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To study correlation of HbA1c and macular thickness changes in diabetic patients after phacoemulsification and small incision cataract surgery (SICS)

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ABSTRACT

Purpose: To study the relationship between HbA1c and macular thickness using Optical coherence tomography (OCT) in phacoemulsification and SICS.
Materials and Methods: Retrospective study where 100 eyes of type 2 Diabetes mellitus patients with mild to moderate Non-Proliferative Diabetic Retinopathy (NPDR) were included. 50 PATIENTS underwent uncomplicated phacoemulsification surgery AND REST 50 FOR SICS and were divided into 3 groups based on HbA1c levels – Group 1: <6.5%, Group 2: 6.5%–8% and group 3: >8%. Nine macular subfields as defined by Early Treatment of Diabetic Retinopathy study (ETDRS) were measured using OCT. The HbA1c level of each patient was measured and compared with the macular thickness as well as visual acuity.
Result: The macular thickness was found to be significantly higher postoperatively in SICS group (251.54 $\pm$ 22.69 μm) than the PHACO group (230.44 $\pm$ 26.47 μm) on post-operative day 7 and it further increased to (267.46 $\pm$ 43.44 μm) in SICS group as compared to phaco group (244.50 $\pm$ 37.30 μm)on postoperative 1 month in group C. CMT was highest if HbA1C levels were more than 8% as compared to other two groups on all post-operative day.
No significant difference was found in BCVA between both the groups on 1 month and 3 months post-operatively.
Conclusion: This study shows that cataract surgery increases the macular thickness and these increases are significantly higher in the SICS than in PHACO eyes on the POD 7, 1 month and 3 months after surgery, especially if HbA1c levels are more than 6.5%, which resolves to near normal levels in phaco group by POD 3 months. This indicates that phacoemulsification is more preferable surgery then SICS in adults with regard to postoperative increase in macular thickness. Also good control of HbA1c levels significantly decreases post-operative visual problems.

1. Introduction

Diabetes mellitus (DM) is well-known for causing multiple organ damage and life-threatening outcomes due to abnormal small vessel formation. Diabetic retinopathy (DR) is one of the manifestations of chronic diabetes causing leakage and neovascularization.[1] Since many decades, the diagnos is of DM is based on either fasting plasma glucose levels or 2 hours postprandial glucose levels. It was only in 2010 that plasma glycosylated haemoglobin or HbA1c $\geq$ 6.5% was accepted by the American Diabetes Association as cut-off for DM an this modality helps to evaluate the glycosylated Hb over the past 3 months. It is now proved that HbA1c levels are better predicators of DR than any other routinely employed tests. DR can manifest in multiple forms as retinal haemorrhages, ischemia, neovascularization, and macular edema especially with poorly controlled HbA1c levels and long standing DM.[2] Out of these, macular edema is the most important predictor of poor visual outcome in diabetics, particularly

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after cataract surgery.[3] It shows a higher incidence of macular edema (DME) which can either be ascribed to new vessel formation or immediate post- operative inflammation.[4]Optical coherence tomography (OCT) is a easy, quick, non-invasive tool that is immensely useful to an ophthalmologist to evaluate neovascularisation and assess the status of the macula. The central macular thickness(CMT) or foveal thickness is used to measure macular edema in DR and DME being the most common cause for sub-optimal visual outcome after routinely performed lens surgeries.[5] This research focuses on the influence of HbA1c levels on foveal thickness pre and post uncomplicated phacoemulsification and SICS surgeries.

2. Materials and Methods

This was a retrospective study conducted in the Ophthalmology department of Dhiraj Hospital, Vadodara. A total of 100 patients with type 2 DM were enrolled with us, out of which 50 patients underwent uncomplicated phacoemulsification with acrylic hydrophilic foldable IOL implantation and rest 50 underwent uncomplicated SICS with rigid PMMA IOL implantation . All the surgeries were performed by a single surgeon with uniform pre and postoperative protocol. All the participants gave informed consent before the study. The study also adhered to the tenets of the Declaration of Helsinki. The study was reviewed and approved by the institutional Ethics Committee of our hospital.

Patients known to have type II diabetes with mild to moderate Non-Proliferative Diabetic Retinopathy (NPDR), without pre-existing macular edema (on OCT, macular thickness of $<$280 microns) and co-existing senile cataract with nuclear sclerosis grade II to IV were included in our study. None had a history of the previous laser or intravitreal injections. The patients were subdivided into 3 groups based on their HbA1c levels as follows: Group 1 - HbA1c $<$6.5 %, Group 2-6.5 to 8% and Group 3 : $>$8%. The fasting blood sugar levels (FBS) and postprandial blood sugar(PPBS) levels were also measured pre and post-operatively in all patients who were already on diabetic treatment.

A complete ophthalmic workup including visual assessment using Snellen's chart(best corrected visual acuity) which was then converted to LogMAR for analysis, slit-lamp examination and tonometry were also done. The cataract grading was based on the LOCS III classification. Diabetic retinopathy evaluation was done by viewing dilated posterior segment, both pre and postoperatively on day 1, day 7, 1 month and 3 months. Optical Coherence Tomography (Topcon 3D OCT 1000) was also done preoperatively & postoperatively to measure foveal thickness by ETDRS grid. Three-dimensional macular thickness map analysis program was used to measure retinal thickness values in the fovea, parafoveal and perifoveal areas. Parafoveal areas were defined as the area between central 1-mm circle and the surrounding circle with 3-mm diameter (i.e. area between 1- and 3- mm diameters) in four equal quadrants (i.e. superior, inferior, temporal, and nasal), while perifoveal areas were defined as the area between parafoveal and surrounding circle of 2 mm width. OCT analysis of each map was done to find cystic spaces or diffuse retinal thickening.

Group 1- Phacoemulsification through a standard 2.8 mm of limbal incision was done and foldable PCIOL was implanted in 50 eyes . We used Catarhex easy machine by Oertli for phacoemulsification . The average phaco power was between 50%-60% and absolute phaco time was 15 .9 $\pm$ 7 seconds while the entire procedure took 14.5$\pm$ 5.5 minutes.

Group 2- Manual SICS was done through a 5.5 to 6.5 mm incision with sclerocorneal tunnel and PMMA PCIOL was implanted in 50 eyes. The average SICS time was 12.7$\pm$ 6.5 minutes.

All the surgeries were uneventful and same post-operative medications were used in both the groups after surgery. (steroid-antibiotic combination eyedrops were used 4 times a day for one week followed by 3,2,1 weekly tapering in operated eye).

2.1. Statistical analysis

All the results are expressed as the number, percentage and mean $\pm$ standard deviation(SD). Average Central Macular Thickness (CMT) between the two groups (phaco and SICS) was calculated and tabulated. Data was statistically analysed using Student's t-test. P-value $<$0.05 was considered as significant level. SPSS 2.0 was used for post hoc statistical analysis.

3. Results

Our study included 100 eyes of 100 patients, 50 underwent SICS and 50 patients underwent phacoemulsification procedure. Out of them, 33 patients belonged to group 1, 34 belonged to group 2 and 33 belonged to group 3 (Table 1). Intergroup variation in preoperative macular thickness was found to be statistically insignificant between SICS and PHACO groups.

A higher value of foveal thickness was observed in the SICS group than PHACO group during follow up. The highest and significant difference in macular thickness was found in group C on day 7 (251.54$\pm$22.68 μm, p =0.015), 1 month(267.46$\pm$43.44 μm, p=0.031) and 3 months (260.75$\pm$48.44 μm, p=0.002) postoperatively in SICS patients. The foveal thickness resolved to near normal in the group A, but group B and C respectively showed a significant (p =0.005) difference during the final follow up on 3 months follow up, with a value of 240.72 $\pm$ 65.81 μm and 237.19 $\pm$ 40.70 μm in group B and C for PHACO patients and a 251.50 $\pm$ 59.36 μm and 260.75 $\pm$ 48.44 μm in SICS. (Table **??**).

Table 1: Demographics and Preoperative information of all subjects

Parameters		Group 1 (<6.5)	Group 2 (6.5 – 8)	Group 3 (>8)	P
BCVA (LogMAR)	Phaco	0.75±0.420	0.82±0.34	0.84±0.39	0.002
	Sics	0.83±0.753	0.73±0.23	0.93±0.77	0.048
Age (year)	Phaco	55.06±9.77	54.13±4.23	62.67±8.33	NS
	Sics	57.39±10.54	60.56±6.44	68.93±11.35	NS
Gender (Male/Female)	Phaco	7/9	8/9	8/9	NS
	Sics	8/9	9/8	10/6	NS
CMTμm (±SD)(Preop)	Phaco	193.00±31.11μ	220.50±49.32μ	225.19±23.77μ	0.554
	Sics	188.00±35.76	232.43±41.68	235.98±25.45	0.498
HbA1c (mean±SD)	Phaco	4.92±1.58	7.41±1.45	9.84±1.23	0.001
	Sics	5.03±1.88	7.73±1.23	9.43±1.08	0.028

Thus, glycemic index plays an important role in predicting the macular thickness post-operatively especially in patients undergoing SICS while phaco group showed return of macular thickness to baseline by 3 months. (Table 2).

There was no statistically notable difference in pre and postoperative BCVA for all three groups. On post-operative 3 month, BCVA was comparible between SICS and phaco patients (p=0.322, p=0.441, p=0.284 respectively) and there appears to be no association between the best corrected visual acuity (BCVA) and different levels of HbA1c. (Table 3)

4. Discussion

Most of the cataract surgeries are associated with post-operative inflammation due to disruption of the blood-retina barrier (BRB) which leads to increased capillary permeability from the perifoveal network and fluid accumulation within retina, both intra and extracellular. One of the oldest and most commonly performed cataract procedure-Small Incision Cataract Surgery (SICS) has a larger incision, higher chances of damage to iris, and increased intra-operative tissue manipulation thereby, higher chances of inflammation. A newer modality of treatment-Phacoemulsification is a closed chamber surgery, causes lesser damage to ocular structures and anterior chamber reaction when done well. However, there is no evidence as to the significance of HbA1C control on the macular thickness of diabetic patients following cataract surgery.

Rostos et al in their review study suggested that when diabetic patients undergo cataract surgery, it might accelerate pre-existing diabetic macular oedema leading to poor visual outcome.[6,7] Some other researchers have also suggested that even in the absence of pre-existing DME, diabetic patients tend to have a higher propensity of developing DME after uncomplicated cataract surgery.[8]

Analysis done over the years between PHACO and SICS procedures showed that the macular thickness was higher in SICS group. Many authors showed significant difference in macular thickness between PHACO and SICS group on 3^{rd} day, 7^{th} day, 3^{rd} month and 6 months post-operative follow ups.[9] A study done by Dr. Indranil Roy et al on total 224 patients who were randomised to two groups- phaco and SICS, found mean central foveal thickness in SICS group was more than that of phaco group on post-op 1^{st}, 7^{th}, 42^{nd} and 180^{th} day. On day 180, mean central foveal thickness in SICS group was significantly (p=0.032) more than phaco group.[10] Another study conducted by Dr. Dimpy et al on 100 eyes undergoing manual SICS showed that macular thickness was comparable preop and day 1 postop, while CMT increased in all patients at 4 weeks and 8 weeks and returned to near baseline values in most of the patients by 12 weeks.[11]

CME is the accepted as one of the frequent causes for suboptimal visual outcome after cataract surgeries and constitutes the most common cause of un predicted vision loss after many ocular procedures according to a research by Ray and D 'Amico et al in 2002.[5] Loewenstein and Zur et al (2010) reported a rate of clinical CME as 0.1-2.35% following modern cataract extraction procedures.[12]

Our study found a significant increase in CMT in SICS group as compared to phacoemulsification on postoperative day 7(p=0.015), 1 month (p=0.031) and 3 months (p=0.002) in group C. An increase in macular thickness was also noted in group B(p=0.043) on POD 7 which returned to near normal values by 1 month and showed no significant difference (p= 0.427). Also group A showed no significant change in CMT on all post-operative days due to their well-controlled sugar levels, and only a non-significant difference was noted between SICS and phaco groups on POD 7 and 1 month. This indicated a strong correlation between poorly controlled HbA1C levels, causing significant visual morbidity postoperatively.

A similar correlation of HbA1c and postoperative macular edema in eyes with diabetic retinopathy was noted after phacoemulsification and SICS for as long as 12 months.[13] Progression of DR can be slowed down with judicious use of medications for controlling blood glucose

Table 2: Comparision of foveal thickness in each group pre and postop

HbA1c	Group Code		Mean	SD	p value
<6.5 (N=16)	Baseline	Phaco	193.00	31.113	P = 0.422
		Sics	201.50	28.515	
	POD 1	Phaco	210.00	49.497	P = 0.126
		Sics	221.73	35.465	
	POD 7	Phaco	205.50	30.406	P = 0.056
		Sics	219.00	39.465	
	POD 1 MONTH	Phaco	212.50	19.092	P = 0.040
		Sics	226.00	16.433	
	POD 3 MONTHS	Phaco	195.00	33.941	P = 0.067
		Sics	211.00	37.476	
6.5 – 8 (N=18)	Baseline	Phaco	220.50	49.320	P = 0.353
		Sics	232.60	44.213	
	POD 1	Phaco	240.39	57.998	P = 0.027
		Sics	252.86	53.826	
	POD 7	Phaco	243.83	51.903	P = 0.043
		Sics	257.86	58.623	
	POD 1 MONTH	Phaco	260.83	72.989	P = 0.427
		Sics	264.65	66.167	
	POD 3 MONTHS	Phaco	240.72	65.806	P = 0.028
		Sics	251.50	59.367	
>8 (N=16)	Baseline	Phaco	225.19	23.772	P = 0.546
		Sics	223.64	27.578	
	POD 1	Phaco	226.13	28.714	P = 0.044
		Sics	238.63	24.578	
	POD 7	Phaco	230.44	26.470	P = 0.002
		Sics	251.54	22.687	
	POD 1 MONTH	Phaco	244.50	37.299	P = 0.003
		Sics	267.46	43.443	
	POD 3 MONTHS	Phaco	237.19	40.696	P = 0.002
		Sics	260.75	48.443	

levels and hyperlipidaemia according to the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Eye Study.[14] The Wisconsin Epidemiology Study of Diabetic Retinopathy (WESDR)[15] showed that poorly controlled HbA1c levels with higher fluctuations in blood glucose levels increased the incidence of DM E over a 10-year period (Klein et al. 1995) . The Diabetes Control and Complication trial (DCCT)[16] and the UK Prospective Diabetic Study (UKPDS),[17] both of which were prospective randomized studies, showed that intensive glycaemic control and reduction of HbA1c levels are associated with a decrease in the rates of development as well as progression of diabetic retinopathy (DR) and DM E. OCT was utilized for more precise qualitative and quantitative assessment of macular thickness pre- and postoperatively.

In our study, the visual acuity did not deteriorate even if the macular thickness increased at 1 month postoperatively because removal of cataract caused significant clarity in visual axis of patient. Good visual acuity persisted even at 3 months postoperatively in both SICS and phaco group. According to Eriksson et al, changes in macula occurring post-operatively is only transient in the short-term (6 weeks), even if patient has DR , and final visual outcome is non-inferior.[14] Therefore, diabetic patients may not show significant difference from the nondiabetic patients when we evaluate the short- term post-cataract surgery visual recovery. A reduction of HbA1c levels from 7.9% to 7.0% in type 2 diabetes resulted in reduction in the frequency of laser treatments needed.[17] In type 1 patients, a reduction of HbA1c values from 9.1% to 7.1% and improved blood glucose control reduced the risk of developing DR by 76% within 6.5 years, the risk of DR progression by 54%, and the risk of developing proliferative diabetic retinopathy (PDR) by 47%.[18] Therefore, an optimal level of less than or equal to 7% HbA1c levels should be aimed for an individual patient, from an ophthalmologist's point of view.[19] DCCT mentions the risk of developing CSME to be 23% for those patients who are on long term insulin treatments. The incidence of pseudopakic cystoid macular edema rang es from 1%–30% depending on the risk factors defined for an individual, but the incidence remains on a higher side for diabetics. Unsal et al[20] observed that the mean

Table 3: Comparison of BCVA in each group

HbA1c	Group Code		Mean LogMAR	SD	p value
<6.5 (N=16)	Baseline	Phaco	0.75	0.420	P = 0.089
		Sics	0.67	0.120	
	POD 1	Phaco	0.22	0.140	P = 0.438
		Sics	0.27	0.180	
	POD 7	Phaco	0.15	0.100	P = 0.485
		Sics	0.18	0.060	
	POD 1 MONTH	Phaco	0.12	0.800	P = 0.067
		Sics	0.18	0.140	
	POD 3 MONTHS	Phaco	0.10	0.008	P = 0.322
		Sics	0.16	0.160	
6.5 – 8 (N=18)	Baseline	Phaco	0.82	0.340	P = 0.497
		Sics	0.80	0.360	
	POD 1	Phaco	0.23	0.170	P = 0.362
		Sics	0.20	0.070	
	POD 7	Phaco	0.19	0.110	P = 0.495
		Sics	0.16	0.270	
	POD 1 MONTH	Phaco	0.1	0.090	P = 0.442
		Sics	0.13	0.110	
	POD 3 MONTHS	Phaco	0.06	0.080	P = 0.441
		Sics	0.09	0.060	
>8 (N=16)	Baseline	Phaco	0.84	0.390	P = 0.262
		Sics	0.76	0.040	
	POD 1	Phaco	0.21	0.140	P = 0.354
		Sics	0.16	0.160	
	POD 7	Phaco	0.19	0.100	P = 0.120
		Sics	0.14	0.090	
	POD 1 MONTH	Phaco	0.11	0.060	P = 0.234
		Sics	0.09	0.040	
	POD 3 MONTHS	Phaco	0.09	0.020	P = 0.284
		Sics	0.08	0.030	

CMT (371 μm) in eyes with DME was significantly higher than the eyes with PDR (256 μm) and Non-Proliferative Diabetic Retinopathy (NPDR) (253 μm). Another study in contrast to our research states that no correlation exists between HbA1c levels and CMT in patients undergoing phacoemulsification.[21] The limitations of this study include shorter duration of follow-up (3 months), small sample size and duration of diabetes.

5. Conclusion

In this study, we found a correlation between HbA1c levels and macular thickness in diabetics undergoing phacoemulsification and SICS. A large number of patients undergoing SICS and belonging to group C showed a significant increase in central foveal thickness, beginning from 1st postoperative day till 3 months, but phacoemulsification group showed only slight increase in foveal thickness on postoperative 1 month which returned to near baseline levels by 3 months post-operatively. This indicates phacoemulsification procedure as an excellent choice for cataract removal in diabetics, thus avoiding unwanted complications. However, HbA1c levels had no correlation with the final outcome in BCVA in our study.

6. Source of Funding

None.

7. Conflict of Interest

None.

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