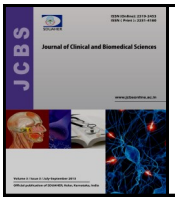

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Clinical Investigation

Foveal and Parafoveal Retinal Thickness in Healthy Pregnant Rural North Indian Women

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Abstract

Background: Fluid accumulation during pregnancy may affect the retinal thickness. With increasing use of Spectral Domain Optical Coherence Tomography (SD-OCT), it is imperative to establish a normative database of retinal and choroidal thickness in all trimesters of pregnancy and in healthy non-pregnant women to reliably detect early abnormalities. **Objectives**: To determine the foveal and parafoveal retinal thickness in healthy pregnant rural north Indian women. **Materials and Methods**: This cross-sectional study included healthy, rural, north Indian women in the age group of 18-30 years. Group 1 consisted of 20 eyes of 20 pregnant women in the first trimester; Group 2 consisted of 20 eyes of 20 pregnant women in the second trimester; Group 3 consisted of 20 eyes of 20 pregnant women in the third trimester; and Group 4 (control group) consisted of 20 eyes of 20 non-pregnant women. The macula map analysis protocol of Nidek RS 3000 Lite SD OCT was selected for analysis of retinal thickness. By default, data from the right eye was used in all subjects. The differences between the groups were analysed utilizing one way ANOVA using Post–Hoc Bonferroni correction and $p < 0.05$ was considered statistically significant. **Results:** A statistically significant difference for foveal thickness was found among the Group 1–3 ($P< 0.001$) and Group 3-4 ($P< 0.0001$). A statistically significant difference in the parafoveal region was found only in superior inner macula (SIM) region between Groups 2-3 ($P< 0.03$), 3-4 ($P< 0.01$). **Conclusions**: Pregnancy affects the retinal thickness and especially in the third trimester.

Key-words: Pregnancy, foveal thickness, parafoveal thickness, optical coherence tomography.

Introduction

Pregnancy results in many hormonal, metabolic, hematologic, vascular and immunological changes.[1] The ocular system is also affected by physiologic changes in pressure, corneal sensitivity, increased corneal thickness and visual function.[2]

Some pathologic conditions reported to develop in pregnancy include central serous chorioretinopathy (CSR), hypertensive and vascular disorders and uveal melanoma. Pregnancy also affects pre-existing ocular conditions such as diabetic retinopathy, tumors, and immunological disorders.[3] CSR has also been reported in the third trimester in healthy pregnant women.[4] It is well known that there is accumulation of 4–6 litres of fluid in the intra- and extracellular areas over the course of normal pregnancy in healthy women.[5] This may also affect the retina which may reflect in an increase in both total macular volume (TMV) and foveal thickness (FT).[6] An increase in retinal thickness due to fluid accumulation is found in many ocular disorders such as diabetic retinopathy, age-related macular degeneration, CSR and retinal vein occlusion.[7] Assessment of the macular region is also an important parameter for staging and monitoring of glaucoma.[8] Subtle changes in macular thickness can be difficult to appreciate on traditional investigations, such as fundus photography, slit lamp bio-microscopy and fluorescein angiography (FA).[9]

OCT is a new, non-invasive, noncontact, transpupillary imaging technology that can image retinal structures in vivo. OCT uses low coherence interferometry of light to obtain cross-sectional

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images of the retina using the optical backscattering of light off different structures of the eye to form images. This is similar to the use of acoustic waves in B-scan ultrasonography.[10] This technology makes it possible to reliably appreciate refined details of the posterior segment of the eye and quantify them on a micron scale.[11-13] OCT Technology has improved considerably since its advent, with increase in the resolution of images and higher acquisition speed. Standard OCT systems such as Stratus OCT, uses time-domain detection, achieving scan rates of 400 A-scans per second and an axial resolution of 8–10 μm. More recently, Spectral/Fourier domain OCT (SD-OCT) systems provide higher sensitivity, much higher speed of acquisition (greater than 20,000 A-scans per second) and better resolution (5–7 μm), thus making it possible to acquire large, volumetric data sets in a relatively much shorter time frame.[11] OCT is now used routinely in ophthalmology to investigate the retina for diagnosis, inspection, or follow-up of treatment processes.

Studies have reported significant differences in macular thickness amongst subjects of different race,[14] gender,[15,16] and age. [17] These demographic variations may be important parameters when comparing macular thickness measurements and diagnosing ocular diseases. Only a few studies have been conducted to determine changes in retino-choroidal thickness during pregnancy.[5-6] [18-19] Increase in retinal thickness during pregnancy may have diagnostic and prognostic significance as it has been suggested that a positive correlation may exist between increased central retinal thickness and increasing proteinuria in patients with pre-eclampsia. Another study has found that the choroidal thickness as measured on SD-OCT in pre-eclamptic women is significantly thinner as compared to choroidal thickness in healthy pregnant women, probably due to vasospasm. [18] OCT provides a reliable non-invasive method of obtaining information reflecting the relationship between the retina, subretinal space, and retinal pigment during pregnancy.[20] Enhanced depth imaging (EDI) OCT images makes it possible to measure the choroidal thickness by manually measuring from the outer border of the hyper-r reflective line corresponding to the retinal pigment epithelium to the inner surface of the sclera.[18] These features of OCT technology may prove useful in the early detection of adverse vascular events compromising an optimal pregnancy course.

With increasing use of SD-OCT, it is imperative to establish a normative database of retinal and choroidal thickness in all trimesters during pregnancy and in healthy non-pregnant women to reliably detect early abnormalities, with due consideration to age based and demographic differences. This study aims to provide normative data of the retinal thickness in healthy pregnant rural north Indian women in a defined narrow age group.

Materials and Methods

Study population: This study included 60 healthy pregnant women (60 eyes) and 20 healthy non-pregnant women (20 eyes) who served as a control group. Group 1 consisted of 20 eyes of 20 healthy women in the first trimester; Group 2 consisted of 20 eyes of 20 healthy women in the second trimester; Group 3 consisted of 20 eyes of 20 healthy women in the third trimester; and Group 4 (control group) consisted of 20 eyes of 20 healthy non-pregnant women. All the participants were enrolled from a single medical college hospital located in a rural part of north India. The research adhered to tenets of the Declaration of Helsinki for research involving human subjects. The study protocol was approved by the Institutional Ethics Committee and informed consent from all the participants was taken. All healthy pregnant rural women were recruited from the Department of Gynaecology and Obstetrics and healthy rural non-pregnant patients were selected from women reporting to Department of Ophthalmology for minor anterior segment ailments such as chalazion, mild allergic conjunctivitis, blepharitis and meibomitis.

Procedures: All candidates underwent comprehensive ophthalmic evaluation including refraction, best corrected visual acuity (BCVA), applanation tonometry by Goldmann applanation tonometer, anterior segment slit-lamp biomicroscopy and fundus evaluation with direct and indirect ophathalmoscopy after full dilatation. OCT testing was performed using the Nidek RS-3000 Lite (Software version NAVIS EX 1.1.0.0; Nidek Co. Ltd, Gamagori, Japan) after mydriasis with 1% tropicamide drops. All testing was carried out by the same operator on all subjects. By default, data from the right eye was used in all subjects.

Inclusion criteria: The study group included healthy pregnant women in first, second and third trimester between 18 to 30 years of age while the control group included healthy non-pregnant women in a comparable age group. Common inclusion criteria for all groups included best corrected visual acuity (BCVA) 20/20 (Snellen).

Exclusion Criteria: Women with refractive errors higher than - 0.50 or ± 0.50, having systemic diseases such as diabetes mellitus and hypertension, ocu-

lar diseases such as glaucoma, uveitis, retinopathy, amblyopia or history of laser therapy and trauma or intraocular surgical intervention.

All subjects were scanned using the commercially available SD-OCT , Nidek RS 3000 Lite. This instrument is a SD-OCT utilizing OCT phase fundus method to image the surface of the fundus instead of scanning laser ophthalmoscope (SLO). It has a resolution of 20 μm in the horizontal direction (X-Y) and 7 μm in depth direction (Z) .The scan speed is max 53000 A scans/second with an acquisition time of 1.6 seconds. The B scan sampling rate is 256.The macula map analysis protocol was selected on the Nidek RS 3000 Lite SD OCT. Macula is divided into 9 regions with 3 concentric rings measuring 1 mm (innermost ring), 3 mm (inner ring) and 6 mm in diameter (outer ring) centered on the fovea. The innermost 1 mm ring is the fovea while the 3 mm inner ring (parafoveal region) and 6 mm outer ring (perifoveal region) are further divided into four equal regions (Fig. 1)

OCT identifies the layers of the retina and determines macular thickness by measuring the distance between the inner limiting membrane (ILM) and the inner boundary of retinal pigment epithelium (RPE) in each of the 9 regions. It reconstructs a false-color topographic image displayed with numeric averages of thickness measurements for each of the 9 map regions within a 6×6 mm area centered on the fovea. Quality of the scan is indicated by a color scale, which has to be in the green range to be considered a good quality scan. Three measurements were taken from the retina and the average of three measurements was used. Retinal thickness was analysed for the fovea (central 1 mm) and the parafovea (1-3 mm diameter ring). In addition, retinal thickness for the perifoveal region (3-6 mm ring) was also analysed.

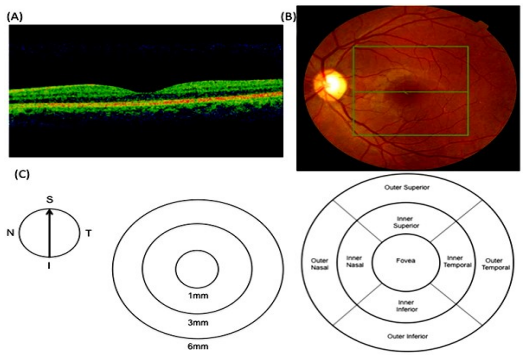
Statistical Analysis

The data obtained in the study is presented as mean ± SD. The differences between the groups is analysed utilizing one way ANOVA using Post–Hoc Bonferroni correction. $P < 0.05$ was considered as statistically significant. All the statistical analyses were performed using SPSS for windows, version 11.5.

Results

This study included 60 healthy pregnant women (60 eyes) and 20 healthy non-pregnant women (20 eyes) who served as a control group. Group 1 consisted of 20 eyes of 20 healthy women in the first trimester; Group 2 consisted of 20 eyes of 20 healthy women in the second trimester; Group 3 consisted of 20 eyes of 20 healthy women in the third trimester; and Group 4 (control group) consisted of 20 eyes of 20 healthy non-pregnant women. The age group of all participants was in a defined, narrow band of 18-30 years. Fig 1. Show an example of macular thickeness measurements obtained with Nidek SD-OCT Systems (RJ–3000 Lite). The mean Retinal Thickness measurements (RT), Foveal Retinal Thickness measurements and Para Foveael Retinal Thickness measurements in women is the four groups in as are probocnted in Table 1,2 and 3 respectively μm ± SD are presented in table 1,2 and 3 respectively. Fig 2. Shows the mean RT measurements of the women is the four groups in μm.

Fig 1. Depiction of macular thickness measurements obtained with Nidek SD-OCT system (RS-3000 Lite)



(A). Fundus photograph of a healthy subject (B). Depiction of standard ETDRS map (C) map diameters centered on fovea (left) and 9 standard ETDRS regions (right).

Central 1 mm ; fovea, 1-3 mm diameter ring; parafovea , 3-6 mm ring ; perifoveal region.

Discussion

Several studies on the variations of macular thickness measurements in normal subjects according to age, race, gender and refractive error/ axial length have been reported [7][13-14] [17][21-23]. However, there is a paucity of studies investigating the retinal and choroidal changes during pregnancy.

A study conducted by Demir et al found that the retinal thickness was increased in the third trimester. [5] The mean foveal thickness (FT) in the study group was found to be increased as compared to the the mean foveal thickness in the control group but it was not statistically significant This increase was thought to be due to pregnancy-related fluid retention in the retinal tissue. In parallel with their results, Cankaya et a also

Fig 2. Mean RT in µm of the healthy pregnant and non-pregnant women

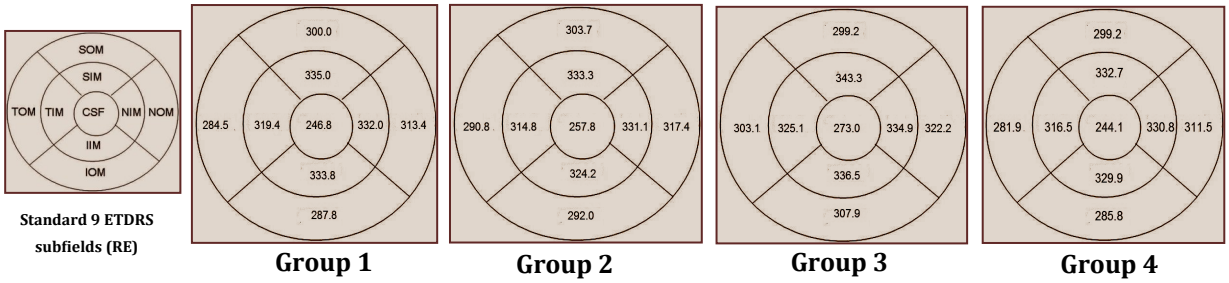


Table 1. Mean Retinal Thickness in the 9 ETDRS Subfields of the normal pregnant and non pregnant women

Sub fields	Group 1µm ± SD	Group 2 µm ± SD	Group 3 µm ±SD	Group 4 µm ± SD
CSF	246.8 ±11.0	257.8 ± 21.9	273.0 ± 31.9	244.1 ± 8.7
SIM	335.0 ± 9.2	333.3 ± 9.7	343.3 ± 15.0	332.7 ± 8.2
NIM	332.0 ± 8.4	331.1 ± 14.3	334.9 ± 15.4	330.8 ± 6.6
IIM	333.8 ± 10.2	324.2 ± 21.9	336.5 ± 15.4	329.9 ± 9.2
TIM	319.4 ±10.2	314.8 ± 19.5	325.1 ± 17.2	316.3 ± 8.6
SOM	300.0 ± 7.2	303.7 ± 10.3	299.2 ± 15.3	299.2 ± 9.2
NOM	313.4 ± 8.9	317.4 ± 11.0	322.2 ± 27.1	311.5 ± 10.6
IOM	287.8 ± 9.2	292.0 ± 12.6	307.9 ± 32.8	285.8 ± 7.0
TOM	284.5 ± 9.7	290.8 ± 15.6	303.1 ± 28.9	281.9 ± 6.6

Table 2. Mean Foveal Retinal Thickness of the normal pregnant and non pregnant women

Group 1	Group 2	Group 3	Group 4
246.8 ±11.08	257.80 ±21.9	273.05 ±31.9	244.10 ±8.7

In parallel with their results, Cankaya et a also found that the retinal thickness is increased in the last trimester and also in the second trimester[6]. There was statistical significance among the Group 1–2 , Group 1–3, Group 2–4, and Group 3–4 for FT. There was no statistical significance among the Group 2–3 and Group 1–4 for FT. In contrast, Atas et al found that the macular central subfield and foveal center thickness were significantly thinner

Table 3. Mean Para Foveal Retinal Thickness mong the normal pregnant and non pregnant women

Sub fields	Group 1	Group 2	Group 3	Group 4
SIM	335.0 ± 9.2	333.3 ± 9.7	343.3 ± 15.0	332.7 ± 8.2
TIM	319.4 ± 10.2	314.8 ± 19.5	325.1 ± 17.2	316.3 ± 8.6
IIM	333.8 ± 10.2	324.2 ± 21.9	336.5 ± 15.4	329.9 ± 9.2
NIM	332.0 ± 8.4	331.1 ± 14.3	334.9 ± 15.4	330.8 ± 6.6

in healthy pregnant groups than healthy non-pregnant group[18]. Our study corroborates that retinal thickness is increased in the third trimester as there was statistical significance among the Group 1–3 ($p<0.001$) and Group 3-4 ($p<0.0001$) for FT. There was no statistical significance among the Groups 1-2, 2-4 and 1–4 for F.

The foveal thickness is higher in our study (246.8 ± 11.0 µm, 257.8 ± 21.9 µm, 273.0 ± 31.9 µm, 244.1 ± 8.7 µm in groups 1,2,3,4 respectively) as compared to the values determined by the studies mentioned above (Table 2). This may be due to inter– machine differences as it is known that data is not interchangeable between different OCT machines due to different segmentation algorithms [11] [24] [25-28]. Each commercial OCT system has its own unique software for determining quantitative measurements of ocular structures. Also, the fast macular thickness scanning protocol was used in the studies by[6][18-19] instead of the macula map protocol which was used in our study. The Nidek RS-3000 Lite utilizes a different method - the OCT phase fundus - in place of scanning laser ophthalmoscope (SLO) to image the surface of the fundus which might affect the results. Demographic variations may also lead

to discrepancies. Variations in foveal fixation may be present even in individuals with no retinal pathology and this may cause a significant discrepancy as most SD-OCT systems assume foveal fixation. Scan decentration of 0.50 mm may result in foveal thickness measurements in error by about 45% [29].

The overall accuracy of ETDRS retinal thickness plots depends on B Scan density, position of the scan with respect to the foveal center, and magnitude of subject axial length differential. Errors in these parameters may be cumulative and result in significant error in computing retinal thickness from SD-OCT volumes[24]. Though positioning of patient, foveal centration and quality of scans was checked before approval of the scan, slight differences may affect results.

A literature search revealed only two studies determining the retinal thickness of the parafoveal region in pregnancy[5][18]. The parafoveal retinal thickness in all the quadrants of superior inner macula (SIM), temporal inner macula (TIM), Inferior inner macula (IIM) and nasal inner macula (NIM). A statistically significant difference in the parafoveal retinal thickness was found only in SIM region between Groups 2 -3 ($P< 0.03$) and Groups 3 – 4 ($P< 0.01$) (Table3). The SIM was found to have the highest retinal thickness during all trimesters as well as in the non-pregnant group. Group 1: SIM 335.0 ± 9.2 µm, Group 2: SIM 333.3 ± 9.7 µm, Group 3: SIM 343.3 ± 15.0 µm , Group 4: SIM: 332.7 ± 8.2 µm. Demir et al also reported highest retinal thickness for the upper quadrant (SIM) in third trimester of pregnancy (321.31 ± 12.28 µm) and also in the control group (311.62 ± 12.71 µm) [5] . The SIM quadrant has the highest value in all groups in Atas et al study as well [18].

Additionally, in our study, in the perifoveal region, statistically significant differences were found only in inner outer macula (IOM) between Groups 1-3 ($P< 0.006$) and Group 3-4 ($P< 0.002$) and temporal outer macula (TOM) between Groups 1-3 ($P< 0.007$) and Group 3-4 ($P< 0.002$). Further studies are needed to confirm whether these regions are more susceptible to changes in retinal thickness. The results of our study confirm that in addition to age, sex, axial length and refractive error, pregnancy can also influence the macular thickness and also provides normative data for retinal thickness in healthy pregnant rural north Indian women. The limitations of our study included the number of participants and the study being cross–sectional rather than longitudinal as observing the same participants during all trimesters may elucidate finer points on the changes in the retina during a healthy pregnancy.

Conclusion

Pregnancy affects the retinal thickness, especially in the third trimester. Normative data on the changes in the retina in healthy pregnant women will be valuable in differentiating early pathological changes and may have prognostic and diagnostic significance in various conditions such as pregnancy induced hypertension, preeclampsia, gestational diabetes and pre-existing diabetes mellitus with pregnancy. More population based studies on pregnant women are needed to establish a normative database of retinal thickness with each commercially available OCT machine as data is not interchangeable between different OCT machines. Age based and demographic variations should also be kept in consideration.

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