), does not reach the same effects of pain relief probably due to the fact the "the simple viscoelastic had covered the tissues with the eye tissues".

In conclusion, considering the sample and the simplicity of the end-point, this is a confirmatory study that can be useful for cataract surgeron.

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