

ICare Tonometry: Reliability and Validity in Diabetic Patients

Purpose

Reliability and validity of ICare tonometer was evaluated for its accuracy on IOP measurements in diabetic patients and controls. Central and peripheral corneal pressures, within and between groups were compared.

Methods

This is a prospective study conducted from March 2015 to June 2015 in a tertiary hospital. Group 1 included central and peripheral IOP measurements in diabetics, Group 2 included central and peripheral IOP measurements in controls, Group 3 composed of central IOP measurements in diabetics and controls, and Group 4 was peripheral IOP measurements in diabetics and controls. Statistical analysis was performed by MedCalc statistical software.

Results

Sixty eyes of 60 participants constituting 30 diabetics and 30 controls were recruited. Mean age in diabetics and controls was 52.63 (+/- 11.87) and 41.7 (+/- 16.53) years. Male to female ratio was 18 (60%) and 12 (40%) in diabetic group while 12 (40%) and 18 (60%) in control group. Mean central and peripheral IOP in diabetics was 15.20 (+/- 3.15) and 14.10 (+/- 3.95). And in controls 13.97 (+/-2.70) and 13.73 (+/- 3.16) mm of Hg was found. Pearson coefficient (r) of -0.28, -0.19, 0.12 and 0.22 was found respectively for groups. Paired sample t test showed t values of 1.74, 0.45, -1.06 and -0.28 obtained respectively. Statistical significance was considered when $p < 0.05$. Reliability of ICare tonometer was performed by calculating Cronbach's alpha and intraclass correlation coefficient. Calculated Cronbach's alpha was 0.44, 0.32, 0.22 and 0.37 respectively. Intraclass correlation coefficient of -0.27, -0.19, 0.12 and 0.22 as single measures were found respectively. ICare tonometer validity was determined by ROC curve and accuracy was calculated by AUC difference that revealed 0.23, 0.06, 0.14 and 0.35 respectively. Limits of agreement were evaluated by Bland-Altman difference plots.

Conclusion: ICare tonometry reliably measured ocular pressures in all groups with comparable values. Diabetic central pressures were negatively correlated with controls. Central and

peripheral pressures showed slightly higher values in diabetics compared to controls.

Keywords: ICare tonometry, diabetics, controls, reliability, validity, accuracy, limits of agreement

1. INTRODUCTION

Diabetes mellitus being the high risk factor for glaucoma development, therefore it is essential to identify and diagnose in its early stages by intraocular pressure (IOP) measurement. Despite the availability of several tonometers Goldmann applanation tonometer is considered as gold standard however makes its use restricted in some circumstances due to patient incompatibility and postural abnormalities.

Newly introduced ICare tonometer (Finland Oy, Espoo, Finland) is popular for its rapidity and ease of acquaintance of intraocular pressure (IOP) values in unanesthetized corneas. Hence it is used not only to diagnose and follow up glaucoma patients but also used as domiciliary tonometer. When tested against Goldmann applanation tonometer (GAT) in normal 42 healthy subjects it yielded small statistical insignificant positive bias.¹ IOP readings obtained by ICare tonometer in 178 primary open angle glaucoma patients were comparable to GAT values.² Previous study of ICare tonometer in assessing influence of measuring position of probe in 40 normal subjects showed good correlation between central and peripheral pressures.³

Present study was carried out to evaluate ICare tonometer reliability and validity of IOP measurements in diabetic patients and normal subjects in addition to evaluation of central and peripheral corneal pressures.

2. MATERIALS AND METHODS

Present study was prospective and comparative intraocular pressure measurements recorded by newly introduced ICare tonometry (Figure 1) in thirty diabetic and thirty non-diabetic participants. Consecutive walk in outpatients to ophthalmology department with known history of diabetes mellitus were selected along with normal subjects. Pre measurement verbal consent was obtained from study subjects as ICare tonometry is noninvasive method after giving instructions regarding measurement procedure.



Figure 1 ICare tonometer

Pre existing corneal pathological lesions, previous ocular inflammations and surgeries, and diabetic retinopathy changes were excluded that might interfere with pressure measurements plausibly due to generalized microangiopathy of basement membrane throughout the body including angle structures and retinal vasculature. POAG excluded from current study as this investigation focuses on evaluating central and peripheral IOP in diabetics and controls. Suspicious arousal of IOP rise in diabetics facilitates early glaucoma diagnosis because diabetes mellitus is a risk factor for glaucoma development in addition to slightly pachymetric increase in IOP probably due to diabetic status leading to falsely high readings which has to be confirmed by phasing and visual field recordings.

This paper evaluates central and peripheral corneal pressure measurements by ICare tonometer so that a normative data of intraocular pressures shall be deduced between normal subjects and diabetic patients. Reasons for conducting this study on diabetic patients are to find out existence of pressure variation in diabetics compared to controls as glaucoma incidence is more common in diabetics than in normal population. Another reason is to draw conclusion regarding whether actual measured IOP is normal to diabetic patients as IOP ranges from 9 mm to 21 mm of Hg. Furthermore IOP was compared with normal subjects to study existence of differences or similarities within and between groups.

Consultants including research scholars recorded the pressures that were using ICare tonometer very well and experienced, routinely measuring IOP as a part of regular ophthalmic examination. With the device held perpendicularly we took at most care to click when the ICare probe is at central cornea and for peripheral corneal pressures just within temporal/nasal limbus.⁴ Reasons for testing central versus

peripheral IOP is that central and peripheral pressure varies greatly as the corneal thickness gradually increases towards its periphery.

Accurate (when ICare displays without hyphen and non flickering P on display screen) central and peripheral IOP measurements were recorded. Single beep is associated with pressure recording where as dual beep indicated errata and prolonged brief beep means end of the final measurements. ICare automatically records average of five readings and sixth reading will be the average value. Statistical analyses performed by MedCalc statistical software. Although efficacy and reliability of rebound tonometer is extensively studied to the best of authors' knowledge there are no articles on reliability and validity of ICare tonometer investigated in diabetic patients in addition to comparison of central and peripheral corneal pressures.

Specificity of a test or device is the ability to correctly identify true negatives that is, those without disease and sensitivity of a test or device is the ability to correctly diagnose true positives that is, those with disease. Receiver operating characteristic (ROC) curve analysis helps in calculating specificity and sensitivity rate of a test or device through calculations of area under the curve (AUC) that provides test accuracy which ranges from 0 to 1. AUC of 1 implies perfect 100% accuracy and 0.6 onwards it is graded as fair, good, excellent and high accuracy.

3. RESULTS

Total of 60 eyes of sixty participants consisting of 30 known diabetic patients and 30 normal subjects were studied. Uniocular pressure measurements were considered for convenience of statistical analysis. Mean age in diabetic group was 52.63 years (+/- 11.87) ranging from 30-75 years with 18 males (60%) and 12 (40%) females. Mean age in control group was 41.7 years (+/- 16.53) ranging from 18-70 years with 12 (40%) males and 18 (60%) females. Statistical significance was considered when p value was at or less than .05.

Mean central and peripheral corneal pressure in diabetic group was 15.20 (+/- 3.15) and 14.10 (+/- 3.95) mm of Hg. Mean central and peripheral corneal pressure in controls was 13.97 (+/- 2.70) and 13.73 (+/- 3.16) mm of Hg. (Table 1) Mean difference (MD), standard error of the Mean, Pearson correlation coefficient (r), confident intervals at 95%, t values, degree of freedom (DF), and p values in diabetic and controls is shown in Table 2.

Cronbach's alpha was calculated as it is an index and measure of reliability of internal consistency of close relatedness of recorded pressures shown in Table 3.⁵ Intraclass correlation coefficient (ICC) was calculated as it is a measure of reliability of pressure measurements shown in Table 4 and graphically represented in Figure 2, 3, 7 and 8.⁶

ROC curve analysis was performed as it is a fundamental tool for determining validity in terms of its diagnostic test ability to discriminate diseased cases from normal cases through sensitivity and specificity rates. The area under the ROC curve (AUC) was calculated to find out accuracy of how well a given pressures could be distinguished between diabetic and control groups. AUC with sensitivity and specificity rates, AUC difference, z values and p values are shown in Table 5 and 6. ROC curves are shown through Figure 4, 5, 9 and 10.

Validity of ICare was analyzed by Bland Altman plots (1986 and 1999) or difference plots to compare two measurement techniques in terms of limits of agreement (LoA). In this graphical method, difference between two measurement techniques are plotted against the average of two methods shown in Figures 6a, 6b, 11a and 11b. Horizontal lines are drawn at mean difference and limit of agreement, which are defined as mean difference \pm 1.96 times the standard deviation of the difference.⁷⁻⁹

Z-score was calculated that indicated how many standard deviations of pressure varied from the mean pressure. A 'z' score which is greater than zero represents pressure greater than mean pressure. A z-score equal to 0 represents pressures equal to mean pressures. A z-score equal to 1 represents pressure that is 1 standard deviation greater than mean pressure; a z-score equal to 2 means 2 standard deviations of pressures greater than mean pressures.

DISCUSSION

Present study investigated intraocular pressure measurements recorded by ICare tonometer for its reliability and validity in 30 diabetic patients and 30 normal subjects in addition to evaluation of central and peripheral corneal pressures. Statistical analysis was performed within and between groups. IOP measurements were normally distributed according to Gaussian standard curve.

Mean age in diabetic group was 52.63 (\pm 11.87) years (range 30 -75) and mean age in control group was 41.7 (\pm 16.53) years (range 18-70) in contrast to the previous study that showed mean age of 45.9 (\pm 19.8) years ranging from 18-85 years.¹⁰ Another study reported mean age of 21.5 years (\pm 3.2) that included 42 normal study subjects and reported limits of agreement of \pm 5.11 mm Hg.¹

Yamshita et al study showed a least bias for peripheral corneal pressures than central corneal pressures however ICare temporal pressures values were closest to Goldman applanation values in 102 normal eyes. Muttuvolu et al reported significant greater reading of central corneal pressures with peripheral corneal pressure in 40 normal subjects similar to the present study's results.¹¹

Within group analysis

Evaluation of central and peripheral corneal pressures in diabetics (Group 1) and controls (group 2) were statistically first analyzed followed by reliability and validity assessment of ICare tonometric pressure measurements.

Descriptive statistical analysis in diabetic group showed a slight increment in the central pressure compared to peripheral pressure (p 0.35, p 0.005) probably to glycosylated hemoglobin levels and hyperglycemic status and which have been correlated with higher IOP levels.¹² Central and peripheral IOP did not deviate substantially in control group as calculated mean pressures were similar (p 0.04, p 0.03) (Table 1)

Table 1 showing descriptive statistics of pressures in diabetics and controls

N=30	Mean	SD	SEM	95% CI for mean	P value
cIOP-DM	15.20	+/- 3.15	0.57	14.03 to 16.37	0.35
pIOP-DM	14.10	+/- 3.95	0.72	12.63 to 15.58	0.005
cIOP-CT	13.97	+/- 2.70	0.49	12.96 to 14.97	0.04
pIOP-CT	13.73	+/- 3.16	0.58	12.55 to 14.91	0.03

cIOP: central intraocular pressure; pIOP: peripheral intraocular pressure

Mean pressures reported in this present study were similar in contrast to Muttuvelu et al study that showed greater significant central ICare corneal pressures than peripheral corneal pressures in normal subjects probably as cornea gradually thickens towards periphery therefore higher pressures are likely to be expected.

In group 1 and 2, central and peripheral IOP showed inverse relation as the Pearson correlation coefficient was -0.28 and -0.19 with poor correlation (p 0.30, p 0.78). (Table 2)

Table 2 showing paired sample t test within and in between groups

N=30	MD	SE of MD	r	95% CI	T value	DF	P value
Group 1	-1.10	1.04	-0.28	-3.23 to 1.03	-1.06	29	0.30
Group 2	0.23	0.83	-0.19	-1.92 to 1.46	-0.28	29	0.78
Group 3	1.23	0.71	0.12	-2.68 to 0.23	1.74	29	0.09
Group 4	0.37	0.82	0.22	-2.04 to 1.31	0.45	29	0.66

Alpha coefficient ranges in value from 0 to 1 and may be used to describe the reliability of pressures. Higher the score, more reliable the generated scale is. Accepted and reported Cronbach's alpha which is

an index of reliability of 0.7 however low values of 0.44 and 0.32 were calculated in the present study respectively in group 1 and 2. (Table 3)

Table 3 Internal consistency measurement of relatedness within and in between groups

N=30	Group 1	Group 2	Group 3	Group 4
Cronbach's alpha	0.44	0.32	0.22	0.37
95% lower confidence limit	-0.05	-0.27	-0.45	-0.18

The Rankin paper discussed intraclass correlation coefficient (ICC) for a reliability assessment using average and single measurements. Intraclass correlation coefficient provides a scalar measure of agreement or concordance between groups. Value 1 represents perfect agreement and 0 as no agreement at all. Group 1 showed strong agreement when average measurement of -0.75 was considered compared to group 2 where ICC for average measurement showed fair agreement by -0.45.¹³

(Table 4)

Table 4 showing intraclass correlation coefficient within and in between groups

N=30	ICC Single measures	95% confidence interval	ICC Average measures	95% confidence interval
Group 1	-0.27	-0.57 to 0.09	-0.75	-2.67 to 0.17
Group 2	-0.19	-0.51 to 0.18	-0.45	-2.14 to 0.31
Group 3	0.12	-0.24 to 0.46	0.22	-0.65 to -.063
Group 4	0.22	-0.15 to 0.53	0.36	-0.35 to 0.69

Figure 2 shows box and whiskers plots that revealed increased width of the box for central corneal pressures than peripheral corneal pressures and also revealed increased range of values for peripheral corneal pressures than central corneal pressures in diabetic patients implying acceptable measure of reliability of ICare tonometry as far as central pressures were considered. Slight increase in the peripheral corneal pressure noted in group 2 compared to central corneal pressures with a fair agreement of ICare tonometry when control pressures were considered. Therefore ICare pressures in diabetics showed strong reliability compared to control pressures that showed a fair amount of agreement or reliability

(Figure 3)

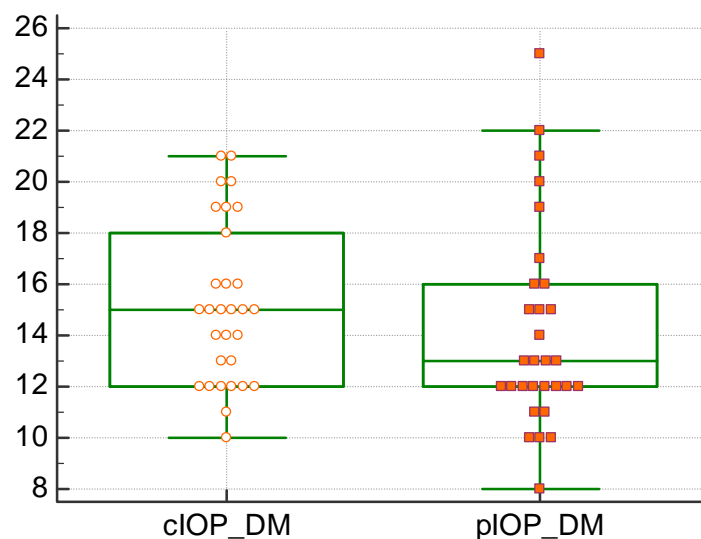


Figure 2 Intraclass correlation coefficient of central and peripheral IOP in diabetics

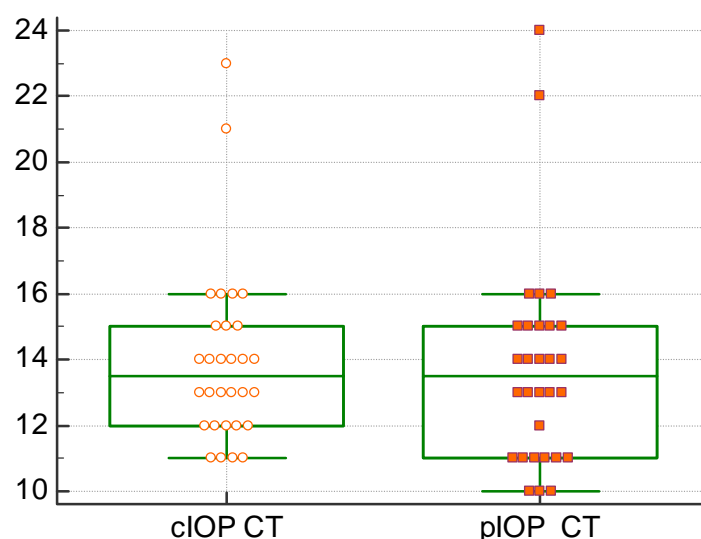


Figure 3 Intraclass correlation coefficient of central and peripheral IOP in controls

ICare tonometric pressure measurements were validated when ROC curve and area under the curve was calculated separately for pressure values in both groups with hundred percent sensitivity and specificity. (Table 5) However when ROC curves were compared, pair wise differed in analysis in both groups. AUC differences were narrow for group 1 and 2 (0.23, 0.06) suggesting that ICare pressures showed a fair amount of validity. Group 1 showed z value of 0.77 mm of Hg of standard deviation between central and peripheral corneal pressures compared to controls that showed a 'z' value of 0.13 mm of Hg almost similar measurements between central and peripheral corneal pressures with 0.05 AUC difference. (Table 6)

Table 5 showing ROC curve analysis of central and peripheral IOP in controls and diabetics

N=30	AUC	SE	95% CI	P value	Sensitivity	Specificity
clOP-DM	1.00	0.00	1.00 to 1.00	<0.0001	100%	100%
clOP-CT	1.00	0.00	1.00 to 1.00	<0.0001	100%	100%
plOP-DM	1.00	0.00	1.00 to 1.00	<0.0001	100%	100%
plOP-CT	1.00	0.00	1.00 to 1.00	<0.0001	100%	100%

Table 6 showing pair wise comparison of ROC curve analysis of IOP in diabetics and controls

N=30	AUC difference	SE	95% CI	Z statistics	P value
Group 1	0.23 0.64, 0.86	0.29	-0.34 to 0.80	0.77	0.44
Group 2	0.06 0.67, 0.62	0.43	-0.80 to 0.91	0.13	0.90
Group 3	0.15 0.87, 0.72	0.26	-0.36 to 0.67	0.58	0.56
Group 4	0.35 0.98, 0.64	0.23	-0.09 to 0.79	1.55	0.12

ROC curve for group 1 revealed peripheral corneal pressures curve moving to the left corner of graph compared to central pressures and in group 2 ROC curve plotting showed almost overlap of these curves for central and peripheral corneal pressures suggesting that pressures are equivalent however showed poor validity for ICare pressures. (Figure 4 and 5)

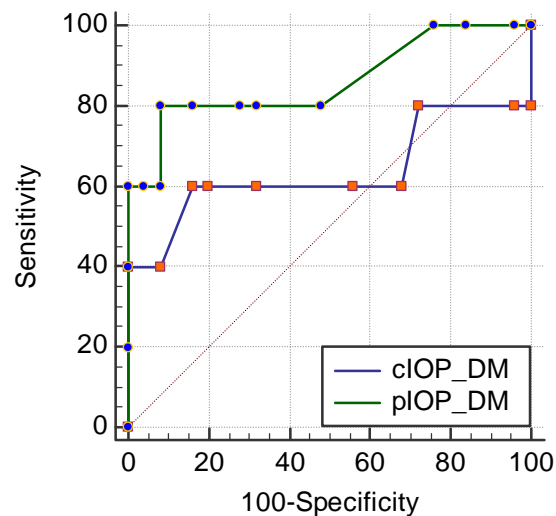


Figure 4 Comparison of ROC curves of central and peripheral IOP in diabetics

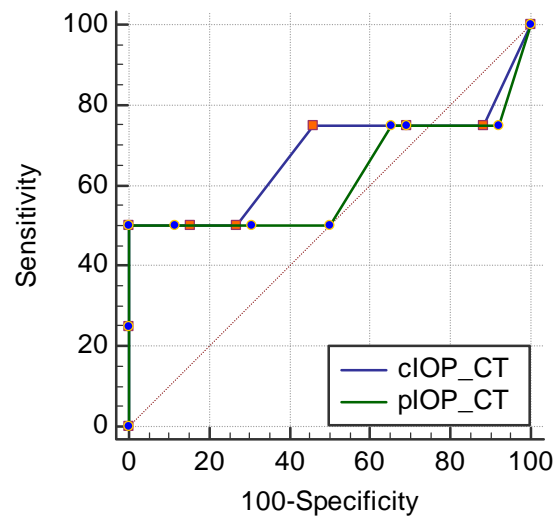


Figure 5 Comparison of ROC curves of central and peripheral IOP in controls

All the data points fell within 95% limits of agreement (except 1 point outside LoA) of ± 1.96 standard deviation of bland-Altman difference plots with a positive bias of 1.1 mm of Hg (95% CI of 12.3 to -10.1 mm of Hg) in group 1 suggesting very good agreement of ICare pressures. (Figure 6a) Similarly for group 2, showed positive bias of 0.2 mm of Hg with 95% confident intervals of 9.1 to -8.6 mm of Hg and all data points (except 2 points) fell within limits of agreement implying good agreement of ICare tonometric pressures. (Figure 6b)

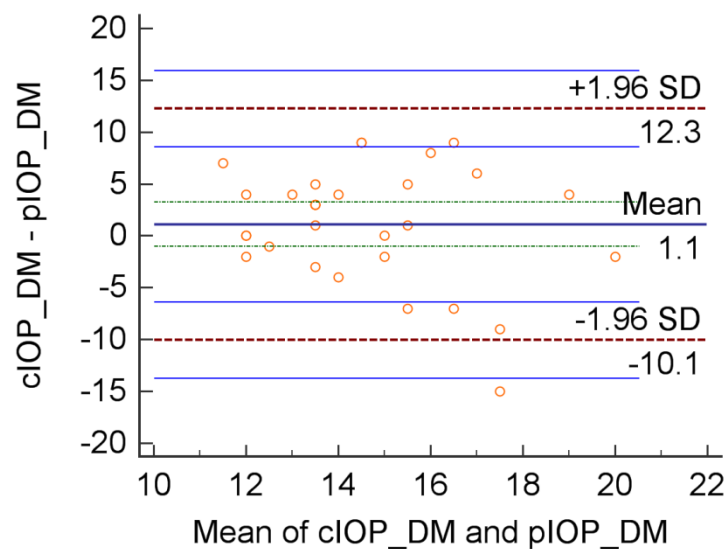


Figure 6a Bland Altman analysis of difference plots showing limits of agreement between central and peripheral IOP in diabetic patients (95% CI -10.1 to 12.3, N=60)

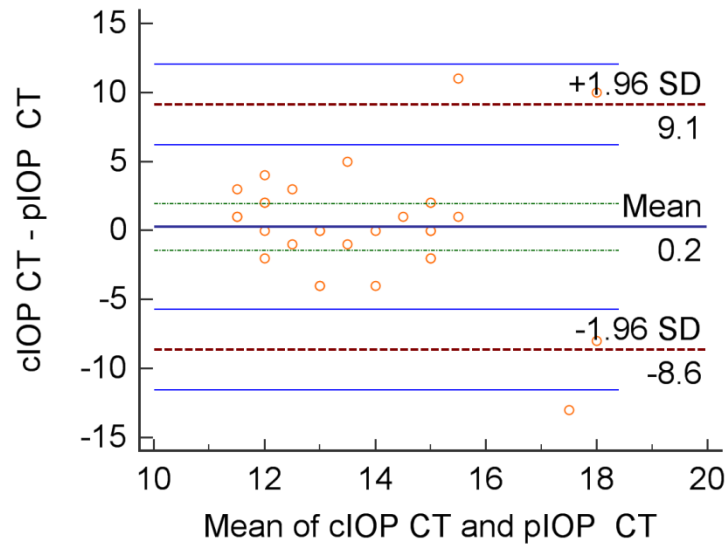


Figure 6b Bland Altman difference plots showing limits of agreement between central and peripheral IOP in controls (95% CI -8.6 to 9.1, N=60)

Between group analysis

Central IOP in diabetic and control groups (Group 3) and peripheral IOP (Group 4) were statistically evaluated for their association and correlation. Paired sample t test in group 3 and 4 showed low positive correlation (r 0.12, r 0.22) (Table 2) Pearson's correlation coefficient is an inappropriate measure of reliability because the strength of linear association, and not agreement, is measured (it is possible to have a high degree of correlation when agreement is poor).¹³

A paired t-test assesses whether there is any evidence that two sets of measurements agree on average. However, it is the difference between within-subjects scores that is of interest (taking the mean score of all subjects has potential to provide misleading estimates).

Cronbach's alpha which is a tool for assessing reliability found to be not acceptable as the values were 0.22 and 0.37 of group 3 and 4 with narrow 95% confident intervals (-0.45 to -0.18). (Table 3) ICC found to be for average measurements were 0.22 and 0.36 that indicated poor acceptability of ICare pressures in group 3 and 4. (Table 4)

Intraclass correlation coefficient of central pressures in diabetics spread over a wide range where as narrow range was plotted in box and whisker plots. (Figure 7) When compared of the peripheral IOP in group 4 they seem to correlate however with the median pIOP found to be at the beginning of measurements in diabetic patients compared to controls. (Figure 8)

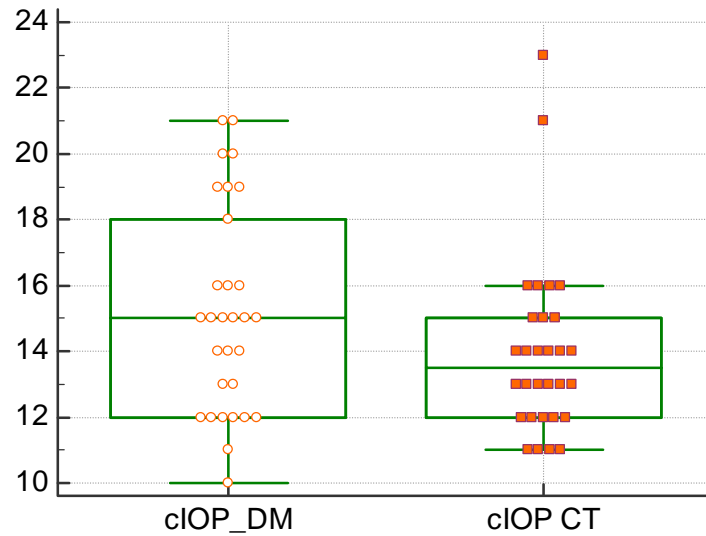


Figure 7 Showing intraclass correlation coefficient of central IOP in DM and CT

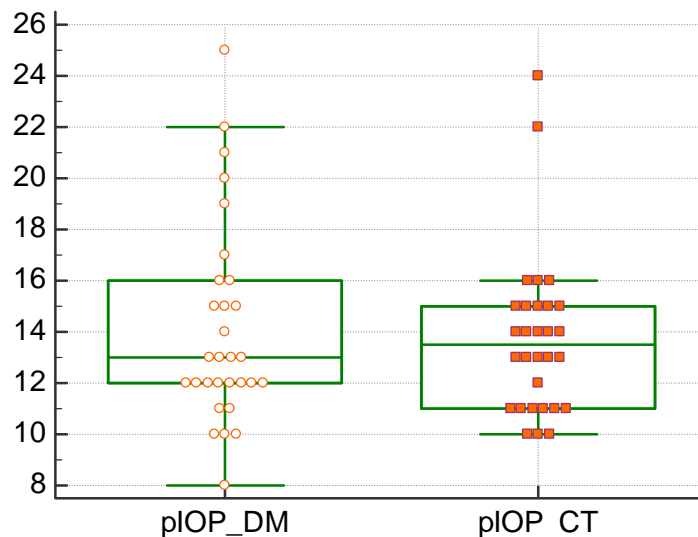


Figure 8 Showing intraclass correlation coefficient of peripheral IOP in DM and CT

ROC curve analysis showed AUC difference of 0.15 and 0.35 in group 3 and 4 with z value of 1.55 mm of HG standard deviation in group 4. (Table 6) ROC graph revealed curve shift towards the left corner of the graph suggesting acceptable validation of ICare pressures at the same time depicting good accuracy of central corneal pressures in controls than central corneal pressures in diabetics. (Figure 9) ROC drawing revealed peripheral IOP curve in diabetics shifting completely to the left corner of the graph indicating high accuracy compared to peripheral corneal pressure curve in controls. (Figure 10)

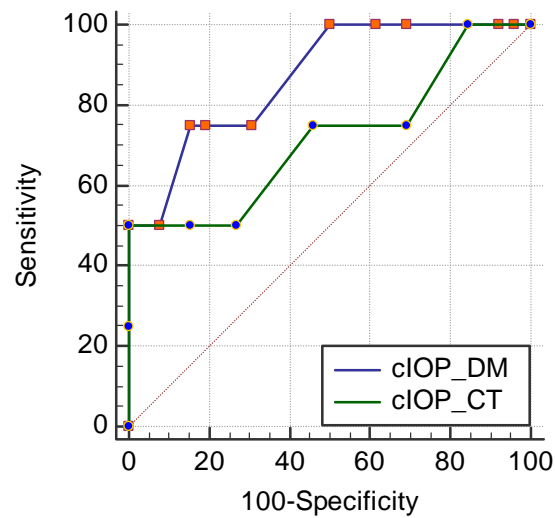


Figure 9 Comparison of ROC curves of central IOP in diabetics and controls

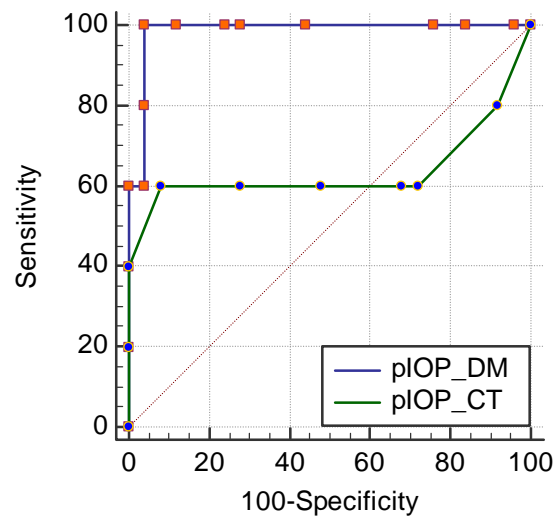


Figure 10 Comparison of ROC curves of peripheral IOP in diabetics and controls

Acceptable and good Limits of agreements found in group 3 as more than 95% of data points fell within dotted horizontal lines (except one data point) with a mean positive bias of 1.2 mm of Hg. (Figure 11a). Peripheral IOP between diabetics and controls showed good agreement as 95% of data points fell within limits of agreement. (Figure 11b)

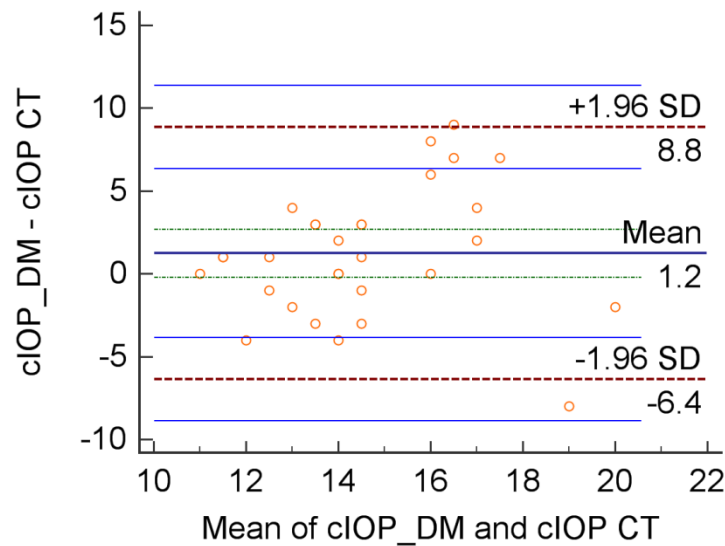


Figure 11a Bland Altman difference plots showing limits of agreement between central IOP in diabetics and controls (95% CI -6.4 to 8.8, N=60)

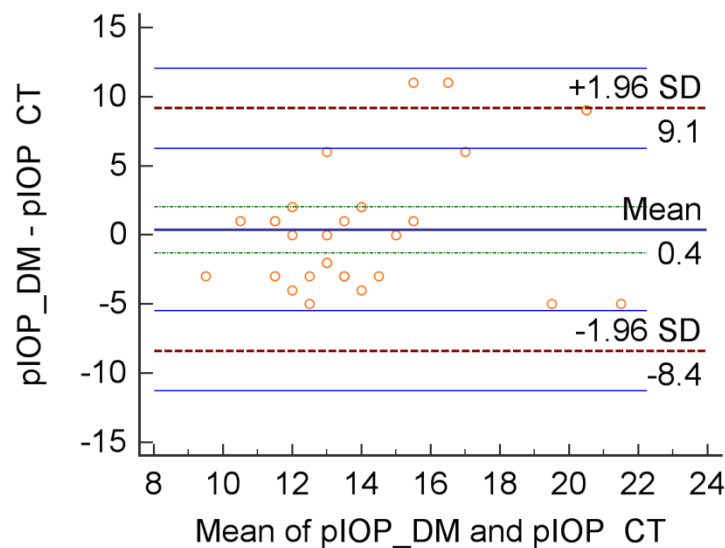


Figure 11b Bland Altman difference plots showing limits of agreement between peripheral IOP in diabetics and controls (95% CI -8.4 to 9.1, N=60)

Inverse correlation of central IOP measurements found between control and diabetic group suggesting pressure variation in diabetic patients that is lower pressure in controls is associated with higher pressures in diabetic patients. ($r = -0.20$) There was no correlation seen with peripheral corneal pressures between groups. Negative t values suggested low mean sample pressures. Negative Z score of -1.49 mm Hg for central pressure suggested raw score less than the mean pressure and 1.49 standard deviations

away from the mean in diabetic patients were found. p values calculated for both one tail and two tails test were not statistically significant although p value for central IOP was near 0.05 (p 0.07). There was no correlation observed with central pressures in both groups. Negative Z score suggested units of standard deviation in which raw score is below mean pressures. (Table 6)

ICare Validity Tests

Diagnostic validity of ICare pressures was determined by calculating sensitivity and specificity rates, positive and negative predictive values from ROC curve analysis. ICare accurately measured pressures in all the groups with hundred percent sensitivity and specificity implying its validation in IOP measurements. (Table 5)

However when pair wise comparative ROC curve analysis was performed within and between groups there seems to be reduction in its accuracy and the results were not significantly different as p value was more than 0.05. ICare measured very good accuracy (AUC of 0.86) for peripheral corneal pressures in diabetics than central corneal pressures (AUC 0.64) in group 1. ICare tonometer measured fair amount of accuracy in controls equally for both central and peripheral corneal pressures (AUC 0.67, AUC 0.62). (Table 6)

ICare accuracy improved to very good accuracy (AUC 0.87) for central pressures in diabetics than central pressures of controls (AUC 0.72) in group 3 validating the utility of ICare tonometer. Surprisingly in group 4 ICare performance showed excellent almost perfect accuracy (AUC 0.98) in measuring peripheral pressures in diabetics compared to peripheral pressures (AUC 0.64) in controls. (Table 6)

Two false positive each for central IOP in controls and diabetic patients found with specificity rate of 93 percent. Upper limit of 95% confidence interval for positive predictive value was 80% and for negative predictive value was 15 percent.

Three false positive values found for peripheral IOP measurements in controls. Specificity rate of 95% with upper limits of 95% confident interval for positive predictive value was 69% and for negative predictive value was 09% for peripheral pressures in control group. Six false positive values calculated for peripheral IOP in diabetic patients. Specificity of 89% found with upper limit of 95% confident interval for positive predictive value was 48% and negative predictive value of 9% found. Sensitivity is not calculated as the study sample included only non glaucomatous normal patients.

In younger subjects of 18-30 years range, higher central ICare pressures recorded similar to the results of Gonza lez meijome study. Negative correlation found between central and peripheral ICare pressures in control group in contrast to high correlation revealed from Gonza lez meijome study.

Klein B E reported higher mean pressures in 2366 diabetic patients than 381 non diabetics and suggested careful IOP recordings in diabetics as there is increased risk of glaucoma occurrence.¹⁴

Krueger reported statistically significant higher IOP and reveled correlation of insulin resistance states, hyperglycemia and glycosylated hemoglobin levels with higher IOP measurements in diabetic patients. This study in addition to hypothesize that glucose mediated corneal stiffening due to collagen cross linking might be responsible for IOP overestimation in diabetic patients.

Queiros A revealed mean central IOP of 14.9 (+/- 2.8) mm of Hg and peripheral IOP of 14.1 (+/- 2.5) and 14.5 (+/- 2.7) mmHg at nasal and temporal corneal locations respectively that included 153 patients, age ranging from 21 to 85 years with mean age of 55.5 (+// 15.2) years. This study showed higher significant correlation between central and peripheral pressure measurements and reported IOP recorded at nasal cornea reveals a slightly lower pressures on average and correlated with central pressures. The study concluded with good agreement between both nasal and temporal readings in correlation to central pressures and recommended acceptable and reliable pressure measurements.

Limitations

All age groups included in this prospective study may not pin point effect of age factor and IOP increase in diabetics. These findings might be correlated with slightly increased corneal thickness by pachymetry, exclusion of which and small sample size were the limitations of the study.

4. CONCLUSION

In conclusion, central and peripheral corneal pressures were not associated with statistically significant difference between controls and diabetic group. ICare tonometer measurements were comparable, reliable and valid in recording IOP in both the groups. While recording pressures in diabetic patients moderately elevated IOP values are expected as revealed from this study. ICare tonometric central corneal pressure measurements yielded 95% specificity rates of identifying true negatives in controls as well diabetics where as peripheral corneal pressure recordings in controls revealed 95% specificity rates and slightly lower specificity rates of 89% of identifying true negatives in diabetic group.

5. Conflicts of interest statement: Authors have no financial or proprietary conflicts of interest

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