



Intervention

Effects of patient education and therapeutic suggestions on cataract surgery patients: A randomized controlled clinical trial

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ABSTRACT

Objective: This paper describes a randomized controlled single blind study testing the effects of a patient education intervention combined with positive therapeutic suggestions on anxiety for cataract surgery patients.

Methods: 84 patients participated in the study. Physiological and behavioral indicators of anxiety were compared between a regularly treated control and an intervention group receiving an audio CD containing information, relaxation, and positive imagery.

Results: We found that the intervention group was calmer throughout the four measurement points of the study ($p = .004$; $d = 0.71$) and they were more cooperative ($p = .01$; $d = 0.60$) during the operation. The groups did not differ in sleep quality before the day of the operation, heart rate during the procedure, and subjective Well-being.

Conclusion: Findings indicate that preoperative information combined with positive suggestions and anxiety management techniques might reduce patient anxiety in the perioperative period of cataract surgery, but further research is needed to investigate the benefits of such interventions and to uncover the underlying mechanisms.

Practice implications: Patient education interventions providing additional anxiety management techniques are recommended for use prior to cataract surgery.

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1. Introduction

Anxiety is the most common negative affect associated with surgery as well as a reliable predictor of postoperative mood and pain sensation [1,2]. Former studies confirmed that cataract surgery patients often experience fear and anxiety [3–5] not only during but also before and after the operation, and during post-operative visits [6,7]. The consequences of high perioperative anxiety range from increased pain sensitivity [2], blood pressure and heart rate [8], medication requirement [9], and reduced compliance during the procedure [10]. In addition, researchers found elevated intraocular pressure as a result of stress [11,12].

To decrease perioperative distress and to overcome its negative side-effects the use of psycho-educational intervention is advised in the literature [13,14]. So far only a handful of studies evaluated

the effectiveness of such interventions for cataract surgery, even though it is one of the most common elective surgical procedures worldwide [15]. Researchers reported that providing information on the procedure, on the experience of undergoing surgery and on the potential risks decreased anxiety immediately after the operation [16] and one month after the procedure [17].

Another approach for mitigating anxiety during medical procedures is the use of positive verbal suggestions [18–20]. Suggestions are messages in an interpersonal communication which evoke automatic psychological, behavioral or emotional responses in the receiver [21]. They most likely assert their effects through priming mechanisms. Although suggestions are one of the most important tools of hypnosis, suggestive techniques can be successfully used without formal hypnosis induction as well [20]. Studies support that suggestions have beneficial impact on various surgical outcomes [22,23], and specifically on mitigating procedural anxiety (e.g. [24–26]).

The effectiveness of positive suggestions have been already investigated in ophthalmic surgery. One of the studies found that an intervention just before radial keratotomy increased the

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subjective Well-being of patients the day after surgery, but did not decrease unnecessary movements during operation and pain experience [27]. Another report showed that relaxing suggestions played during cataract surgery improved patient and surgeon satisfaction and patients' level of relaxation while they did not show beneficial effect on cardiovascular measures and respiration rate [28].

So far no studies evaluated the effectiveness of a combination of preoperative information and positive suggestions in cataract surgery. Furthermore former studies usually looked at a small number of measurement points thus only providing information on a subset of the previously identified stages of perioperative distress [7].

The aim of our present study was to investigate the effectiveness of a preoperative psycho-educational intervention containing both information and positive verbal suggestions on reducing perioperative anxiety while measuring outcomes from pre- during and post-surgery as well as from the first postoperative visit.

2. Method

2.1. Participants

Based on the data retrieved from the study of Holden-lund [24] the a priori calculation in G*Power 3.1.3 [29] determined that a minimum total sample size of 34 would be needed in a repeated measures between subjects design to show a significant difference in postoperative anxiety ($d = -0.98$; $\alpha = 0.01$; $1 - \beta = 80$; number of measurements = 4; correlation among repeated measures = .50).

The study was carried out between 1st February 2011 and 27th November 2011. We recruited participants from patients enlisted for cataract surgery at the Europmed Orvosi Szolgáltató Kft's Healthcare Center in Budaörs, Hungary. Patients (a) above the age of 17; (b) who could understand Hungarian; (c) who had no prior cataract surgery; and (d) ones with no hearing disability were eligible. Patients with a prior cataract surgery were excluded to avoid heterogeneity in anxiety resulting from the familiarity of the procedure [30,31]. Of the 122 patients who were assessed for eligibility, 111 were randomized and 84 completed the study (30 male and 54 female). (For further details refer to Fig. 1.). All but one of the participants (Arabic) were Caucasian, age ranging from 28 to 92 years ($M = 69.17$; $SD = 11.30$).

2.2. Procedure

The study was conducted according to the Helsinki Declaration of 1975, as revised in 2000, and has been approved by the Hungarian Medical Science Association's Science and Research Ethics Committee (permit reference number: 6327-0/2011-EKU (200/PI/11.) with attachment: 20391-0/2010-1018EKU (824/PI/10.)). All participants provided signed informed consent.

The recording of baseline characteristics was followed by group allocation. A research assistant randomly assigned participants to a control or an intervention group using 20 non-transparent cards labeled 'control group' or 'intervention group' which were reshuffled for every participant. To assure blindness of the study team and the hospital staff the assistant was only responsible for group allocation and was not involved in further stages of the study, furthermore patients were instructed not to inform anyone as to which condition they had been assigned to. Subsequently, the intervention group listened to the intervention from a CD player through headphones and received a copy for home use, while control group patients received the regular clinical treatment and did not participate in psychological preparation. The assistant instructed intervention group participants to listen to the recording four times before the surgery to ensure some practice

in the relaxation and imagery techniques. They were also told that the last time they should listen to the tape was on the night before the operation.

The intervention script was developed by the eye surgeon who conducted the operations (K. G., fourth author) and a hypnotherapist experienced in using positive suggestions in medical contexts (E. J., second author). The recording was 15 min 27 s in length and was read out by K.G. The script provided information on the phases of the operation and the recovery period, while using positive suggestions and introducing relaxation and imagery techniques. For example the CD encouraged patients to focus their attention on controlling their breathing and to imagine a safe place during the operation. Some examples from the script: 'When you arrive in the forefront of the operating room you'll get a number of eye drops (...) It'll be good to know that with every drop your pupil will get more dilated and dilated and your eye will get more and more anesthetized as long as it's needed.'; 'First your eye will be cleaned with a disinfectant solution (...) Some imagine this like a pleasant cool breeze that washes away not only bacteria but the remaining tension as well.'

In the perioperative room after the initial medical examination, patients got one Xanax pill (0.25 mg of Alprazolam—as an anxiolytic, a standard procedure in the healthcare center). Patients spent approximately 30 min in the perioperative room.¹ To control as many confounding factors as possible, only one surgeon performed all the operations (K. G., fourth author) in the same operating room (OR) with the same surgical staff. After the operation, patients returned to the perioperative room where they rested with their eyes closed for 20 min, and were discharged shortly after a brief examination. The following day patients returned for a postoperative visit where the intervention group patients were asked of the number of times they had listened to the recording at home. Most participants claimed to have listened to the recording four times ($M = 4.21$; $SD = 2.16$). Although two patients did not listen to the tape at home at all, they were still included in the intervention group as they had listened to the tape once at the medical center.

2.3. Measures

The study included eight measurement points: 1. 'First meeting' (before group allocation); 2. 'Before surgery' (in the perioperative room after the initial medical examination and premedication); 3. 'Surgery 1' (at first incision); 4. 'Surgery 2' (at the start of Phacoemulsification, approximately 3 min into the surgery); 5. 'Surgery 3' (just before the patient left the operating table, approximately 7 min after first incision). 6. 'End of surgery' (immediately after the operation) 7. 'After surgery' (at the end of the 20 min rest period). 8. 'Postoperative visit' (before medical examination at the postoperative visit).

2.3.1. Baseline characteristics

We recorded several baseline characteristics at the First meeting measurement point: To determine any differences in trait anxiety between the two groups we used the trait anxiety subscale of State Trait Anxiety Inventory (STAI) [32] (20 items, Cronbach's $\alpha = .88$). The Low Vision Quality of Life test (LVQoL)

¹ The other medications used before the surgery was as follows: Oxybuprocain 4 mg/ml eye drop 3 times during the last 10 min before operation (an anesthetic), Cyclopentolate hydrochloric 5 mg/ml eye drop used 3 times in the last hour before the operation (a pupil dilator), levofloxacin 5 mg/ml eye drop used 5 times during the last 24 h preceding the operation (an antibiotic). If the anesthesiologist judged it necessary outside the operating theater, 1–3 puffs of Cordaflex spray were used (sprayed under the tongue on the oral mucous membrane, active ingredient: Nifedipine, 5 mg per puff). If high blood pressure occurred in the operating theater Ebrantil was used intravenously (50 mg per dose, active ingredient: Urapidil).

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