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Predictors of pain during phacoemulsification under local sedation: A multicentric study

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MOTS CLÉS

Chirurgie de lacataracte ;Douleurperopératoire ;Anesthésieophtalmologique ;Prise en charge de ladouleur ;Douleurpostopératoire

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Abstract

Purpose:

To assess the risk factors for pain during cataract surgery under local anesthesia.

Methods:

This multicentric observational study assessed risk factors for pain during cataract surgery from June to November 2020 in a private clinic and two university hospitals (France). Adults who underwent cataract surgery under local anesthesia with conscious sedation were consecutively included. Exclusion criteria were locoregional anesthesia and an inability to communicate. Once the surgical drape was removed, patients rated the pain on a numerical rating scale (NRS) from 0 to 10, after the surgical drape was removed. Clinical and biometric parameter data were retrieved from medical records. Multivariate logistic regression was used to determine factors associated with pain during cataract surgery.

Results:

Among the 387 eyes (330 patients), 53 (13.7%) were classified by patients as painful (numerical rating scale [NRS] score \geq 4). An intraoperative painful eye (NRS score \geq 4) was associated with intraocular lens (IOL) power<19 D (OR=2.78, P=0.005), chronic analgesic use (OR=4.34, P=0.011), and brown or white type of cataract (OR=5.68, P=0.008).

Conclusion:

In conclusion, anesthesia should be adapted for myopic eyes with IOL power<19 D, chronic analgesic use, and brown or white cataract. A larger study may help develop a predictive score for pain that could, for example, be integrated into a biometer

Résumé

Objectif.

— Évaluer les facteurs de risque de douleur lors de la chirurgie de la cataracte sousanesthésie locale.

Méthodes.

— Cette étude observationnelle multicentrique a évalué les facteurs de risque de douleur pendant la chirurgie de la cataracte de juin à novembre 2020 dans une clinique privée et deux hôpitaux universitaires (France). Les adultes ayant subi une chirurgie de la cataracte sous anesthésie locale potentialisée par une sédation consciente ont été inclus de manière consécutive. Les critères d'exclusion étaient l'anesthésie locorégionale et l'incapacité de communiquer. Une fois le drap chirurgical retiré, les patients ont évalué la douleur sur une échelle numérique de notation (ENR) de 0 à 10. Les données des paramètres cliniques et biométriques ont été extraites des dossiers médicaux. Une régression logistique multivariée a été utilisée pour déterminer les facteurs associés à la douleur pendant la chirurgie de la cataracte.

Résultats.

—Parmi les 387 yeux (330 patients), 53 (13,7 %) ont été classés par les patients comme douloureux (score ENR \geq 4). Un oeil douloureux en peropératoire (score ENR \geq 4)était associé à une puissance de la lentille intraoculaire (LIO) < 19 D (OR = 2,78, p = 0,005), à l'utilisation chronique d'analgésiques (OR = 4,34, p = 0,011), et au type de cataracte brun ou blanc (OR = 5,68, p = 0,008).

Conclusion.

—En conclusion, l'anesthésie devrait être adaptée pour les yeux myopes avec une puissance de LIO < 19 D, l'utilisation chronique d'analgésiques et la cataracte de type brun ou blanc. Une étude plus vaste pourrait aider à élaborer un score prédictif de la douleur qui pourrait, par exemple, être intégré dans un biomètre.

Introduction

The World Health Organization (WHO) estimates that65.2 million people worldwide have visual impairment due to cataract, so it is the second leading cause of visual impairment (33%) [1]. Cataract remains the leading cause of bilateral blindness in the world (48%), representing 18 mil-lion people and cataract surgery is the most performed surgical procedure in the world; therefore, cataract surgery is a public health issue. Fichman was the first to describe large series of topical surgery, which contributed to the democratization of local anesthesia and quickly became the most widely used method in the early 2000s [2].

Many studies have compared the different modalities of anesthesia and also to allow for a deescalation in case of equivalence [3], which responds to the need to limit the costs and invasiveness of this surgery. As an example, the2018 Massachusetts expert panel report identified locoregional anesthesia as a risk factor for adverse events [4].Pain has been shown to impair patient cooperation which is critical to the success of cataract surgery [5]. To date, only a few studies have analyzed the predictors of pain and above all [5—9], they have not used the statistical models recommended for analysis of the pain scale score[10] (Table 1). The main objective of our study was to deter-mine the preoperative factors associated with pain during phacoemulsification under topical sedation.

Methods and materials

This study followed the STROBE checklist for reporting observational study findings [11].

Design

This was an observational, prospective, multicentric study.

Ethics statement

The present study was approved by the ethics committee of Montpellier University Hospital (IRB 202000443) and was registered at ClinicalTrials.gov (NCT04353843).

Setting and population

Participants were recruited in a private clinic and a university hospital, from June to November 2020. We consecutively included adults who have undergone cataract surgery under local anesthesia potentialized by conscious sedation over the period considered. Exclusion criteria were locoregional anesthesia and an inability to communicate (language bar-rier, deafness). The usual protocol nation and received conscious intravenous anesthesia with spontaneous ventilation during surgery. Anesthesia of the ocular surface involved using

Oxybuprocaine, tetracaine or both or xylocaine gel. Midazolam, Sufentanil, and Paracetamol or propofol was used as the sedation protocol. Five surgeons were involved. The phacoemulsification machines used were Centurion (Alcon)or Constellation (Alcon). The standard phacoemulsification technique was performed by a clear corneal incision, using the divide and conquer method. A foldable intraocular lens(IOL) was inserted in a 2.2-mm incision, then antibiotic prophylaxis with Aprokam was used as recommended and incisions were hydro sutured [12].

Outcome

The primary objective was to identify pre-operatory factors predicting pain during phacoemulsification. Secondary objectives were to identify intraoperative factors related to pain and to assess the capacity of the surgeon to detect the patient's pain.

Data sources

Before removing the surgical drape from the patient, surgeons noted whether or not they considered that the patient experienced pain during surgery. Once the surgical drape was removed, patients rated the pain on a numerical rating scale (NRS), from 0 to 10. Then, in the ambulatory surgery sector, patients were asked about their consent to participate in the study. Collecting the first NRS score before asking for consent ensured no effect on the patient's answer. No patient refused to participate. Then, patients again rated the pain on the NRS, in case the patient was disturbed by the anesthesia in the first place. We retrieved all clinical data from medical records: age, sex, anesthesia protocol performed, personal treatment, weight, eye color, type of cataract, history of ocular surgery, diabetes, adverse events during surgery, biometric parameters, emmetropizing IOL power, best-corrected visual acuity using the logarithm of the minimum angle of resolution (log MAR) and IO pressure. Emmetropizing IOL power was calculated with the SRK/T formula with an A-constant of 119.3.

Statistical analysis

Continuous variables are described with median (interquartile range [IQR]). Categorical variables are described with number (percentage). Missing data are indicated only if present. Mann-Whitney test was used to compare continuous variables. Chi-square test (or Fisher's test) was used to com-pare categorical variables. A logistic regression analysis was performed because of the skewed distribution of the NRS data and the impossibility to normalize it [13]. The explanatory variable was "intraoperative pain". To determine this variable, we dichotomized the NRS score according to the literature. An NRS score ≥ 4 defined the pain [14]. Continuous covariates were classified according to quartiles because data for some were not normally distributed. Two multivariate logistic models were constructed based on preselected parameters from the univariate analysis ($P \leq 0.20$), one for preoperative factors and one for intraoperative factors. Two procedures (stepwise and forward) were used to obtain the most appropriate logistic regression model, and both led to the same final model. Absence of multicollinearity was verified by using the variance inflation factor. Odds ratios(ORs) and 95% confidence intervals (CIs) were estimated. P < 0.05 (two-sided test) was considered statistically significant. Statistical analyses involved using R 4.0.3 (Vienna,

Austria).

Table 1Previous studies evaluating risk factors for pain related to cataract surgery.							
Study	Participants Age, sex	Inclusion/ Consecutiveness	Outcome	Model	Results		
Omulecki et al., 2009 [5]	203 eyes 203 patients Age and sex: not detailed	5 months consecutive	Intraoperative pain	Not detailed	Less pain: Female, rural, younger, lower VA		
Aslankurt et al., 2014 [6]	78 eyes 78 patients Age and sex: not detailed	Not detailed Not detailed	Intraoperative pain	Univariate: <i>t</i> -test Spearman correlation	More pain: dominant side, women		
Dadaci et al., 2016 [7]	92 eyes 92 patients Age: 66.9 (10.6) F/M: 45 (49)/47 (51)	Not detailed Not detailed	Intraoperative and postoperative pain	Univariate: Chi ² , <i>t</i> -test	Less pain: diabetic, NSAI		
Kang et al., 2017 [8]	142 eyes 142 patients Age: 67.5(12.5) F/M: 72 (51)/70 (49)	6 months Not detailed	Intraoperative and postoperative pain	Multiple linear regressions ^a	More pain: greater IOP, AL and ACD		
Liu et al., 2020 [9]	466 eyes 321 patients Age: not detailed F/M: 275 (59)/191 (41)	9 months Not detailed	Intraoperative pain	Multiple linear regressions ^a	More pain: Female, younger, higher education level		

The baseline characteristics of the participants are presented as number (%) mean (SD). ACD: anterior chamber depth; AL: axial length;

^a None of the studies using a linear model specified whether the numeric score pain distribution was normal. Using a linear model without checking this assumption falsely maximizes the power, but gives biased results.

Table 2Baseline characteristics of patients undergoing cataract surgery.					
Variable	Overall, <i>n</i> = 387 eyes ^a	Missing value			
Operated eye (left/right)	199 (51)/188 (49)				
Age	74 (69–80)				
Sex (Female)	234 (60)				
History of surgery	204 (53)				
Eye color					
Blue	79 (20)				
Brown	230 (59)				
Green	78 (20)				
Type of cataract		2			
Brown or white	22 (5.7)				
Soft	26 (6.7)				
Standard	339 (88)				
Diabetes	76 (20)				
Diabetic retinopathy	27 (7.0)				
Psychotropics use	63 (17)	22			
Analgesics use	19 (5.2)	22			
Alpha blockers use	22 (6.2)	22			
Hypotensive eyedrops use	22 (6.2)	22			
Log MAR	0.30 (0.20-0.40)				
IOP, mmHg	15.0 (13.0–18.0)				
AL, mm	23.53 (22.81–24.36)				
SE, Diopters	-0.5 (-2.4-1.2)	16			
ACD, mm	3.05 (2.82–3.34)	38			
Km, mm	7.69 (7.48–7.89)	1			
WTW, mm	12.00 (11.70–12.30)	223			

ACD: anterior chamber depth; AL: axial length; IOP: intraocular pressure; Log MAR: logarithm, minimum angle of resolution; Km: mean keratometry; SE: spherical equivalent; WTW: white-to-white. ^a Median (interquartile range).

Results

Participants

A total of 387 eyes for 330 patients were included between June and November 2020; 60% of patients were females. The median (IQR) age was 74 (69—80) years; 19 (5.2%) patients were chronic analgesic users, 204 (53%) had a history of ocu-lar surgery, and 57 had sequential cataract surgery during the study. Clinical characteristics of patients are in Table 2.

Preoperative factors associated with intraoperative pain

A total of 53 (13.7%) patients had eye pain (NRS score \geq 4).On multivariate analysis, postoperative pain was associated with the preoperative factors IOL power < 19 D(OR = 2.78, 95% CI: 1.36—5.63; *P* = 0.005), chronic analgesic use (OR = 4.34, 95% CI: 1.31—13.2; *P* = 0.011), brown or white type of cataract (OR = 5.68, 95% CI: 1.46—20.4; *P* = 0.008)and history of ocular surgery, although not significantly(OR = 2.01, 95% CI: 1.02—4.12; *P* = 0.05) (Table 3).

Intraoperative factors associated with intraoperative pain

Both univariate and multivariate models showed intra-operative pain associated with iris complications (OR multivariate = 7.83, 95% CI: 3.47—17.6; P < 0.001), surgery duration \geq 20 minutes (OR multivariate = 12.3, 95% CI:4.29—36.3; P < 0.001), blood pressure increase (OR multi-variate = 4.71, 95% CI: 1.18—17.3; P = 0.022) and Miochol-injection (acetylcholine chloride) (OR multivariate = 4.02,95% CI: 1.15—13.9; P = 0.027) (Table 4).

Surgeon's sensitivity and specificity to identify patients with pain

The sensitivity of surgeons to identify patients with pain(NRS score \geq 4) was 0.57 (95% CI: 0.43—0.70) and specificity0.96 (95% CI: 0.93—0.97).

Discussion

Few studies have investigated the predictive factors of pain for cataract surgery, and have investigated them with biased statistical methods. We found an association between intraoperative pain and the following preoperative factors: emmetropizing implant power < 19 D, chronic use of analgesics, and white or brown cataracts. We identified an association between intraoperative pain and the intraoperative factors: iris complications, operative time \geq 20 minutes, blood pressure increase and intracameral use of Miochol.

Preoperative factors of pain during surgery

Intraoperative pain was associated with emmetropizing implant power < 19 D. To our knowledge, this is the first study to analyze the pain during cataract surgery accord-ing the power of the emmetropizing implant. This variable accounts for the biometric proportions of the eye in a more complete way than a single biometric measure. In2017, Kang et al. reported on 142 Asian patients (Table 1), finding that large ACD and AL were associated with more pain [8]. We also found a statistically significant association between large AL and pain on univariate analysis (AL \geq 24.36 mm, P = 0.027). Myopia is associated with lens-iris diaphragm retropulsion syndrome (LIDRS), characterized by excessive anterior chamber deepening, retropulsion of the iris, and extreme widening of the pupil, causing pain during cataract surgery [15]. Wilbrandt et al. first described this phenomenon in people with strong myopia, with the pathophysiological hypothesis of a laxity of the zonule due to a total resting of accommodation in myopic eyes. Further studies are needed to clarify the association between these biometric parameters and pain.

In our study, chronic use of analgesics was associated with intraoperative pain, which is consistent with the literature. Chronic use of analgesics could increase the sensitivity to pain, and decrease sensitivity to local anesthetics such as lidocaine [16,17].

Table 3 Preoperative factors associated with intraoperative pain.							
Variable	Univariate analysis			Multiva	Multivariate analysis		
	OR	95% CI	P-value	OR	95% CI	P-value	
IOL power < 19.0 D (first quartile) ^a	2.65	1.42-4.88	0.002	2.78	1.36-5.63	0.005	
Chronic analgesic use ^a	3.25	0.62-5.30	0.20	4.34	1.31-13.2	0.011	
Type of cataract							
Standard (reference)	-	_		_	_		
Soft	2.18	0.76-5.46	0.11	2.64	0.89-7.51	0.061	
Brown or white	2.73	0.93-7.05	0.048	5.68	1.46-20.4	0.008	
History of surgery ^a	1.73	0.96-3.20	0.075	2.01	1.02-4.12	0.05	
Hypotensive eyedrops use ^a	1.97	0.62-5.28	0.20	2.61	0.79-7.43	0.087	
Diabetic retinopathy ^a	2.39	0.90-5.73	0.062				
Age \geq 80 years ^a	0.43	0.17-0.93	0.048				
Operated eye (right vs. left)	0.60	0.33-1.08	0.091				
Alpha blockers use ^a	1.98	0.62-5.30	0.20				
SE < -3.375 D (first quartile) ^a	0.62	0.33-1.20	0.15				
$AL \ge 24.36 \text{ mm} (\text{last quartile})^{a}$	1.99	1.07-3.64	0.027				
$IOP \ge 18 \text{ mmHg} (last quartile)^a$	1.11	0.57-2.08	0.75				
Hypotensive eyedrops use ^a	1.97	0.62-5.28	0.20				

AL: axial length; IOL: intraocular lens; IOP: intraocular pressure; SE: spherical equivalent; OR: odds ratio; CI: confidence interval. Regarding the choice between IOL power and axial length, we prioritized IOL power in our multivariate analysis due to its broader capture of ocular characteristics and confirmed absence of multicollinearity in our results. ^a Yes vs. no.

We found that brown or white cataract caused more pain. This finding seems intuitive because extraction of such cataracts usually takes longer, and dislocation of larger and harder cataracts probably places more stress on the iris and zonula, thus resulting in more pain.

We have shown that a history of eye surgery was associated with more pain during cataract surgery, although not significantly. This finding is in line with previous studies and could be related to lower anxiety and pain expectancy before second eye surgery [18—20].

Variable	Univariate analysis			Multivariate analysis		
	OR	95% CI	P-value	OR	95% CI	P-value
Iris complication ^a	6.39	3.10-13.1	< 0.001	7.83	3.47-17.6	< 0.001
Surgery duration						
< 10 min (reference)	_	-		_	_	
10-20 min	1.43	0.72-2.85	0.30	1.11	0.52-2.36	0.78
\geq 20 min	15.0	6.16-38.3	< 0.001	12.3	4.29-36.3	< 0.001
Blood pressure increase ^a	6.18	2.08-18.0	< 0.001	4.71	1.18-17.3	0.02
Additional AC drug						
None (reference)	_					
Blue	3.13	1.16-7.68	0.017	1.46	0.41-4.60	0.54
Miochol	10.06	3.95-29.5	< 0.001	4.02	1.15-13.9	0.027
AC: anterior chamber; OR: odds			\$ 0.001	4.02	1.15-15.9	0.027

Intraoperative factors associated with pain

In our study, intracameral use of Miochol was associated with pain. Pain after intracameral use of acetylcholine is related to ciliary muscle spasm. Our study confirms the existence of visceral pain related to this chemical mediator [21–23].

We found an association between longer duration of surgery (≥ 20 minutes) and pain which is consistent with the study of Rothschild et al. [24]. O'Brien et al. did not find this association probably because of a limited sample of 100 patients [25]. A long surgery may be associated with potentially painful operative complications and with decreased effect of local anesthetics over time. Indeed, the duration of action of local anesthetics ranges from 5 to10 minutes for Oxybuprocaine (according to the monograph)to about 10 minutes for intracameral 1% lidocaine [26,27].However, we compared the different modalities of surface anesthesia used and did not find any difference in pain(Supplement 1). This observation goes against the accepted idea that Tetracaine is more effective than Oxybuprocaine but is consistent with the study of Reynders et al., which did not find any difference between Oxybuprocaine alone and Oxybuprocaine combined with Tetracaine in human eyes[28]. To our knowledge, the only study directly comparing Oxybuprocaine to Tetracaine is a veterinary study, which did not find any difference [29].

We found iris complications associated with pain which is consistent with the literature [30].

We are the first to report an association between high blood pressure and pain during cataract surgery. However, whether the increase in blood pressure causes the pain orthe pain causes the increase in blood pressure is difficult to determine.

Cataract surgery patients are elderly, with an aver-age age of 74 years in our population, very close to the73.5 years found by the DREES national study in 2016 [31]. This population is specifically affected by comorbidities, including systemic hypertension [32]. Hypertension and agitation remain the most common intraoperative medical events during cataract surgery [33]. Hypertension could be associated with intraoperative pain because it would lead to an increase in IOP by vitreous thrust and thus zonular disinsertion or posterior capsular rupture [34].

Our surgeons tended to minimize the patient's pain almost half the time but were highly specific and almost always right when they considered that a patient was in pain. We can

explain the reduced sensitivity by the difficulty in assessing pain via grimaces because of the surgical drape. The high specificity can be explained by the choice of the NRS threshold at 4 (corresponding to the pain level requiring an analgesic for the French High Authority of Health [14]), which is probably lower than the threshold at which a patient is obviously in pain. For example, one can easily imagine having headaches with a NRS of 5 without giving external signs of pain.

Limitations and of the study

Our study has several limitations. First, we included patients with a history of recent or past eye surgery, cataract, or other procedure, including those who underwent cataract surgery on both eyes during our inclusion period so we could perform the study under "real life" conditions and to verify that patients experience more pain during a second surgery in our population. This bias was limited by adjustment for previous surgery in multivariate analysis. Second, our study was multicentric, with several surgeons, machines and protocols involved, which, for a non-interventional study, may seem a source of bias. Also, these potential biases were analyzed and no adjustment in multivariate analysis was necessary on them.

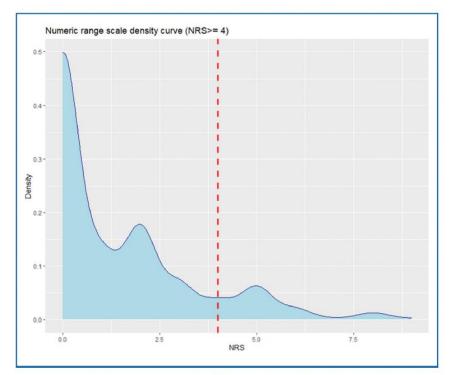


Figure 1. Density curve for numerical rating scale score. The NRS mean (SD) is 1.39 (1.88). The red dotted line represents the pain dichotomization value. NRS: numeric range scale; SD: standard deviation.

Regarding the relation between the blood pressure increase and pain, we did not collect the temporality of this increase during surgery, which does not allow us to say whether the increase preceded the pain or the opposite. Although the data collection was quite extensive, some potential confounders were not collected, such as the age of surgeons, which might have been associated with better surgical skills and therefore less intraoperative pain. Additionally,

given the retrospective nature of our study, it would have been beneficial to collect data on conditions like pseudo exfoliation and the use of iris retractors, as these are potentially painful scenarios that were not accounted for. Concerning the strengths, our study uses unbiased statistical methodology. Most of the studies that evaluate pain using the visual analog scale have methodological weak-nesses concerning statistical analysis. Indeed, they often use distribution-based method considering a normal distribution of pain scores, with no precision on the normality of the visual analog scale score distribution, which in practice is often false, as shown by the density curve of our study (Fig. 1). Most cataract patients have little or no pain and therefore the distribution of values is highly skewed at one extreme; moreover, the sample size is often small to moderate, which exacerbates the statistical bias. Consequently, the statistical value of the results obtained is altered [10]. The studies by Kang et al. and Liu et al. used multiple linear- regressions considering a normality of pain distribution, without verifying it. This falsely increases power and leads to potentially biased results. In addition, the magnitude of the Beta coefficients found is low, which in practice has little clinical implication. Moreover, these two studies were carried out in Korea and China, respectively, which targets Asian populations with particular biometric conformations and may hamper the extrapolation of the results. All these reasons may explain a divergence of their results from ours. Thus, to minimize the bias, we performed a logistic regression by dichotomizing the pain according to a threshold from the 2020 HAS report considering this threshold (NRS = 4) as the one according to which the pain should be man-aged [13,14]. Moreover, unlike other studies, we assessed patients' pain before informing them of possible inclusion in our study, in order not to influence the scores. A patient who is informed before surgery that he or she will be assessed for pain may experience anxiety and be more vigilant to the slightest source of pain. Finally, our sample was relatively large, with 387 eyes studied, which is the second largest study in existence and offers more statistical power and the possibility of studying more potential pain factors.

Conclusion

Preoperative factors for pain were emmetropizing IOL power < 19 D, chronic analgesic use and white or brown cataract. Intraoperative factors identified were iris complications, surgery time ≥ 20 minutes, blood pressure increase and intracameral use of Miochol. This is the first time that emmetropizing IOL power (< 19 D) has been studied and reported as a risk factor for pain. This parameter seems interesting because it gives a global account of the biometric proportions. Its clinical implication will continue to grow as myopia is growing epidemically worldwide, and an estimated nearly 60% of the population will be myopic by2050 [35]. Other studies should be conducted to establish a predictive pain that could be integrated in a biometer.

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Ethical statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Montpellier University Hospital (IRB 202000443) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Disclosure of interest

The authors declare that they have no competing interest.

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