Volume : 5 | Issue : 7 | July 2016 • ISSN No 2277 - 8179 | IF : 3.508 | IC Value : 69.48

A Prospective Interventional Study of Progression of Diabetic Retinopathy after Uncomplicated Small Incision Cataract

Medical Sciences

KEYWORDS : Diabetic Retinopathy, Small incision cataract surgery, Macular edema

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ABSTRACT

Diabetes rates are rising all over the world and Diabetic Retinopathy (DR) ,one of the most frequent complications of diabetes, affects approximately 50% of diabetic subjects.

The purpose of this prospective study was to investigate the onset and course of diabetic retinopathy, the incidence of macular edema and visual outcome following uncomplicated phacoemulsification with Posterior Chamber Intra Ocular Lens implantation in a group of well controlled diabetic patients with cataractwith or without mild/moderate nonproliferative diabetic retinopathy and without Clinically Significant Macular Edema at baseline.

This study was done at the Regional Institute of Ophthalmology, Kolkata. Patients who gave informed consent and those meeting inclusion criteria were randomly selected from the outpatient department.60 eyes of 60 consecutive diabetic patients having cataract with well controlled systemic parameters were included in the study conductedfrom January 2012 to June 2013.

Follow up was done for 6 months.Statistical analysis was done by chi square and Fisher's exact test.

The progression of diabetic retinopathy was statistically more significant in DR group compared to no DR group.

Also, statistically significant post operative improvement of VA in no DR group compared to DR group was seen.

≥ 40 letters improvement occurred in 79.5 % of cases of without Macular Edema (ME) group whereas 27.2% of cases achieved the same in the macular edema group.

We found that the progression of diabetic retinopathy was 18.3% which was significantly more (29%) in DR group compared to 11% in No DR group. We also found that the incidence of ME is 18% which exclusively appeared in postoperative DR group.In conclusion, diabetic patients scheduled for cataract extraction should be informed that surgery may have an adverse influence on diabetic retinopathy and that this may affect the final visual outcome and expectation.

INTRODUCTION :

The effect of cataract surgery on the postoperative course of diabetic retinopathy(DR) is unclear. Jaffe and Burton [1] reported the development of a severe exudative form of diabetic macular edema following cataract extraction. Other authors [2-4] have also described postoperative progression of diabetic retinopathy resulting in poor vision. In contrast, Sebestyen[5] found that cataract surgery was not associated with the progression of diabetic retinopathy, as in his series of patients similar progression was observed also in the unoperated fellow eye.

The 1997 guidelines of the Royal College of Ophthalmologists state that all forms of DR may become more severe following cataract surgery.[6] However, much of the evidence upon which this statement was based came from retrospective case note reviews of patients undergoing extracapsular cataract surgery.[7,8]

The purpose of this prospective study was to investigate the onset and course of diabetic retinopathy, the incidence of macular edema (ME) and visual outcome following uncomplicated small incision cataract surgery (SICS) with Posterior Chamber Intra Ocular Lens (PCIOL) implantation in a group of well controlled diabetic patients (HbA1C<7) with cataract(PSC or NS grade 1,2) with or without mild/moderate nonproliferative diabetic retinopathy(NPDR) and without Clinically Significant Macular Edema (CSME) at baseline.

MATERIALS AND METHODS :

Specific objectives were :

1) To assess incidence or progression of Diabetic Retinopathy level following SICS

2) To assess change in central macular thickness (CMT) by spectral domain optical coherence tomography (OCT) following SICS at every follow up.

3) The outcome of SICS in diabetic cases in terms of best corrected visual acuity.

This study was done in the Regional Institute of Ophthalmology Kolkata. Patients were randomly selected from the outpatient department who attended OPD for their dimness of vision and who were suffering from type 2 diabetes mellitus. A proper written informed consent was taken .The subjects belonged to various districts of West Bengal, Bihar and Jharkhand.

STUDY POPULATION

60 eyes of 60 consecutive diabetic patients diagnosed with cataract and having no DR, mild or moderate non proliferative diabetic retinopathy (NPDR) according to ETDRS criterion (appendix–I) and without CSME with well controlled systemic parameters were included in the study as study group.

Follow up was done for 6 months.

.Patients were deemed to be enrolled in the study after they had given written consent and fulfilled the inclusion criteria. Approval from the institutional ethical committee was obtained.

Patients underwent small incision cataract surgery by an experienced surgeon and followed up at 1 month, 3rd month and 6th month thereafter.

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Inclusion criteria:
Type 2 Diabetes patient with cataract (NS Grade-1, 2 and PSC) with either no DR or NPDR without CSME requiring surgery as per visual demand of the patient.

Glycated hemoglobin HbA1c <7.

Systolic and diastolic blood pressure <150 mm Hg and <90 mm Hg respectively with or without antihypertensive medications

Exclusion criteria:
Eyes with evidence of CSME or PDR as defined by ETDRS criterion.

Patients with signs of vitreomacular traction on either biomicroscopy or OCT or USG examination.

HbA1C>7.00 any time during the course of study.

Systolic BP ≥150, diastolic BP≥90, urinary microalbumin creatinine ratio> 300.

Patients with media is dense enough which hindered with proper visualization of fundus or acquisition of images.

Loss of vision due to other causes.

Retinopathy in two eyes deemed to marked asymmetry i.e. >1 level in ETDRS chart.

Glaucoma, ocular hypertension and other ocular disorders.

Patient who underwent any other treatment viz. surgery, laser, IVT injections for DR.

Any deviation from peroperative and postoperative treatment protocol.

Any complication during surgery including vitreous loss or posterior capsule rupture.

Sample Size:
A minimum of 60 eyes of 60 diabetic patients with diagnosis of cataract with or without diabetic retinopathy, and without CSME were included in the study.

Study design:

Prospective interventional case series.

Statistical analysis was done by chi square and Fisher's exact test.

Study Parameters:
1) The main outcome measure was the change in status of DR

2) Change in CMT as measured by HR OCT in subsequent follow up.

3) Scores for ETDRS visual acuity as recorded at every follow up.

Preoperative examination
A detail medical and ocular history was taken before cataract surgery. This included questions on diabetes treatment, use of antihypertensive medication, and duration of diabetes.

A baseline data including BP measurement, HbA1C level, serum urea and creatinine and lipid profile were recorded. Ocular examination included best corrected visual acuity(BCVA) using ETDRS charts, applanation tonometry, slit-lamp examination, lens status evaluation ,dilated fundus examination with indirect ophthalmoscope and slit-lamp biomicroscopy of the posterior pole with +90 D lens. Where the view of the retina was obscured by the lens opacity the preoperative retinopathy and maculopathy status was assumed to be that recorded on the first postoperative day.

Colour fundus photographs were taken at an angle of 50° with a Topcon TRC-50 VT fundus camera (Tokyo Optical Co Ltd, Japan).The photographs covered fields 1-3 of the 7 standard fields, with stereo pairs of the macula (field 2). When retinopathy had been detected, photographs included at least two additional fields.

Patients were examined at baseline with Spectralis HRA2+OCT, Heidelberg Engineering, Heidelberg, Germany. Software version 1.7.0.0. Infrared OCT was done with Preset Retina and Fast macular scan was done with 16 ART frames of 20°×20° area around macula with 512 A-scan.

We used the term *macular edema* to describe an increase in center point thickness on OCT after cataract surgery in our diabetic cohort. An increase in center point thickness on OCT after OCT scans were performed and the quality of the OCT image assessed as adequate or inadequate. The maximal retinal thickness (in micrometers) was measured at the center point of the fovea and in the perifoveal zone by manually placing computerized callipers at the vitreous–retina and retina–retinal pigment epithelium interfaces.

A patient's DR was graded using the ETDRS grading system. Clinically significant macular edema (CSME) was defined according to ETDRS criteria .Patients were advised to administermoxifloxacin (0.5%) eye drop 4 times a day from 3 days prior to surgery.

Operative Procedure
At the day of operation after antiseptic dressing and draping the patients under study group underwent small incision cataract surgery by a single experienced surgeon. Surgery was done under peribulbar block with lignocaine adrenaline injection. Small Incision technique consisted of self sealed scleral tunnel of 6 mm length fashioned in three steps, a large continuous curvilinear capsulorrhexis, and in-the-bag implantation of a single-piece polymethyl methacrylate lens was used. Patients who had posterior capsule rupture during surgery were not included into the study.

Post operative follow up
All patients were examined postoperatively at day 1, and then re-examined at 1, 3, 6 months after surgery. At each visit review the ETDRS visual acuity and the retinopathy and maculopathy status in both eyes was recorded. Further follow up was arranged as clinical need indicated. All patients who developed either new or recurrent macular oedema within 3 months of surgery (asdefined as retinal thickening evident with macular contact lens examination), underwent fluorescein angiography. The macular oedema was classified as pseudophakic cystoid macular oedema if the fluorescein angiogram revealed a typical petaloid pattern of foveal hyperfluorescence. Patients whose HR OCT revealed a more than 30% increase in their central macular thickness(CMT) were classified as new/recurrent macular edema (ME). Regardless of the presumed aetiology of the postoperative macular oedema all eyes were treated with

medical therapy alone for 6 months (topical and/or regional steroids). Persisting ME after 6 months was then treated with either focal or grid laser photocoagulation treatment as defined by the ETDRS. Any patient who developed CSME more than 6 months after surgery was considered to have new/recurrent diabetic maculopathy and was therefore treated with laser photocoagulation as in the ETDRS[9] guidelines as soon as was practically possible. Any patient whose lens opacity precluded adequate fundus examination preoperatively and was subsequently found to have macular oedema with associated exudates at the day 1 postoperative examination was assumed, for the purposes of data collection and analysis, to have had CSMO at the time of surgery. Such patients were treated with either focal or grid laser photocoagulation treatment as defined by the ETDRS as soon was practically possible.

RESULTS :

The progression of DR was statistically more significant in DR group compared to no DR group.

Figure 1 about here:Status Of Retinopathy Of Individual Patients At Pre-Operative State(In Numbers)

Furthermore progression of DR occurred in 11 (18.3%) cases out of 60 cases. Out of 11, 4 (36%) cases were from NO DR group and 7 cases (64%) were from DR group.

Table 1 shows PROGRESSION OF DR (number of eyes)

Eighty four percent(27 out of 32) cases achieved ≥ 40 letters improvement in NO DR group compared to only 54%(15 out of 28) cases who achieved the same in DR group .Chi square test was performed between the DR and NO DR group and P=0.01 which was obtained statistically significant.

Table 2 shows theVA (As Per Etdrs Chart) After Sics In Relation To Dr (Number Of Eyes With Percentage).

ME appeared in 11 cases out of which 6 in mild DR group and 10 in moderate DR group and no one in no DR group. Chi square test was done between no DR and DR group and data was found to be significant.

P value- 0.009

Chi square – 11.096

Out of 11 cases of ME which appeared after 1 month of cataract surgery, only 3 cases persist after 6 month and 8 cases of ME resolved.

Table 3 shows postoperative incidence of me computed by hr oct in relation to preoperative status of DR.

The incidence of ME in non progressive group of DR is 12 % (6 out of 49) where as in progressive group of DR incidence of ME is 45% (5 out of 11). A Fisher's exact test was performed .The data was found to be significant with p value 0.02

Table 4 shows Postoperative course of DR and onset of ME in relation to the preoperative status of DR

Table 5 shows comparision of VA in diabetic eyes with and without ME after SICS

Above table shows that ≥ 40 letters improvement occurred in 39 out of 49 cases i.e. in 79.5 % of cases of without ME group whereas only 3 cases out of 11 i.e. 27.2% of cases achieved the same in the ME group. It also indicates that final outcome in terms of visual acuity also depends upon status of ME along with DR.

A fisher's exact test was performed in which two groups were created. In no DME group 39 cases achieved ≥ 40 letters visual acuity and 10 ≤ 39 letters. In ME group 3 cases achieved ≥ 40 letters visual acuity and 8, ≤ 39 letters.

The data was found to be significant with p value – 0.001.

DISCUSSION :

Though there is no previous study following SICS in diabetic patients, the DR progression rate of 18% (Figure:2) in our study is consistent with previously reported progression rates ranging from 21% to 25%[14,15,16] 12 months after cataract surgery or 25%[17] 6 months after surgery.

The reported rate of DR progression after cataract surgery in a cohort of patients similar to our own ranges from15% to 43%[5,18,19,20,21]. The rate of retinopathy progression that we report is therefore consistent with existing published data.progression after SICS was more evident particularly in patients with pre-existing diabetic retinopathy (64% of eyes with DR compared to 36% eyes of with No-DR) with a statistically significant rate of occurrence ($p < 0.05$) (Figure 5) which corroborates with Pollock et al[8]

Eighty four percent (27/32 eyes) of cases of post operative no DR group achieved ≥ 40 letter improvement compared to 53% (15/28 eyes) of DR group achieving the same.

Incidence of macular edema in our study appeared significantly in preoperative DR (all 11 cases of incidence) group compared to No-DR (0 cases)

This clearly shows that preoperative diabetic retinopathy status of cases was a contributing factor for development of DME postoperatively.

79.5% of cases achieved ≥ 40 letters improvement (ETDRS) in cases without ME whereas only 27.2% of cases achieved the same in ME group and the data was found to be significant. Pollock et al[22] also reported that in eyes that developed clinical CME the visual acuity outcome was less favourable, especially in the sub group with pre-existing DR where 75% of patients achieved vision of only 6/15 to 6/30.

This study suggest that outcome of SICS in terms of visual acuity is also significantly influenced by association of ME along with DR. It also showed that visual outcome following cataract surgery was especially poor in patients who showed postoperative progression.Thus, in the presence of significant DR, postoperative VA may be suboptimal and the results of surgery may be disappointing.

STATUS OF RETINOPATHY OF INDIVIDUAL PATIENTS AT PRE-OPERATIVE STATE (IN NUMBERS) :(FIG 1)

Table 1 :PROGRESSION OF DR (number of eyes)

NO DR		POST OP DR				Total
		MILD NPDR	MOD NPDR	PDR		
PRE OP DR	NO DR	32(53)	3(5)	1(1.6)	0	36(59.6)
	MILD NPDR	0	8(13.3)	6(10)	0	14(23.3)
	MOD NPDR	0	0	9(15)	1(1.6)	10(16.6)
Total		32(53)	11(18.3)	16(26.6)	1(1.6)	60

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Table 2 shows theVA (AS PER ETDRS CHART) AFTER SICS IN RELATION TO DR (NUMBER OF EYES WITH PERCENTAGE).

COUNT NO DR		POST OP DR				Total
		MILD NPDR	MOD NPDR	PDR		
POST OP VA	≥40	27(45)	9(15)	6(10)	0	42(70)
	21-39	4(6.66)	2(3.33)	6(10)	0	12(20)
	≤20	1(1.66)	0	4(6.66)	1(1.66)	6(10)
Total		32	11	16	1	60

Table 3 shows POSTOPERATIVE INCIDENCE OF ME COMPUTED BY HR OCT IN RELATION TO PREOPERATIVE STATUS OF DR.

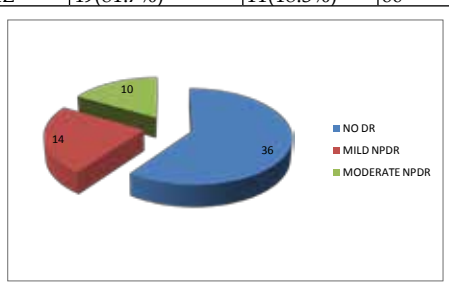
PRE OPERATIVE STATUS OF DR	ME APPEARED AFTER 1 MONTH	ME PERSISTING AFTER 6 MONTHS
NO DR(36)	**0**	**0**
MILD DR(14)	**6**	**1**
MOD DR (10)	**5**	**2**

Table 4 shows POSTOPERATIVE COURSE OF DR AND ONSET OF ME IN RELATION TO THE PREOPERATIVE STATUS OF DR

	NO CHANGE OF DR		CHANGE OF DR	
PREOPERATIVE DIABETIC STATUS	WITHOUT ME	WITH ME	WITHOUT ME	WITH ME
NO DR (n = 36)	31(86%)	1(2.7%)	4(11%)	0(0%)
DR (n = 24)	12(50%)	5(20.83%)	2(8.3%)	5(20.83%)
TOTAL (n = 60)	43(71.67%)	6(10%)	6(6.67%)	5(8.33%)

Table 5 shows COMPARISION OF VA IN DIABETIC EYES WITH AND WITHOUT ME AFTER SICS

	WITHOUT ME	WITH ME	TOTAL
≥ 40	39(65%)	3(5%)	42(70%)
21 – 39	8(13.3%)	4(6.7%)	12(20%)
≤ 20	2(3.3%)	4(6.7%)	6(10%)
TOTAL	49(81.7%)	11(18.3%)	60



STATUS OF RETINOPATHY OF INDIVIDUAL PATIENTS AT PRE-OPERATIVE STATE (IN NUMBERS) :(FIG 1)

Table 1 :PROGRESSION OF DR (number of eyes)

		POST OP DR				Total
		NO DR	MILD NPDR	MOD NPDR	PDR	
PRE OP DR	NO DR	32(53)	3(5)	1(1.6)	0	36(59.6)
	MILD NPDR	0	8(13.3)	6(10)	0	14(23.3)

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