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Impact of preoperative testing on ophthalmologic and systemic outcomes in cataract surgery

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PURPOSE. *To evaluate the incidence of ophthalmologic and systemic complications in patients who undergo cataract surgery without preoperative tests compared to subjects undergoing cataract surgery preceded by preoperative tests.*
METHODS. *The randomized controlled study included 1276 consecutive patients admitted to the Institute of Ophthalmology of the University of Modena and Reggio Emilia for cataract surgery. The patients were randomly divided into two groups: 638 were assigned not to undergo preoperative evaluation based on routine medical tests and electrocardiograms; the other 638 underwent preoperative evaluation based on said tests. Ophthalmologic and systemic complications were assessed intraoperatively and 1 month after surgery.*
RESULTS. *Eleven intraoperative complications occurred in the group without preoperative tests and eight in the group with preoperative tests; at 1 month six complications were recorded in the group without tests and five in the group with tests. Systemic adverse events occurred intraoperatively in four patients, whereas no systemic adverse event was recorded at 1 month in either group. No statistically significant differences were observed between the two groups.*
CONCLUSIONS. *The findings of this study have broad applicability, because the sample is representative of the population existing in numerous social and healthcare settings; they are of value for administrative purposes, because they may be taken as reference in resource allocation plans; and they have medicolegal implications, as the resulting conduct of healthcare providers is supported by a rigorous scientific study. (Eur J Ophthalmol 2004; 14: 369-74)*

KEY WORDS. *Preoperative tests, Cataract, Day surgery, Healthcare policy*

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INTRODUCTION

Blindness associated with the presence of cataracts is a worldwide social and health concern and cataract removal represents the most frequently performed surgical procedure in the elderly in industrialized countries.

Worldwide, cataract causes a total of 19.34 million cases of bilateral blindness, accounting for 43% of all blindness. The expansion in world population and lengthening of the average lifespan have resulted in a significant increase in the number of people with this pathology (1).

On a worldwide scale it is projected that each year an estimated 4 to 6 million new cases of cataract-in-

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duced blindness will occur, 1 million people will be treated for cataract-induced blindness, and 3 to 4 million persons with cataract-induced blindness will die. From these data it is possible to deduce a net world increase in cases of cataract-induced blindness of 1 million per year (2).

In Italy, 240,334 cataract operations are performed each year, 38,000 in the region of Emilia Romagna alone. The number of operations increased by 72% in the 5-year period from 1996 to 2000 (Regional Health Agency data).

Given the relevance of this pathology from a standpoint of epidemiology and public health, as well as the importance of surgical correction, the rate of cataract surgery must necessarily increase to cope with the growing demand associated with the rise in average life expectancy and health expectations. This implies the need to reduce technical and personnel costs and the amount of time required for each operation.

The costs of surgery are influenced by two types of factors: 1) the organizational model adopted within the healthcare facility and 2) effective prevention of complications.

From an organizational viewpoint, in recent years there has been an increasing trend toward performing cataract surgery on an outpatient basis: the percentage of patients admitted to day surgery rose from 62.7% in 1996 to 97.68% in 2000. In May 2003 the region of Emilia Romagna chose to transfer cataract surgery to an ambulatory setting. At present, in the Institute of Ophthalmology of the University of Modena and Reggio Emilia, cataract removal takes place in an ambulatory setting in 98.05% of cases.

With regard to the management of surgical patients, the guidelines for anesthesiologic evaluation in day surgery published by the SIAARTI (Italian Society of Anaesthesia, Analgesia, Reanimation and Acute Care) provide that tests and examinations should be prescribed according to the type of surgery and the patient's conditions, as no general rules may be established for surgical categories. In fact, the scientific evidence regarding the impact of laboratory tests and other examinations on risk assessments and the patient's anesthesiologic outcome is judged inconclusive. Optimizing the selection of patients who will undergo surgery (preoperative evaluation) is a decisive step in the direction of reducing costs, as preoperative tests may be dispensed with. A precise calculation of the benefits of eliminating such tests was made in the United States, where the potential savings in the costs of cataract surgery were placed at $150 million a year (3). We made an analogous estimate for the region of Emilia Romagna, according to which the optimization of preoperative patient evaluation would cut costs by approximately 1,200,000 Euro a year.

We therefore verified that there was a significant chance of reducing costs by optimizing the preoperative evaluation of patients scheduled to undergo elective cataract surgery on an outpatient basis and we planned this randomized controlled study (level I interventional study) with the aim of determining whether routine preoperative testing (routine medical tests and electrocardiograms) reduces the incidence of intraoperative and postoperative ocular and systemic complications associated with cataract surgery.

MATERIALS AND METHODS

Definition of study population and exclusion criteria

We enrolled patients of both sexes and different ethnic backgrounds who were consecutively admitted to the day surgery section of our institute of ophthalmology for elective cataract surgery under local anesthesia from October 1, 2002, to November 30, 2003.

The exclusion criteria were ongoing treatment with anticoagulants and subcutaneous insulin therapy. At the time of scheduling the operation, patients were informed of the aims and methods of the present study and, if they agreed to take part, medical staff involved in the study asked them to sign a consent form prepared by the provincial ethics committee.

Sample size estimation

The study was planned on the basis of the following information. According to the literature, the risk of adverse events occurring intraoperatively and postoperatively is about 9% (4, 5); this figure is consistent with the experience of the ophthalmology center in which this study took place. On the assumption that the lack of preoperative tests could increase the risk of occurrence of intra- and postoperative ocular

adverse events to 14% (a 5% increase in risk is the minimum considered relevant), and setting an alpha value of 0.05 and beta value of 0.20 (power=0.80), we estimated a sample size of 638 patients per group (software: sample size 2.0).

Randomization of the study population

There were two stages of randomization

In the first stage, patients were randomly assigned to one of the two study groups: 1) with preoperative testing, 2) without preoperative testing. A randomization list was drawn up at the Department of Hygiene of the University of Modena and Reggio Emilia, which represented the Randomization Centre. On the basis of this list, patients were divided into the two study groups, following telephone consultation between medical staff involved in the study and personnel of the Randomization Centre.

In the second stage, the list of patients belonging to the two study groups was handed over to day surgery personnel, who were instructed to enclose, in a sealed envelope, the results of preoperative tests that patients assigned to the group without preoperative testing brought to the preoperative visit. Patients, who had been instructed at the time of receiving the information sheet, handed over to healthcare personnel the letter from their primary care physician stating the presence or absence of conditions warranting their exclusion from the study. The envelopes were supplied by the Randomization Centre and numbered from 1 to 638, each in a single copy. On the date of the visit, the physician appointed to evaluate preoperative tests refrained from analyzing those contained in sealed envelopes and was informed neither of the patient's identity nor of the scheduled date of surgery.

On the day of surgery, patients assigned to the group without preoperative tests were monitored intraoperatively by means of a pulsimeter.

Data collection and outcomes

The primary outcome considered is an ocular adverse event. Intraoperative ocular adverse events include posterior capsule rupture with/without vitreous loss, partial dislocation of the nucleus/dislocation of nuclear fragments and/or cortical material in the vitreous, increased intraocular pressure, anterior capsule rupture, and iris prolapse. Postoperative ocular adverse events include corneal edema, cystoid macula edema, loosening or breakage of stitches, anterior uveitis, endophthalmitis, secondary glaucoma, dislocation of the intraocular lens, and retinal detachment.

The secondary outcome considered is a systemic adverse event, defined as the intra- or postoperative occurrence of one of the following: acute respiratory, cardio-circulatory, or neuropsychiatric disease; decompensation in analogous, already known chronic disease.

The data regarding the ocular outcomes of cataract removal were assessed at the time of discharge and 1 month after surgery, respectively, by means of an analysis of clinical records and telephone interviews of patients, who were asked to report the results of the examinations performed by their eye doctors 1 month after surgery. Data were thus gathered on four groups of patients: patients with or without ocular adverse events and patients belonging to the group with or without preoperative tests.

The data regarding systemic adverse events were assessed at the same times and using the same methods as above, in this case taking into account the examination performed by the patient's primary care physician 1 month after surgery. Data were thus gathered on four groups of patients: patients with or without systemic adverse events and patients belonging to the group with or without preoperative tests.

Statistical analysis

The between-group differences in terms of the risk of occurrence of ocular adverse events were analyzed by calculating relative risk (RR). The RR was calculated as the ratio between the risk of occurrence of ocular adverse events in Group 2 (without preoperative tests) and the risk of occurrence of ocular adverse events in Group 1 (with preoperative tests). The results are reported in terms of RR, 95% confidence interval (CI), and p value; p values below 0.05 are considered statistically significant. The between-group differences in terms of the risk of occurrence of systemic adverse events were evaluated using the same statistical method. Finally, an assessment was made of the RR of occurrence of both ocular and systemic adverse events in the two groups.

TABLE I - INTRAOPERATIVE OPHTHALMIC COMPLICATIONS

Adverse events	Without preoperative tests, n (%)	With preoperative tests, n (%)
Nuclear or cortex fragments		
Dislocation into the vitreous	5 (0.78)	3 (0.47)
Anterior capsule rupture	2 (0.31)	2 (0.31)
Posterior capsule rupture	4 (0.62)	3 (0.47)
Total adverse events	11 (1.72)	8 (1.25)

TABLE II - POSTOPERATIVE OPHTHALMIC COMPLICATIONS AFTER 1 MONTH

Adverse events	Without preoperative tests, n (%)	With preoperative tests, n (%)
Cystoid macular edema	3 (0.47)	3 (0.47)
Retinal detachment	1 (0.16)	0 (0.00)
Corneal decompensation	2 (0.31)	2 (0.31)
Total adverse events	6 (0.94)	5 (0.78)

TABLE III - INTRAOPERATIVE SYSTEMIC COMPLICATIONS

Adverse events	Without preoperative tests, n (%)	With preoperative tests, n (%)
Arterial hypertension	2 (0.31)	3 (0.47)
Psychomotor agitation	2 (0.31)	1 (0.16)
Total adverse events	4 (0.63)	4 (0.63)

RESULTS

Overall, 1276 patients were enrolled in the study and the results were as follows: 11 ocular adverse events occurred intraoperatively in the study group without tests (5 partial dislocations of the nucleus/dislocations of nuclear fragments and/or cortical material in the vitreous, 2 anterior capsule ruptures, 4 posterior capsule ruptures) and 8 ocular adverse events occurred intraoperatively in the control group with tests (3 partial dislocations of the nucleus/dislocations of nuclear fragments and/or cortical material, 2 anterior capsule ruptures, 3 posterior capsule ruptures) (Tab. I); 6 ocular adverse events occurred postoperatively in the study group without tests (3 cystoid macula edemas, 1 retinal detachment, 2 corneal decompensations) and 5 ocular adverse events occurred postoperatively in the control group with tests (3 cystoid macula edemas, 2 corneal decompensations) (Tab. II).

With respect to systemic adverse events, four occurred intraoperatively in the group without tests (two episodes of arterial hypertension, two episodes of psychomotor agitation) and four in the group with tests (three episodes of arterial hypertension, one episode of psychomotor agitation) (Tab. III); no systemic adverse events occurred postoperatively in either group of patients.

There is no statistically significant increase in the risk of ocular adverse events occurring either intraoperatively ($p=0.49$) or postoperatively ($p=0.76$) in the group of patients without preoperative tests as compared to control group. However, in absolute terms the risk of intra- or postoperative ocular adverse events was higher in the group without preoperative tests compared to the control group (respectively: RA=1.7% versus RA=1.3%

[intraoperative ocular adverse events]; RA=0.9% versus RA=0.8% [postoperative ocular adverse events]), resulting in a RR other than 1 (respectively: RR=0.73 with a CI between 0.29 and 1.78 [intraoperative ocular adverse events]; RR=0.83 with a CI between 0.26 and 2.72 [postoperative ocular adverse events]).

With respect to intraoperative systemic adverse events, the risk in absolute terms is equal in the study and control groups (RA=0.006); hence the RR is equal to 1 with a CI between 0.25 and 3.98 (statistically insignificant between-group difference, p=1.0).

No systemic adverse events occurred in either group in the 30 days following surgery and thus in this case no assessment may be made of the risk associated with the surgical procedure in relation to whether routine preoperative medical tests were carried out.

DISCUSSION

This randomized controlled clinical study has two main advantages: random allocation of patients to one of the interventions and, as a consequence, an increased likelihood that the two groups were similar (from the outset) and that any differences in outcome depended solely on the type of intervention assigned.

The type of eye complications occurring both intraoperatively and at 1 month after surgery was similar in the two groups; the same observation applies for intraoperative systemic complications. The similar nature of the adverse events is further demonstration that preoperative tests are of little value in predicting not only the quantity of adverse events but also the type of complication that is likely to occur.

The percentage of perioperative complications associated with cataract surgery was low and in agreement with the data reported in the literature (6-8). However, given that cataract patients are frequently elderly and have serious coexisting diseases (9-11), the majority of physicians believe that a complete medical check-up with laboratory tests should be carried out before a patient may be considered eligible for surgery (1).

Schein et al (1) have shown that the preoperative tests routinely performed prior to cataract surgery do not significantly increase the safety of the surgery. In fact, in a randomized clinical trial they conducted on 18,189 patients, the cumulative percentage of adverse medical events was the same in the group undergoing preoperative tests and in the no-testing group (31.3 per 1.000); the type of adverse event that occurred was likewise similar in both groups (treatment of hypertension and bradycardia in 60% to 70% of cases).

Smetana and Macpherson (12) have emphasized that laboratory tests prior to an operation have limited clinical value and that physicians should prescribe only those tests whose results, if abnormal, could influence patient management.

Imasogie et al (13) have shown that in ambulatory cataract surgery over 90% of the costs for preoperative laboratory testing could be saved by eliminating routine tests.

The strength of the statistical design used – including the large size of the sample studied – lends credence to the results as well as ensuring their broad applicability, because the sample studied can be considered as representative of the population in numerous social and healthcare settings (owing to the limited number of exclusion criteria and a posteriori stratification of the data).

The results are also important from the standpoint of healthcare administration, as they can be taken as reference in the formulation of plans for distributing available resources so that the amounts saved can be allocated to cover other necessary expenses.

The rigor of the scientific process characterizing a randomized controlled study lends the resulting conduct of healthcare providers a medicolegal basis that justifies the decision of the healthcare organization as a whole and of individual physicians to eliminate preoperative tests in favor of a careful preoperative evaluation of the patient's history.

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