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INFLUENCE OF VERBAL DISTRACTION ON PAIN PERCEPTION DURING CATARACT SURGERY

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Table of Contents

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LIST OF ABBREVIATIONS

ARE – antioxidant response element

CAPA – clinically aligned pain assessment

ECCE – extracapsular cataract extraction

GSH – glutathione

GSSG – oxidized glutathione

ICCE – intracapsular cataract extraction

IOL – intra-ocular lens

MSCIS – manual small incision cataract surgery

NRS – numerical rating scale

OCT – optical coherence tomography

PCS – pain catastrophizing scale

SCA – skin conductance algesimeter

STAI – state-trait anxiety inventory

VAS – visual analogue scale

VRS – verbal rating scale

XOD – xanthine oxidase

1. INTRODUCTION

Cataract extraction is one of the most frequently performed surgeries worldwide. It is generally done under topical anesthesia. However, evidence shows retrobulbar and peribulbar block provide more effective analgesia. With this study we want to investigate if the effect of topical anesthesia can be facilitated using verbal distraction.

1.1. Etiology

The natural lens is a clear, crystalline, biconvex structure that is responsible for one third of the eye's refractive power (1). It is positioned in the posterior chamber of the eye and receives accommodation by the ciliary body (2). The ciliary body is attached to the lens by zonule fibers (2). Unaccommodated, an adult lens has a thickness of four to five millimeters (1).

Gradual opacification of the lens and loss of visual acuity is known as cataract and is most commonly an age-related process (3). Cataracts are a preventable form of vision loss and remain the leading global cause of blindness and moderate to severe vision impairment (4, 5). Surgical lens removal is the only available treatment option (4, 5). Apart from age-dependent disease development other predisposing risk factors have been identified. Those include UV light, alcohol, smoking, dehydration, radiation, corticosteroid use and diabetes mellitus (1).

Lang assumes senile cataract occurrence to be of familial tendency (2), however the precise etiology remains complex and unidentified.

Lens' clarity is maintained by reducing fiber scatter within the lens (1). This is achieved by removal of free radicals and prevention of bond formation with lens proteins (1). Based on this concept, Vinson concludes a direct causal relationship of oxidative stress and lens opacification (6). Furthermore, comparison of serum anti-oxidative enzyme levels in patients with age-related cataract and healthy controls indicate the presence of disequilibrium in the former group (7). These findings suggest the enhancement of the antioxidant defense systems as a mechanism of disease delay and prevention (7).

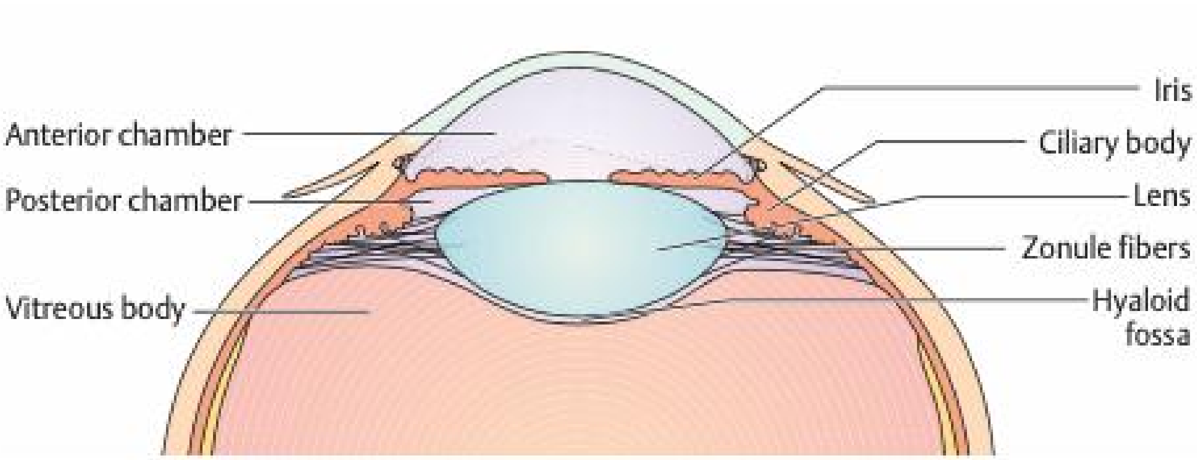

Figure 1. Shape of the lens and its position in the eye taken from Lang G. Ophthalmology. Stuttgart: Thieme; 2007

1.2. Epidemiology

Cataracts are the most important cause of blindness worldwide, contributing to 33.4% of global blindness (8). The estimated global cataract prevalence in adults over 50 years is 47.8% (9). Cataract operations with implantation of an intra-ocular lens belong to the most commonly performed and most effective surgeries in medicine (3). They are responsible for major health care expenditures in Europe and Western countries (3, 9). The 3 subtypes of senile cataract are nuclear, cortical and posterior subcapsular and they vary in prevalence among ethnicities (3). Nuclear cataract presents with yellowing and sclerosing of the nucleus and is more common among Caucasians in the US (3). Cortical cataract is characterized by wedge-shaped areas in the cortical layer and is more prevalent among African Americans in the US (3). Equally present among Caucasians and African Americans is the posterior subcapsular subtype that exhibits plaque-like opacities in posterior cortical layers (3). Although there is a global decline in blindness due to cataracts, blindness is still a frequent complication in countries with lower socioeconomic status (10, 11). The highest prevalence of cataracts is found in western sub-Saharan Africa among adults older than 50 years (10, 11). The greatest decline in the same age group is seen in Asia, tropical Latin America and Western Europe (10, 11). A higher cataract burden is not only associated with lower socioeconomic status and old age, but also with female gender (12). Little improvement in this trend has been observed in the past decades despite the overall improvement of global cataract health care (12).

1.3. Pathogenesis

The lens is responsible for focusing light onto the retina where it is converted into visual signals (13). This is achieved by a single cell type found in various developmental stages (13). The lens is composed of a single layer of epithelial cells and during their development they migrate from the lens periphery to the center to form the nucleus (3, 13). New fiber cells are continuously formed and deposited external to the older cells in the center (3). The main soluble component produced by fiber cells is a structural protein called crystallin (13). Crystallin is important for effective light transmission and lens transparency (13). As the highly metabolically active epithelial cells move centrifugally, cells located centrally are gradually compressed (14). This results in significant sclerosis and opacity (14). Degraded cells within the lens are not removed or remodeled, neither are crystallin proteins performing cell turn-over (13, 15). This lack of renewal makes the lens susceptible to damage during aging (13, 15).

The pathophysiology of cataract is multifactorial and complex (9). Disruption of the lens microarchitecture is characterized by cellular disarray, vacuole formation and high molecular weight protein aggregation (16). These structural changes seems to be responsible for light scattering seen in cataracts (16).

A vital role of this process is attributed to oxidative stress (17). Damage is caused by an imbalance in the redox status in favor of pro-oxidant reactions resulting in peroxidation of nucleic acids, bases, lipids, proteins, and carbohydrate (18). Endogenous reactive oxygen species are formed by various intracellular pathways, for instance as by-products of aerobic metabolism or messengers of signaling pathways (17). Further the eye is also exposed to a broad range of harmful environmental factors and exogenous sources of oxidants such as high pressure of oxygen, light exposure, ultraviolet radiation, ionizing radiation, and pollutants that cause significant damage (18). Oxidative stress is opposed by the action of antioxidants (6). Antioxidants operate by scavenging free radicals, regenerating other antioxidants and inhibiting or activating involved enzymes (6). The primary essential antioxidant glutathione is largely decreased in nuclear cataract due to oxidation of glutathione (GSH) to GSSG (6).

Based on the relation of cataract and oxidative stress, Liu *et al* (17) point out the importance of the Nrf2/Keap1/ARE signaling pathway. It is considered one of the main cellular defense mechanisms against oxidative stress and might be a promising target for preventive and therapeutic interventions in cataract management (17). Nrf2 is a transcription factor that binds to the antioxidant response element (ARE) and is vital for the transcription of antioxidant genes and cell survival (17). Keap1 is a Nrf2 inhibitor that plays a major role in the Nrf2/Keap1-depenent antioxidant protection (17). When DNA demethylation in the Keap1 promoter occurs, the antioxidant effect is abolished (17).

Additionally, Wu *et al* (19) have identified miRNA target genes whose up-and down-regulation possibly relate to the progression of age-related nuclear cataract.

Another important process in cataract formation are post-translational changes of crystallins that lead to crystallin insolubility and aggregation (20). Evidence shows that the majority of protein sulfhydryl groups are lost in mature cataracts, predisposing to cross-linking (6). Possibly responsible for these alterations are prolonged hyperglycemic conditions, elevated calcium levels that induce intracellular cysteine protease calpain, and privation of endogenous calpain inhibitor (20).

Especially at risk for cataract development are patients with diabetes mellitus who have a 5-fold higher prevalence of cataracts (21). Evidence suggests that poor glycemic control may result in upregulation of pro-oxidant enzyme xanthine oxidase (XOD), leading to lens oxidative stress and early genesis of senile cataract (22).

Furthermore, Shiels *et al* (24) have denoted that mutations causing more severe protein damage account for congenital cataract, whereas less severe forms increase the susceptibility to environmental insults and cause age-related cataract. Therefore, congenital cataracts appear to be inherited in a Mendelian fashion with high penetrance, in contrast to age-related cataracts which seem to be multifactorial (25).

1.4. Natural history

Three types of acquired cataracts are known, those are age-related, secondary and trauma related (3). Secondary cataracts follow systemic or ocular diseases (3). The most common predisposing systemic disease is diabetes mellitus (2, 3). Other diseases include myotonic dystrophy, neurofibromatosis and Down syndrome (3). Furthermore, any type of trauma can also result in cataract development, for instance contusion cataract or infrared radiation cataract (2, 3). Senile cataract progresses at an unpredictable rate with increasing age (26). The natural history differs with type, severity and present ocular comorbidity (27). Surgery is generally indicated when the expected visual improvement outweighs the risk of surgical complications (28).

1.5. Clinical manifestations

Cataracts are usually painless and develop gradually (2, 3). Hence, it is important for the clinician to specifically ask for changes in vision and the effect on daily life (3).

The clinical symptoms of cataract can be different for each type (2). Inherent to all forms of cataract is light scattering, varying in severity depending on the degree of pupillary area compromised by the cataract (29). Nuclear cataracts typically affect distance vision, while short sight is intact (3). Patients are often able to read without glasses (30). With posterior subcapsular cataract on the other hand, near vision is affected most and patients commonly experience glare with resulting difficulties when reading or when driving a vehicle (14). Furthermore, posterior subcapsular cataract seems to show the lowest spatial frequency contrast sensitivity, making it difficult for patients to see objects that have a low contrast difference to their surroundings. (29). Improvement of symptoms can be noticed in low light when the dilated pupil allows for more light to pass through the lens (3).

Patients with cortical cataract commonly complain about blurred vision (29). In some cases they also experience monocular diplopia (29). This effect results from water clefts within the lens that cause a refractive index change in the eye (29). A clinical manifestation that is less apparent to patients is a significant interference with color perception, as the cohort study by Ao *et al* emphasizes (31). While the healthy aging lens starts to absorb more at the blue end of the spectrum, cataracts seem to augment this development in color shift (29).

1.6. Classification

Cataracts can be classified according to time of occurrence, maturity and morphology (2). Classification according to time of occurrence distinguishes between acquired and congenital cataract (2). The latter two classification systems focus on the severity of visual impairment and morphological changes in the nucleus, which is important information for the timing of a surgical procedure (2). One common grading system is the Lens Opacities Classification System III (LOCS III) (3). Comparison of the slit lamp picture with standard photographic color plates allows for grading of severity of cataracts (3).

1.7. Risk Factors for cataract formation

Various risk factors for cataract development have been identified. The Taizhou Eye Study recognizes age, increased outdoor activity, no eye protection, high myopia, high low-density lipoprotein, low high-density lipoprotein, lower education level and increased pickled food intake to be related to cataract (32). Substantial evidence has additionally pointed out current smoking as an important predisposing factor (9, 33). Furthermore, Nam *et al* (33) linked Asthma, Tuberculosis and Iron deficiency to cataract formation. Although it is arguable, if Asthma and Tuberculosis itself cause the disease or if it is rather a consequence of treatments like systemic steroids, which are widely believed to predispose to cataract formation (1, 9, 33). Additionally, chlorpromazine taken by patients with schizophrenia appears to increase the risk of cataract (9). A more obvious correlation has been established between diabetes and cataract (1, 9, 34). Kelkar *et al* (34) reveal a 2-5 times higher likelihood of diabetic patients to develop cataracts, more often occurring at an earlier age.

A study with African diabetics suggests a higher cataract risk with sunlight exposure (35). This is supported by Gupta *et al* (5) who concluded a higher disease incidence in areas with more sunlight exposure compared to those with less.

1.8. Diagnostic methods

1.8.1. Slit lamp

Cataract is diagnosed in the clinical setting by the use of a slit lamp, which allows for thorough examination of the anterior eye segment and also the posterior area if additional lenses are used (1, 36). It is used to detect the type and grade the severity of cataract (3). Furthermore, it can be used for tonometry with the application of fluorescein and blue light (1). The slit lamp examination is the hallmark of an ophthalmologic evaluation, however the quality of evaluation depends immensely on operator's skill and experience.

1.8.2. Visual acuity

Evaluation of cataracts is most commonly performed through visual acuity (30). It is conducted using a logarithmic letter chart with high contrast between the letters and the backround (29). Although routinely done for preoperative cataract assessment, Kessel et al emphasize its rather limited value when used solely in predicting postoperative results (36).

1.8.3. Anterior chamber depth

The anterior chamber depth is the measure from the anterior surface of the cornea to the anterior surface of the lens, routinely calculated using a pentacam device (37). It determines the postoperative position of the IOL placed during cataract surgery and therefore plays a crucial role in minimizing refractive errors after surgery, as pointed out by Ning *et al* (37).

1.8.4. Optical Coherence tomography

In the examination of the macula and other retinal structures, the OCT delivers relevant information and is one of the least invasive techniques used for this purpose (38).

With this diagnostic tool, many pathological processes in the posterior eye segment can be detected that are otherwise clinically occult (1).

1.9. Treatment modalities

1.9.1 History of cataract surgery

In the past, cataracts were usually left untreated up to an advanced stage, when surgery was performed (28). The earliest surgical technique known as couching was introduced around 800BC (39). In this procedure, the opacified lens was pushed out of the visual axis into the vitreous chamber using a pointed instrument (2). In 1747, Jacques Daviel carried out the first extracapsular cataract extraction (40). All surgical cataract procedures before the 1960s focused on removing the opacified lens, without replacing it (3). Hence patients had to wear thick glasses to compensate for the hyperopia that resulted from the lens removal (3). Around 1949, British ophthalmologist Harold Ridley discovered that plastic fragments from cockpit canopies of airplanes were suitable and tolerable as intraocular lenses (3). With improvement in the quality and design of IOLs in the following years, it is possible today to largely correct the patient's refractive error in addition to cataract removal (3). Since Ridley's discovery, many milestones in cataract surgery were obtained. One of them Kelman's introduction of phacoemulsification in 1967, which remains the gold standard procedure in treatment of cataract today (39, 41).

1.9.2. ICCE

Although largely replaced by ECCE in developed countries, ICCE remains a widespread procedure in developing countries (42). In this operation, the entire lens is removed within its capsule through a superior corneal incision using a cryoprobe (2, 30). After that, implantation of an anterior chamber intra-ocular lens or sutured lens or aphakic correction follows (1). Complications like retinal detachment, vitreous loss and macular edema are more likely with this procedure than with ECCE (2, 14).

1.9.3. ECCE

ECCE begins with a corneal incision and capsulotomy (2, 14). After that only cortex and nucleus of the lens are extracted while the posterior chamber is retained (1, 2, 14). Following this, a posterior chamber intra-ocular lens can be implanted (2). ECCE is preferred over ICCE due to lower intraoperative and postoperative complications (14). Nonetheless, complications occur more often than with phacoemulsification (3). Hence, this technique is used preferably for very mature cataracts that cannot undergo phacoemulsification (3).

1.9.4. Manual Small Incision Cataract Surgery

MSICS is a variant of ECCE, which differs from it by its smaller incision and nucleus extraction through a small self-sealing sclero-corneal tunnel (1, 30). It is associated with better visual acuity than ECCE but slightly inferior outcomes to phacoemulsification, which makes it an alternative in countries where phacoemulsification is not available (1, 43).

1.9.5. Phacoemulsification

Phacoemulsification has become the method of choice for cataract surgery (44). Through a small corneal incision or alternatively a scleral tunnel, a viscoelastic device is inserted into the anterior chamber to protect and stabilize ocular structures (1, 14). To enable lens removal, the capsule is then opened by continuous curvilinear capsulorrhexis (2). In the next step, hydrodissection is performed (30). In this procedure a balance salt solution is injected under the capsule rim that allows for the nucleus and cortex to be separated from the capsule (1, 30). The lens is hereby prepared to be emulsified and aspirated by a phacoemulsification device (14). In this process the lens contents are completely removed, leaving only the capsule intact (44). Following phacoemulsification, an IOL is implanted into the capsule using a lens injector containing the folded IOL loaded into a cartridge (14). The wound then usually closes by itself or can be sutured (1). After the procedure a topical, subconjunctival or intracameral antibiotic is routinely administered as well as corticosteroids (1, 14). Phacoemulsification is overall less invasive, is a faster procedure and has a shorter recovery time than ECCE (3).

1.10. Anesthesia in cataract surgery

The majority of cataract surgeries are performed under local anesthesia (2). Advances over general anesthesia include preserved consciousness, minimal cardiac and respiratory disturbances and an early mobilization and discharge of patients (45). Multiple techniques to provide local anesthesia are currently in use. The choice for a certain anesthesia technique can be determined by many different factors, for instance patient comfort or choice, surgeons comfort or choice, efficiency and safer technique (46). A study in Singapore identified patient comfort to be the most important factor in routine cataract extraction, whereas surgeon comfort was the biggest influence in mature cataract extraction (46).

1.10.1 Sub-Tenon Block

In Sub-Tenon Block a blunt tipped cannula is passed through an incision in the conjunctiva and Tenon capsule around the globe curvature into the sub-Tenon's space, where a local anesthetic is injected into (30, 47). Merits of this technique include the low risk of complications such as globe perforation, retrobulbar hemorrhage or periocular hemorrhage due to the use of a blunt cannula rather than a needle (48).

1.10.2 Retrobulbar Block

Retrobulbar anesthesia is generated by delivering a local anesthetic using a needle into the retrobulbar space, a space behind the globe that is surrounded by the extra-ocular muscles and contains the optic nerve and other major nerves of the eye (49). Complications of this approach are globe perforation by the needle, ischemic neuropathy and occlusion of the central retinal artery (50).

1.10.3 Peribulbar Block

Peribulbar anesthesia has evolved as potentially less harmful and progressively replaced retrobulbar block (45). In this approach, the local anesthetic agent is injected outside of the muscle cone (49). Because of needle use, penetration of the globe can be a complication with this technique as well (30). In comparison, retrobulbar block provides more rapid analgesia and akinesia and requires smaller volumes of anesthetic agent than peribulbar block (45, 49).

1.10.4 Topical Anesthesia

Topical anesthesia is provided using local anesthetic drops or gel placed on the surface of the eye (30, 47). With this approach adequate analgesia is provided, but according to one study in a less effective form compared to Peribulbar or Sub-Tenon blocks (30).

1.10.5 General Anesthesia

General anesthesia is indicated for patients unable to cooperate during surgery (14). This includes children, anxious patients, mentally retarded or those with advanced Parkinson disease or rheumatism (2, 30).

1.11 Pain Assessment methods

Reliable pain assessment is crucial in the clinical setting to achieve effective pain management. Acute pain can be evaluated using one-dimensional tools that assess pain intensity.

The Visual Analogue Scale is presented as a line, marked with “no pain” on the left and “worst pain imaginable” on the right end of a 10cm line (51). The patient in whom pain intensity is assessed, is asked to mark a 10cm line on the scale that correlates with his or her state of pain (51). Following that, a score can be gathered by measuring from zero on the left end to the patient’s mark (51).

Hence, the VAS is a suitable tool to assess present pain in patients who are alert and able to communicate (52). It is less appropriate in regard to past pain due to often times inaccurate memory recall or in patients with cognitive impairment (52). Furthermore, this technique is limited by its obligatory use in printed or electronic form (51). Williamson *et al* (51*)* even point out the possible variability in results caused by differences in graphic depiction, for instance in a horizontal vs. vertical manner.

The Numerical Rating Scale is an alternative approach and considered the gold standard in determining pain in an acute setting in conscious patients (53). With this method the patient has to determine his pain level on a 11, 21, or 101-point scale with the descriptors “no pain” represented by zero and “worst imaginable pain” by the highest number on the scale (51). In contrast to the VAS, the NRS can also be used in a verbal manner. This facilitates its use and offers the possibility to assess pain even when the patient is not physically present, for instance in a telephone interview (52). If used in graphical form, it is usually depicted in a point box scale (51).

Belonging to the same category of commonly used pain rating scales is the Verbal Rating Scale. The VRS is a four-point verbal categorical rating scale (52). Pain intensity is typically expressed as ‘no pain‘, ‘mild pain‘, ‘moderate pain‘ and ‘severe pain‘ with assigned numbers from zero to three (51). Williamson et al emphasize that the intervals of pain intensity between the four points are not equal and warns of misunderstanding (51). Furthermore, the smaller number of categories anticipates a larger change in pain intensity to make an improvement or decline visible on the scale, which makes it less sensitive to more subtle changes (51).

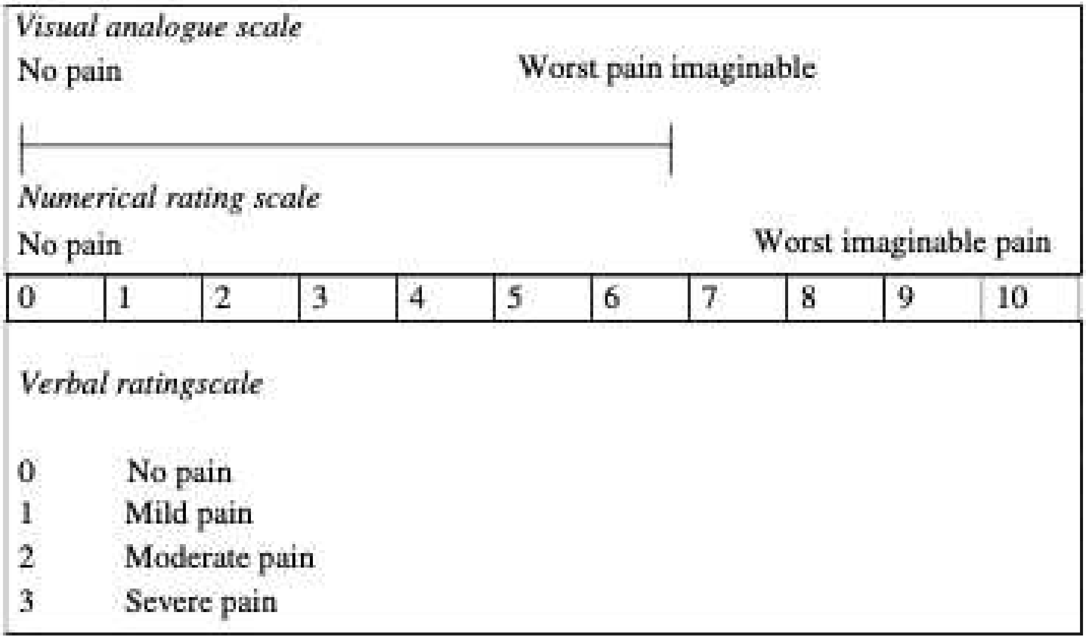

Figure 2. Common Pain rating scales. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. Journal of Clinical Nursing. 2003

All three techniques mentioned here are reliable, easy to use, and economic ways to assess pain in a one-dimensional fashion. Despite that, it is widely criticized that pain intensity alone, as measured by VAS, NRS and VRS, is only a single component in the broad range and multidimensional scale of pain experience and does not grasp its complexity sufficiently (54).

Out of this need for a more sophisticated tool that is able to capture multiple facets of the pain experience, a new assessment tool was developed in 2012 by the University of Utah Health Care, called Clinically Aligned Pain Assessment (CAPA) (54). Consisting of multiple questions regarding comfort, change in pain, pain control, functioning and sleep, the aim is to capture the impact of pain on the patient (54). The questions are not asked in a scripted manner but rather guide a conversation with special focuses between the patient and the clinician, who then documents and codes the gathered information (55).

Table 1. CAPA Tool. Gordon D. Acute pain assessment tools: let us move beyond simple pain ratings. Current Opinion in Anesthesiology. 2015

Comfort	Intolerable
	Tolerable with discomfort
	Comfortably manageable
	Negligible pain
Change in pain	Getting worse
	About the same
	Getting better
Pain control	Inadequate pain control
	Partially effective
	Fully effective
Functioning	Cannot do anything because of pain
	Pain keeps me from doing most of what I need to do
	Can do most things, but pain gets in the way of some
	Can do everything I need to
Sleep	Awake with pain most of night
	Awake with occasional pain
	Normal sleep

The aforementioned pain assessment tools imply that the clinician deals with a patient who is responsive and able to communicate. Alternate settings demand a different approach that enables pain measurement in anaesthetized and unresponsive patients. One such technique is the skin conductance algesimeter (SCA) (56). This tool relies on the increase in sympathetic tone evoked by pain which causes an increase in palmar sweat production, measured by electrodes attached to the hand of the patient. The electrodes convey information regarding evoked fluctuations in skin conductance to a connected monitor and laptop with a software that records the collected data (56). Hence, through the activation of the sympathetic nervous system to a varying degree depending on the pain stimulus, measurable fluctuations in skin conductance and resistance representing the patients pain experience can be obtained

(56). A great advantage of the SCA over similar techniques that also focus on changes in sympathetic activity is, as Hansen et al explain, it's independence on hemodynamic factors like heart rate and blood pressure, which might give false information regarding pain levels, especially in the hemodynamically unstable (56). Furthermore, it gives an objective estimation of the pain experience, devoid of subjective influences reflected by the information conveyed on one dimensional scaling systems.

2. OBJECTIVES

The aim of our study was to investigate the extent of our patients pain experience during cataract surgery and to determine whether distraction in the form of a neutral conversation can facilitate the analgesia provided by a topical anesthetic.

Our hypothesis is that a neutral conversation between the surgeon and the patient during cataract surgery can add to the analgesia provided by an anesthetic and therefore minimize the pain experience.

3. MATERIALS AND METHODS

3.1. Ethical background of data collection

The data for this study was collected at the Ophthalmology department of the University Hospital of Split. The ethical approval was obtained by the Ethics Committee of the University Hospital of Split (500-03/19-01/66). All subjects signed an informed consent before participating in the study.

3.2. Study purpose

Substantial evidence shows the superiority of retrobulbar, peribulbar and sub-tenon block in providing analgesia during cataract surgery compared to topical anesthesia. Nonetheless, topical anesthesia is widely used by ophthalmic surgeons due to its simplicity and low complication rate.

The purpose of this study is to investigate if distraction of patients during the course of a cataract operation under topical anesthesia can augment its analgesic effect. The distraction takes place in form of a conversation between the surgeon and patient about neutral or pleasant topics.

3.3. Subjects

Our study included 101 subjects. 52 of those were female and 49 male patients. Inclusion criteria were diagnosed cataract and eligibility for cataract surgery. Exclusion criteria were complicated cataracts. The subjects were randomly divided via random.org into experimental and control group. The experimental group included 51 subjects, the control group 50 subjects.

Control and experimental group received the same type of surgery that was performed by the same surgeon. The control group received minimal communication in the form of simple surgery related instructions. With the experimental group the surgeon engaged with in a conversation, in addition to giving surgery instructions. The conversation was about neutral or pleasant topics, not comprising too personal themes. The surgeon was instructed to keep the conversation going for the length of the surgery.

To rate the pain experience in our study participants, they were asked to fill out three pain assessing questionnaires. Our main outcome measure was pain and anxiety assessment with PCS, STAI and NRS.

The Pain Catastrophizing Scale (PCS) was used to reflect on past painful events. It depicts pain catastrophizing feelings or thoughts on a 13-item scale, with each item rated on a

5-point scale with the end points 0 (not at all) and 4 (all the time). The PCS yields a total score from 0-52 and three subscales indicating rumination, magnification and helplessness.

With the use of State-Trait Anxiety Inventory (STAI1 and STAI2) questionnaires we determined the degree of state and trait anxiety in the study participants. The scale encompasses 40 items that are rated on a 4-point scale. It reflects the degree of general or permanent anxiety and event related or current anxiety.

The Numerical Rating Scale was applied to assess the level of pain in conscious patients. It is an 11-point scale with end points 0 (no pain) and 10 (worst pain possible).

Furthermore, we gathered data on whether there was prior cataract surgery on the other eye and in which year it took place as well as a comparison between the previous and latest surgery. Additionally, the duration of the surgery and whether complications had occurred was determined.

3.4. Methods

Prior to surgery, all subjects underwent a screening at the Ophthalmology Department of the University Hospital of Split to determine their study eligibility.

On the day of the surgery, subjects first received tetracaine drops to provide analgesia. The operating field was sterilized using 5% povidone-iodine. After speculum application, a corneal incision was performed to allow for viscoelastic injection into the anterior chamber. The stabilized anterior chamber was further manipulated with curvilinear capsulorhexis to allow for lens removal later on. In the next step, hydrodissection was performed. In this process balance salt solution was injected to separate the lens nucleus from the capsule.

Following that, phacoemulsification under the “divide and conquer” technique was performed. This breaks down the nucleus into quadrants that are emulsified and absorbed by the phacoemulsification device, which was the Infinity (Alcon, USA). The removed lens is replaced by an intraocular lens that is implanted with a lens injector containing the folded intra-ocular lens. The wound was hydrated and cefuroxime injected in the anterior chamber.

3.5. Statistical methods

We used Student t-test to test for differences. ANOVA repeated measurements were used to test for differences between groups in STAI1 and STAI2. To correlate STAI2 and NRS with the operation duration we used multiple regression tests. The significance level was set at $p<0.05$. Statistical analysis was done with the use of Statistica 10 statistical software (StaSoft, USA).

4. RESULTS

The present study included 101 study participants who were operated for cataract between August 2018 and January 2020. Table 1 depicts the characteristics of our study participants. Of the total 101 participants 52 were female, accounting for 51.49%. 49 study participants were male, amounting to 48.51%. The subjects were divided into experimental and control groups. The first group included 51 participants and the latter 50 participants, accounting for 50.50% and 49.50%, respectively. 49 out of 101 subjects had prior eye surgery on the other eye.

Table 2. Study participant characteristics

	Frequency in [n/N]	Frequency [in %]	Total
Female	52/101	51.49	52
Male	49/101	48.51	49
Experimental	51/101	50.50	51
Control	50/101	49.50	50
Previous surgery on fellow eye	49/101	48.51	49

The questionnaires filled out by the study participants before the surgery were Pain Catastrophizing Scale (PCS) and State-Trait Anxiety Inventory (STAI). PCS subgroups are PCS rumination, PCS magnification and PCS helplessness. We performed Student t-test to evaluate differences in questionnaire results in the experimental and control group (Table 2). The total PCS score and STAI in experimental and control groups yielded a P of 0.826 and 0.714, respectively. No statistically significant difference was found for PCS subgroups rumination (P=0.451), magnification (P=0.705), nor helplessness (P=0.902). The t values are 0.22 for PCS total score and -0.37 for the STAI questionnaire. The degree of freedom is 99 for all variables.

Table 3. Questionnaire results prior to surgery

	Intervention (N=51)	Control (N=50)	df	t-value	*P**
PCS rumination	4.06±4.95	3.31±4.96	99	0.76	0.451
PCS magnification	2.70±3.67	2.98±3.75	99	-0.38	0.705
PCS helplessness	5.44±6.63	5.27±6.81	99	0.12	0.902
PCS total score	12.20±14.28	11.57±14.48	99	0.22	0.826
STAI	28.96± 11.35	29.82±12.23	99	-0.37	0.714

Data are presented as mean±standard deviation

*t-test

Table 3 depicts the t-test results for NRS and STAI taken from experimental and control group after the surgery. P value for NRS is 0.127 and 0.545 for STAI. Degree of freedom is set at 99. T values are -1.54 for NRS and -0.61 for STAI. No statistically significant difference was found.

Table 4. Questionnaire results after surgery

	Intervention (N=51)	Control (N=50)	df	t-value	*P**
NRS	1.40±1.57	1.92±1.82	99	-1.54	0.127
STAI	20.86±2.24	21.27±4.28	99	-0.61	0.545

Data are presented as mean±standard deviation

*t-test

Testing for differences with the variables comparison with previous eye surgery and duration of surgery in minutes in interventional and control group yielded p values of 0.137 and 0.082, respectively (Table 4.) For comparison with previous eye surgery options were 1= second surgery was more painful, 2= second surgery was less painful and 3= both surgeries were equally painful. T value for comparison with previous eye surgery is 1.51 and -1.76 for duration of surgery.

Table 5. T-test for comparison with previous eye surgery and surgery duration

	Intervention (N=51)	**Control (N=50)**	**df**	**t-value**	***P****
Comparison with previous eye surgery	2.38±0.80	2.04±0.77	47	1.51	0.137
Duration (in min.)	7.66±1.45	8.16±1.39	99	-1.76	0.082

Data are presented as mean±standard deviation
*t-test

Investigating differences in STAI questionnaire taken from experimental and control group prior and after surgery, we performed t-test (Table 5). No statistically significant difference was found as depicted by the p value of 0.848. Degree of freedom was set at 99 and t value distribution gives a value of 0.19.

Table 6. Difference of STAI questionnaires before and after surgery

	Intervention (N=51)	**Control (N=50)**	**df**	**t-value**	***P****
STAI dif	-8.10±10.79	-8.54±12.55	99	0.19	0.848

Data are presented as mean±standard deviation
*t-test

To compare the level of pain during cataract surgery with previously experienced pain in prior surgery on the other eye, we analyzed PCS total score, STAI before and after surgery and NRS results in three groups. As shown in Table 7, 49 subjects of the total 101 study participants had received previous eye surgery. The first group included 11 subjects who experienced the second surgery as more painful, the second group was composed of 16 subjects who expressed the second surgery as less painful and the third group consisted of 22 subjects who found pain level to be equal both times. The analyzed data are expressed as mean ± standard deviation.

Table 7. Comparison with previous eye surgery

Comparison with previous eye surgery	PCS total	STAI 1	NRS	STAI 2	N
1 (2nd more painful)	16.90±17.10	27.82±10.21	2.00±1.67	20.00±0.00	11
2 (2nd less painful)	13.25±15.25	29.56±11.88	3.06±1.53	22.50±6.81	16
3 (equal)	9.23±12.62	25.59±11.12	1.00±1.54	20.45±1.60	22
All	12.08±14.53	27.39±11.09	1.90±1.78	21.02±4.09	49

Data are presented as mean±standard deviation

Analyzing the difference of pain levels experienced in previous eye surgery compared to the latest cataract surgery we performed the least significant difference (LSD) test (Table 8). Group 1 represents subjects who experienced the second surgery as more painful, group 2 experienced the previous surgery as more painful and group 3 experienced both eye surgeries as equally painful. As shown in table 8, the biggest difference is seen between group 1 vs. group 3 (P=0.208) and group 3 vs. group 1 (P=0.208). Overall, no significant statistical difference was found.

Table 8. Comparison of pain levels in first and second eye surgery

Comparison 1st and 2nd eye surgery	(1) *P**	(2) *P**	(3) *P**
1 (1)		0,621	0,208
2 (2)	0,621		0,405
3 (3)	0,208	0,405	

*least significant difference (LSD) test

To evaluate for correlation between surgery duration and STAI questionnaire after the surgery we used Pearson's correlation coefficient (Figure 9). The correlation was found to be a minimal positive one with a correlation coefficient of 0.076 with a confidence interval of 0.95.

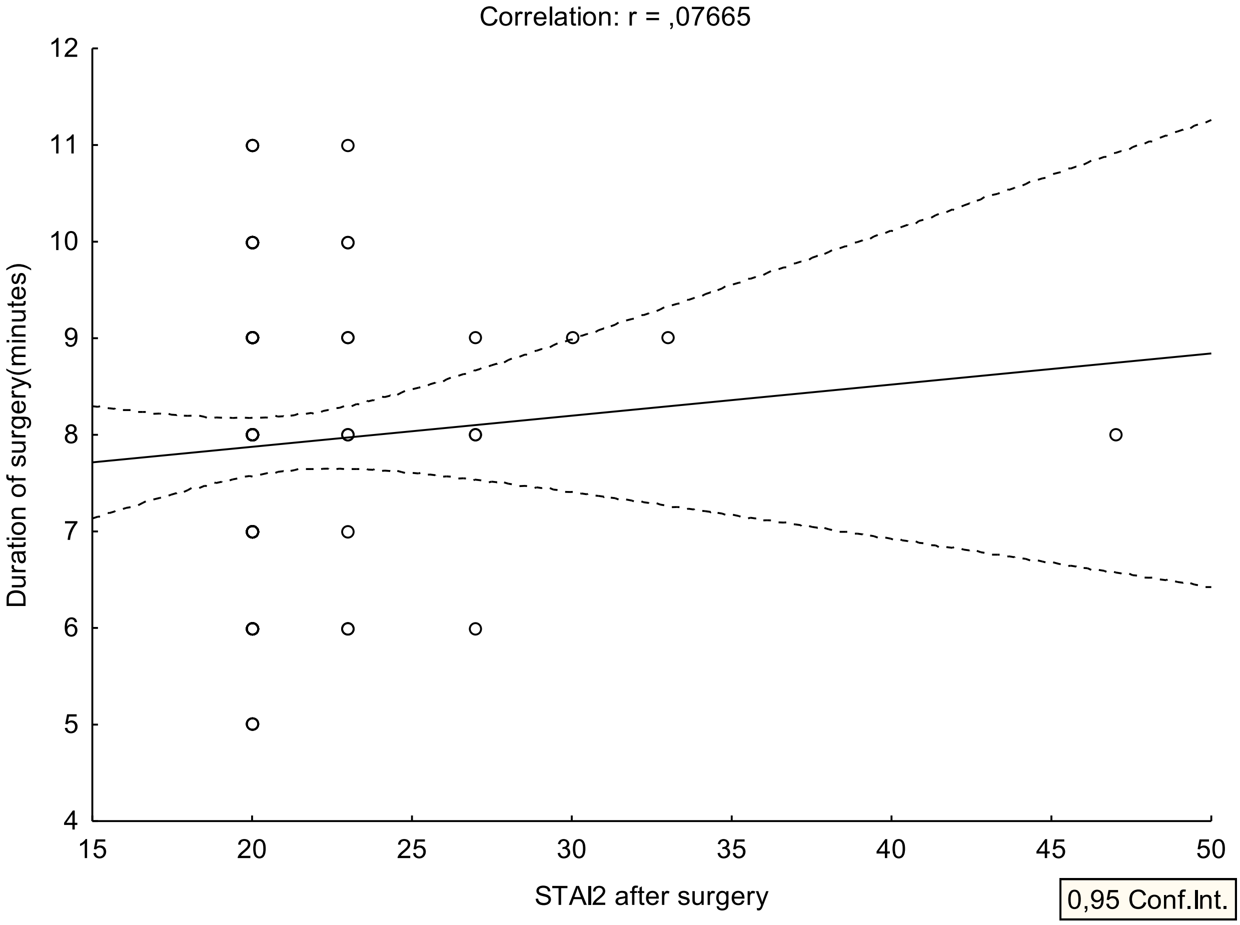

Figure 3. STAI post-surgery vs. duration of surgery (in minutes)

The same test was used to analyze the correlation between the duration of surgery and the NRS, as depicted in Figure 10. Correlation was found to be slightly stronger than in the previous Figure (Figure 9) with a correlation coefficient of 0.32.

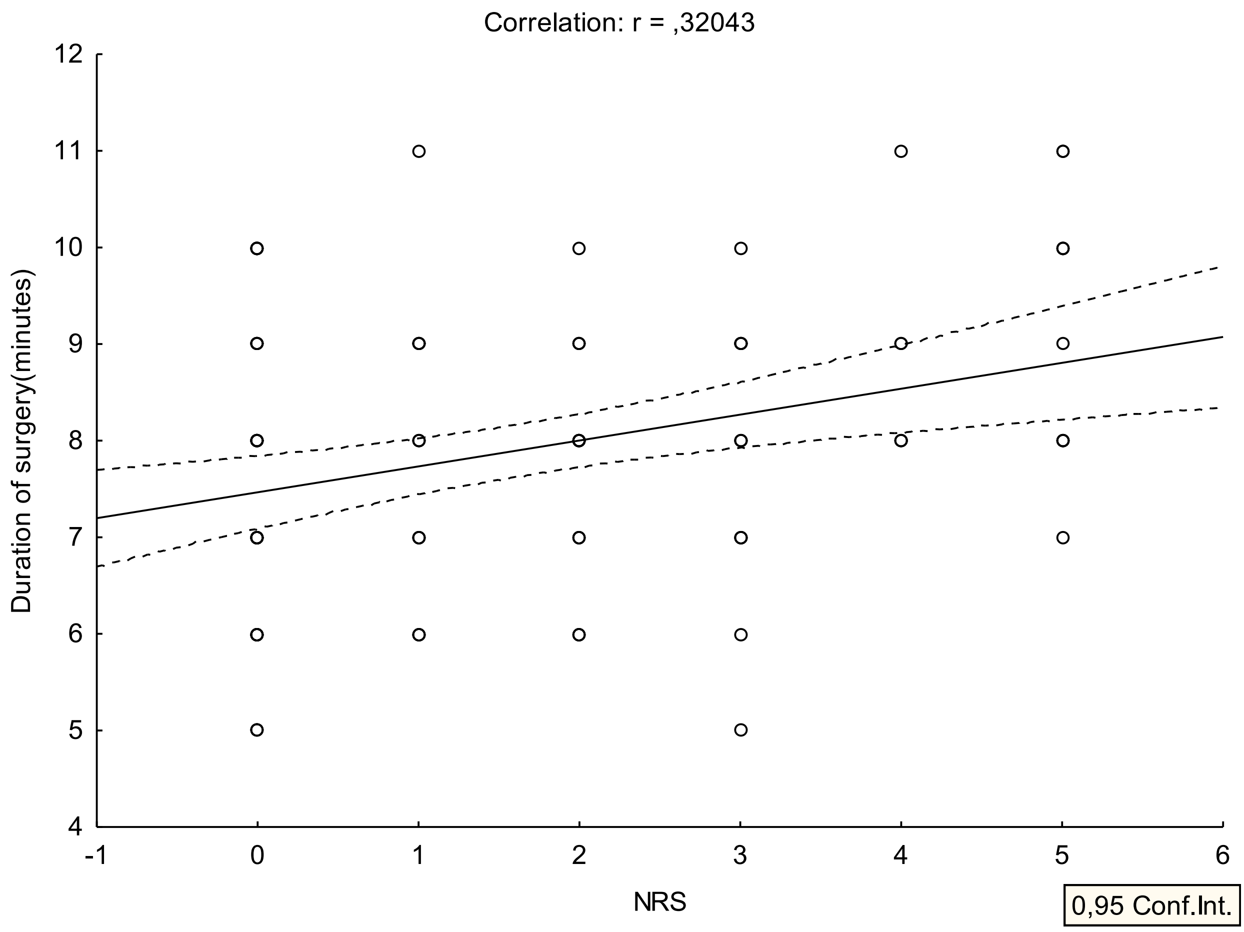

Figure 4. NRS vs. duration of surgery (in minutes)

5. DISCUSSION

Cataract surgery is one of the most performed surgeries worldwide (3). Although retrobulbar and peribulbar block provide more effective analgesia than topical anesthesia, ophthalmic surgeons often choose topical anesthesia for its simplicity and low complication rate. Our aim with this study was to find an augmenting factor to aid in the effectiveness of topical anesthesia.

We hypothesized that distraction of patients in the form of a conversation with the operating surgeon would lower their pain experience during cataract surgery. However, our pilot study did not confirm our hypothesis.

Our data gathered from 101 study participants who were operated from August 2018 to January 2020 at the University Hospital of Split shows no statistical significant difference in pain perception in the experimental group that was talked to during cataract surgery and the control group that only received minor surgery related instructions.

Our study included a higher number of study participants than a previous study on pain perception during cataract surgery from the University of Split, nonetheless future studies could increase the sample size to optimize this pilot study.

To evaluate pain perception and level of anxiety before and after the surgical procedure we used PCS, NRS and STAI. No significant difference was found between the interventional and control group, nor between before and after surgery.

We tested STAI and NRS for correlation with surgery duration. For STAI and duration of surgery no significant correlation could be found. Between NRS and surgery duration however, a slight correlation was identified.

We investigated the differences in STAI results in experimental and control group before and after the surgical procedure. Even though we did not find a significant difference in our data between the groups, the generally short duration of the procedure could be a limiting factor. Testing for differences with the variables duration of surgery and comparison with previous eye surgery also did not reveal any statistical significant differences.

Contradicting to other studies that investigated and compared the pain levels of eye surgeries on both eyes (57), our data did not show an increase or decrease in pain perception with the second eye surgery. Evidence suggests that patients who had undergone an uncomplicated first eye surgery were more likely to feel less anxiety towards the second eye surgery while being more attentive to pain perception during the second procedure. (57) However, our study did not show a significant difference in anxiety level regarding the first eye surgery and the second one. This may explain why their pain perception did not increase during the second eye surgery.

A possible reason for this could be that our subjects did not feel very anxious towards the procedure because they were aware of its short duration and that it was not done under general anesthesia. After an uncomplicated procedure this belief could have been confirmed and hence no difference in STAI before and after the surgery was detected.

Future studies could concentrate not only on differences in STAI before and after surgery but also compare STAI before cataract surgery with other surgical procedures that may cause more anxiety beforehand.

Limitations to our study could be found in the process of pain assessment using pain rating scales. In our study, NRS was performed immediately after the surgical procedure while the surgeon was still present in the operating room. As Topham *et al* emphasize, patients may inflate or deflate their NRS scores to get a certain reaction from their health care provider (54). They may give a lower score to avoid a painful injection or give a higher score to express their suffering (54). This could have influenced our subjects' answers and leaves room for improvement for future studies.

Also, there could be variables that influenced our subjects' pain perception that were not incorporated in our study. Evidence suggests that gender and cultural origins may influence patients' pain expression. Furthermore doctors and nurses interpretation of patients' pain may be influenced by their own beliefs and biases. (54)

Cataract surgeries in the present study had a duration of 5-11minutes. This short duration could account for the difficulty in establishing a correlation with surgery duration and different pain rating scales.

6. CONCLUSION

1. Our study did not confirm the hypothesis that talking to patients about neutral and pleasant topics during cataract surgery can lower their pain perception.
2. We found a slight correlation between pain perception results and duration of surgery.

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8. SUMMARY

Objectives: The objective of this study was to evaluate if distraction of patients during cataract surgery in the form of a conversation with the operating surgeon would augment the effect of topical anesthesia in lowering pain.

Subjects and methods: This study included 101 eye surgeries in total. 52 of our study participants were female and 49 men. 49 subjects had previous cataract surgery on the other eye. The subjects were randomly divided into interventional and control group. The interventional group included 51 subjects that had a conversation about neutral or pleasant topics with the operating surgeon during the surgical procedure. The control group consisted of 50 patients who were only given minor instructions during the surgery. We used Pain Catastrophizing Scale, Numerical Rating Scale and State-Trait Anxiety Inventory to evaluate the pain perception.

Results: The data from our questionnaires did not show a statistically significant difference between interventional and control group. A slight correlation was found between Numerical Rating Scale results and the duration of surgery.

Conclusions: Our hypothesis that a conversation between the surgeon and patient during cataract surgeries could augment the effect of topical anesthesia and decrease pain was not confirmed.

9. CROATIAN SUMMARY

Naslov: Utjecaj verbalne distrakcije na percepciju boli tijekom operacije katarakta.

Ciljevi: Cilj ovog istraživanja bio je procijeniti može li distraktiranje pacijenata tijekom operacije katarakta u obliku razgovora s operaterom povećati učinak topikalne anestezije u smanjenju boli.

Bolesnici i metode: U istraživanje je uključena 101 operacija oka. Od ispitanika u istraživanju 52 bile su žene, a 49 ispitanika muškarci. Prethodnu operaciju katarakta na drugom oku imalo je 49 ispitanika. Ispitanici su nasumično podijeljeni u intervencijsku i kontrolnu skupinu. Intervencijsku skupinu činio je 51 ispitanika s kojima je tijekom operativnog zahvata razgovorao operativni kirurg o neutralnim ili ugodnim temama. Kontrolnu skupinu činilo je 50 ispitanika koji su tijekom operacije dobili samo poneke upute. Za procjenu percepcije boli koristili smo Pain Catastrophizing Scale, Numerical Rating Scale i State-Trait Anxiety Inventory.

Rezultati: Podaci iz naših upitnika nisu pokazali statistički značajnu razliku između intervencijske i kontrolne skupine. Pronađena je slaba korelacija izmedu rezultata Numerical Rating Scale-a i trajanja operacije.

Zaključci: Naša hipoteza da bi razgovor između kirurga i pacjenta tijekom operacije katarakte mogao pojačati učinak topičke anestezije i smanjiti bol nije potvrđena.

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