Report: on the most influential factors (new and existing ophthalmological measurands) that affect IOP measurements made by specific devices

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Outline

The presented reports purpose is to provide an insight in the problematic of IOP (Intra ocular pressure) measurements from the metrological and medical point of view. The most influential factors on the IOP measurements are discussed and provided together with the common praxis of calibration procedures used.

The problematic

The basic problematic for all types of IOP measuring devices is currently the lack of a measurement standard for the purpose of calibration, that could be applied to both contact and non-contact measuring devices from all manufacturers. Currently the variety of approaches to measure IOP together with the usage of manufacturer made standards, which are made solely for their specific device, makes an objective and traceable calibration from the view of metrology, difficult. This lack of an independently designed and universal calibration device makes the comparison of measured IOP between devices challenging. This is of great importance when patients measured IOP differs from device to device (from various manufacturers) that uses the same measurement principle. This problem emerges mainly in the non-contact tonometers, but with the ever more decreasing usage of contact methods that are time consuming for the medical professionals and uncomfortable for the patient, gains on importance.

Contact measurements of IOP are believed in general to be more precise that the non-contact measuring methods. This may be true in most scenarios, as the used measuring principle is more closely connected to the ''direct'' measurements of pressure, but these measurement methods still miss a universal calibration device that would provide the need traceability to basic SI unit.

The main problematic in delivering a reliable and traceable measurements of IOP in the ambulance practice is the lack of metrological knowledge within a majority of medical professionals and the missing legislative directive that would require a routine independent calibration of IOP measurement devices. A routine calibration may be a standard in some EU countries; unfortunately it cannot be said for the entire EU area.

Influential factors on IOP measurements

The factors influencing the measurement of the intraocular pressure (IOP) can be divided into two groups. The first group includes those factors, which affect the interaction of the eye and the measuring device. In this case the measured IOP is not equal to the ''real'' IOP in the eye. These factors are closely connected with the principle of the used measuring method and used measurement device. The second group of factors influencing the IOP is connected with the properties of eye tissue, eye geometry, patience's current health state.

Contact tonometry (CT)

The Goldmann applanation tonometer (GAT) is the "gold standard" in tonometry. Every new tonometer is usually compared with the GAT. Some error sources of the GAT also affect other types of tonometers, especially if the mechanism of the measurement is based on the applanation, as well. The following text shortly presents a short summary of the GAT error sources and provides a brief overview of parameters affecting measurements using non-contact tonometers (NCT) and rebound tonometers (RBT).

The Goldmann applanation tonometry (GAT; the gold standard) Goldmann applanation tonometers are based on the Imbert-Fick law (Kirstein, Elsheikh, & Gunvant, 2011). According to this law, the pressure p inside the infinitely thin, perfectly elastic and dry sphere can be computed from the force F, which causes applanation of the sphere by the area S,

$$p = F/S.$$

The real cornea has a finite thickness with bending resistance represented by corneal rigidity and its surface is not dry. Thus, the law must be modified to the form (Kirstein, Elsheikh, & Gunvant, 2011)

$$F + F_{TF} = IOP \times S + FR,$$

where F_R is the force caused by bending resistance and F_{TF} is the surface tension force. Force developed by the device is generated by pressing the stylus with the attached prism (probe) on the surface of the eye. The amount of force is adjusted by changing the length of a spring within the device. If the applanation diameter is 3.06 mm and the central corneal thickness (CCT) is 500 µm, both forces F_R and F_{TF} are equal and cancel each other out (Ehlers, Bramsen, & Sperling, 1975; Goldmann, & Schmidt, 1957) and the original Imbert-Fick law can be applied.

In general the Goldmann applanation tonometer measures the force necessary to flatten an area of the cornea. This measurement technique is well established and is believed to be one of the most precise and reliable from the currently used IOP measurement methods. As this method is based of force measurements that are applied over a defined area, the main sources of concern from a metrological stand point, is the precision of force value generation, reputability of this force magnitude, surface area determination and measurement error due to human factor as the eye pressure and generated pressure by the device are compared optically. The human factor in this case can be considered as a less significant factor. As the surface area is restricted by the usage of a prism (probe), which is attached to the end of the stylus and its dimensions can be defined with high precision, this factor represents a minor potential influence of the IOP measured value. The more significant factor is the force generation, which in this case is done by mechanical way (changing the length of a spring). To minimize the risk arising from this factor the manufacturers recommend a routine calibration of the device by a dedicated check weight that is represented by a metal bar. The main problem from a metrological point of view is the question of the calibration of this reference weight (as is directly influences the calibration of the device and its weight should be defined with an uncertainty). Further point that is connected with the calibration of these devices is the lack of an independent calibration method not created by the manufacturer.

As follows from the above-mentioned modification of the Imbert-Fick law, the GAT readings are significantly dependent on the biomechanical properties of a cornea, such as corneal rigidity or stiffness. Moreover, a positive correlation between the measured IOP and the CCT was found (for review see Kirstein, Elsheikh, & Gunvant, 2011; Chihara, 2008), i.e. a thicker cornea leads to a higher IOP. Next, it seems that the GAT readings are influenced by corneal curvature and astigmatism (e.g. Hagishima et al., 2010; Mark & Mark, 2003) – the flatter the curvature, the lower the reading; in the case of astigmatism, the results differ if the measuring prism of the GAT is at a steeper or flatter meridian (Mark & Mark, 2003). The measurement can be influenced by laser surgery (e.g. Arimoto et al., 2002) or corneal abnormalities (e.g. Firat et al., 2013). A review of other possible error sources is provided by Rüfer (2000). The IOP can be overestimated, if the blepharospasm occurs, if there is lid retraction or if a Valsalva maneuver is present, and underestimated in the case of stromal or corneal edema etc. Other error sources as the operator's experience, the amount of fluorescein applied to the eye, corneal illumination, tear film properties etc. are connected just with the GAT and are described for example in (Rüfer, 2000).

Rebound tonometers (RBT) are a type of tonometers that determine the IOP from the deceleration of the small probe, which bounces off the cornea (Kirstein, Elsheikh, & Gunvant, 2011; Kontiola 1996). The small magnetized probe is placed in the shaft, which is coaxial with two coils. The first coil serves as a small electromagnetic gun and launches the probe against the cornea. During backward movement after the bounce, the magnetized probe induces the voltage in a second coil. The detected voltage is proportional to the probe speed.

The technical realization of this measurement leaves factors that affect the determined IOP value. Based on the measurement principle the sources that contribute to the possible differences between the measured and ''true'' IOP values originate from the measurement of voltage generated by the coil during the rebound movement, possible error created by the operator caused by the incorrect distance, position and angle of the RBT to the eye of the patient and the initial determination of the voltage/IOP pressure dependency. The most severe factor that affects the measured values is the precision of the measured voltage that is used to determine the IOP and the determined voltage/IOP pressure dependency. Both of these information's that could be used for the evaluation of the measurement uncertainty which is an indicator of the measurement reliability is not known to the metrological community. Both of these factors could and should be tested by a well defined standard that is traceable to the SI, so that an independent measurement capability of these devices is defined.

Most studies show positive correlation of the measured IOP and CCT (Brusini et al., 2006; Iliev et al., 2006; Martinez et al., 2005; Nakamura et al.; 2006, Krzyzanowska-Berkowska & Asejczyk-Widlicka, 2010; Malini et al., 2014; Jorge et al., 2008), i.e. a higher CCT leads to a higher IOP readings; for exceptions see (Chui et al., 2008). Some studies present dependence on the corneal radius (e.g. Krzyzanowska-Berkowska & Asejczyk-Widlicka, 2010), especially in the case of thicker corneas. After corneal refractive surgery (LASIK), the measured IOP decreases (Lam et al. 2010).As well as in the case of NCTs, RBT readings are affected by biomechanical properties of the cornea (Chui et al. 2008; Jorge et al. 2008; Shin et al., 2015), especially with corneal hysteresis (CH) and corneal resistance coefficient (CRF). Shin et al. (2015) reported that a number of parameters significantly affect the IOP readings if considered separately (CH, CRF, CCT, age, axial length of the eye, spherical equivalent), but only CH and CRF influence significantly the IOP in the multiple regression model, possibly due to the connection of other factors with CH and CRF.

Non-contact tonometry (NCT)

Non-contact tonometers are type of applanation tonometers where the applanation is realized by a puff of air, i.e. without direct contact with the cornea, unlike by the GAT contact tonometer. The pressure caused by the puff is increased until the cornea is applanated over a predetermined area. The applanation is determined by optical means, by the usage of an IR (Infra Red) light source that is reflected to the dedicated detector when the eye surface in flattened. The time of applanation and the puff pressure are then used to compute the IOP.

The technical realization of this measurement leaves some factors that affect the determined IOP value. The factors that have a less significant affect on the measurements are the exact measurement of time and air pressure generation (specifically its consistency). The potentially more significant effect is the determination of the distance of the air stream source from the eye and the repeatability of the ideal distance. The most severe factor is without the doubt the evaluation method that determines the IOP pressure. The manufacturers use algorithms to calculate the IOP from multiple quantities (pressure, time, eye tissue flexibility model etc.) that are unknown to the metrological community. This leaves a significant grey area for error in the calculation of the ‘’true’’ IOP value. Based on the previously mentioned technical factors that affect the non-contact measurements of IOP the need for a reference standard to test these devices is evident and much desired.

In the previous paragraph we have concentrated on the technical aspects of the measuring devices and the possible influences originating from the measurement device itself. Other sources of influential factors that are connected with eye imperfections and biological effects are discussed further.

If compared with the GAT, an additional source of error is that the IOP is determined in a very brief instance of time and the IOP can pulsate over time with the cardiac cycle (Queiros et al., 2006). These changes can reach the values of up to 5 or 6 mmHg within one second for some individuals (Kirstein, Elsheikh, & Gunvant, 2011). Recent studies have shown that NCT results are influenced by CCT (for example see Matsumoto et al., 2000; Eysteinsson et al., 2002; Tonnu et al., 2005; Harada et al., 2008; Firat et al., 2013). It has been discovered that the measured IOP is higher in the case of thicker corneas. If compared with the GAT, the NCT are more affected by CCT than the GAT (Matsumoto et al., 2000; Harada et al., 2008). In contrast to the GAT, the NCT readings seem to be independent on the central corneal curvature for normal (physiological) corneas (Eysteinsson et al., 2002; Harada et al., 2008; Firat et al., 2013). The IOP can be markedly influenced by corneal abnormalities and refractive surgery. For example, the readings of NCT as well as the GAT are affected by keratoconus (one of the most frequent corneal degenerations) (Firat et al., 2013). In this case, the IOP values measured by both the NCT and the GAT are significantly influenced by CCT, the thinnest corneal thickness, the curvature and the posterior curvature. The most common refractive surgery is LASIK. The IOP is significantly lower after LASIK (for example Arimoto et al., 2002); the decline of the IOP correlates with the corrected diopter value, surgery-induced changes of CCT and changes of corneal curvature. Thus, the IOP after LASIK must be corrected; according to (Jethani et al., 2016) results, the Ehler’s correction algorithm (Ehlers, Bramsen, & Sperling, 1975) can be used within the normal IOP range for a majority of patients.The CCT was considered the main factor influencing the IOP readings by NCT for a long time. Some modern tonometers like ORA (Ocular Response Analyser, Reichert) or Corvis ST (OCULUS) provide parameters that are indicative of the biomechanical properties of the cornea such as corneal hysteresis CH, corneal resistance factor CRF etc. (e.g. Luce, 2005; Medeiros & Weinreb, 2006). It seems that biomechanical properties affect the IOP measurement more than CCT (e.g. Kotecha et al., 2006). Medeiros & Weinreb (2006) found out that the IOP corrected regarding the cornea biomechanics (cornea-compensated IOP) were not associated with the corneal properties, especially with CCT. In contrast, Martinez at al. (2006) presented a significant dependence of a cornea-compensated IOP on CCT. The cornea-compensated IOP seems to be unaffected by astigmatism (Hagishima et al., 2010). Some corneal surgery can influence the effect of biomechanical properties on the IOP readings as observed for example after penetrating keratoplasty (Feizi & Pakravan, 2012).

Summary of RBT and NCT

The measurement of IOP by NCT and RBT tonometers is affected by many parameters. In the case of eyes with normal corneas and with a normal IOP range, the most important are CCT and biomechanical properties of the cornea, such as CH and CRF. The effect of other corneal parameters, such as the corneal curvature or astigmatism are not so strong. The effect of the CCT seems to be caused primarily by other biomechanical properties (CH, CRF), which are in close relationship with the CCT. The corneal surgery, especially refractive surgery, such as LASIK, or corneal abnormalities (e.g. keratoconus) change CCT and biomechanical properties and cause changes in the IOP readings. Both considered methods realize the measurement in very short time and can be influenced by time-dependent fluctuations of the IOP caused by cardiac rhythm.

Factors affecting the IOP immediately before the measurement

The IOP is determined by the production and outflow of the aqueous humor. These processes (and also the IOP) are affected by many external and internal factors. The results of an IOP measurement can be markedly affected especially by factors with a relatively quick incidence (short-term factors) as are physical activities (for example see Rowe et al., 1976; Krejci et al., 1981; Marcus et al., 1970; Price et al., 2003; Shapiro et al., 1978; Rowe et al., 1976; Najmanova et al., 2016; Moura et al., 2002), hypoxia (Karadaq et al., 2008; Roach et al., 2006; Ersanli et al., 2006; Nebbioso et al., 2014; Cymermann et al., 2000; Bayer et al., 2004), head position (Karim et al., 2012), hydration (Idu et al., 2015; Hunt et al., 2012; Read et al., 2010) and consumption of coffee or energy drinks (Avisar et al., 2002; Chandrasekaran et al., 2005; Ilechie et al., 2011), pupil size (Rutkowski et al., 1972) and accommodation (Armaly et al., 1961). Another important factor is diurnal rhythm (Wilensky et al., 1993).The effects of physical activity on the IOP are still under examination. It is known that the IOP increases considerably during resistance exercise (McArdle et al., 2014). The effect is further magnified by holding of breath during the lift (McArdle et al., 2014). Previous investigations have shown that the IOP decreases during (Rowe et al., 1976; Krejci et al., 1981) and immediately after short moderate aerobic exercise (Marcus et al., 1970; Price et al., 2003; Shapiro et al., 1978; Rowe et al., 1976; Najmanova et al., 2016) (such as walking upstairs etc.). The decrease persisted up to minute five and minute ten after the exercise completion (Najmanova et al., 2016). The magnitude of the IOP reduction increases with exercise intensity (Kiuchi et al., 1994). Additionally, a positive relationship between the initial IOP and the magnitude of its decrease after exercise has been also reported (Najmanova et al., 2016; Ashkenazi et al., 1992; Leighton et al., 1970; Becker et al., 1955; Stewart et al., 1970) as well as a correlation between the magnitude of the decrease and the initial heart rate (Najmanova et al., 2016). The underlying mechanism of this response is still poorly understood. It seems that hypoxia affects the IOP, although published studies did not find unanimous results. Some observations show increase of the IOP (Ersanli et al., 2006; Karadak et al., 2008; Sommer et al., 2007; Bosch et al. 2010), whereas other experiments presented decrease (Cymerman et al., 2000; Pavlidis et al., 2006). Bayer et al. 2004 reported no significant changes. The effect vanishes during acclimatization (Pavlidis et al., 2006; Sommer et al., 2007; Bosch et al., 2010; Cymerman et al., 2000). All the observed changes were evaluated as clinically insignificant with regard to the eye health. In the presented studies, the effect of hypoxia was joined with the atmospheric pressure decrease (hypobaric hypoxia) as happened with the sea level change. Thus, the separate effect of both considered factors is unknown and should be subject to other research. In some cases, it is necessary to measure the IOP when the subject is in a lying

position. The significant increase of the IOP was reported when lying compared to sitting up (Karim et al., 2012). Since some patients (e.g. in ward block) may change their posture (and the head position) immediately before measurement, it is important to study the time progress of the IOP changes induced by the body posture and the corresponding head position. Dehydration of body causes significant IOP decrease (Hunt et al., 2012; Idu et al., 2015), whereas water retention in the body leads to IOP increase as well as consumption of coffee and energy drinks (Read et al., 2010; Avisar et al., 2002; Chandrasekaran et al., 2005; Ilechie et al., 2011).The pupil dilation leads to IOP increase (Rutkowski et al., 1972). Thus, all activities or drugs affecting the pupil size could potentially affect the IOP too, for example a stay in the dark or emotional stress. The effect of accommodation is not unanimous and depends on the refractive error (Yan et al., 2014; Armaly et al., 1961). The IOP of given subjects depends on its diurnal rhythm (Wilensky et al., 1993; Duke-Elder et al., 1952). The subjects can be divided into two groups (Duke-Elder et al., 1952) with one-phase or two-phase regime. Depending on the regime, the IOP reaches its maximum early in the morning or in the afternoon. Thus, if the IOP values from different days are compared, this dependence should be respected.

Conclusion

Within this report that deals with the most influential factors on IOP measurements we have shown multiple factors that affect the measured values of IOP. The origin of these factors was from the measurement device principle itself as well as from the biological aspects. Multiple typical representatives of both contact and non-contact IOP measurement methods were analyzed and specific critical influential factors were determined. Throughout the measuring methods and used devices the factors that affect the ''true'' measured IOP vary, but there is one component that is common to all of these devices, and that is the lack of a calibration standard that is independent from the manufacturer that could set the difference from the ''real'' pressure and the indicated pressure by the individual IOP measuring devices. By having a universal calibration procedure and standard for all types IOP measuring devices (or most commonly used types) we could determine their measurement uncertainty. This would make a direct comparison of the measurement methods (by a specific device) possible by the means of calibration standard. This possibility to calibrate the IOP measuring devices would increase the confidence in the measurement of IOP by the means of introducing uncertainty to the measurements, thus reducing the number of possible miss treatment of patients with IOP pressures on the boundary values that would indicate a glaucoma condition. Furthermore the possibility of comparing the IOP measurements would be valuable for medical experts as a source of reliable data for future research in this area. In order to ensure that the IOP measuring devices (used in medical practices on base of which medication is prescribed) are calibrated and deliver a precise and reliable measurement of IOP, a legislative action that would set a compulsion calibration of these devices in set interval should be realized.

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