ABSTRACT

Introduction: Physiotherapists commonly use the manual inclinometer and Flexicurve for the clinical measurement of thoracic spinal posture. The aim of this study is to examine the concurrent validity of the Flexicurve and manual inclinometer in relation to the radiographic Cobb angle for the measurement of thoracic kyphosis. **Methods:** Eleven subjects (7 males, 4 females) underwent a sagittal plane spinal radiograph. Immediately following the radiograph, a physiotherapist measured thoracic kyphosis using the Flexicurve and manual inclinometer before the subjects moved from position. Cobb angles were subsequently measured from the radiographs by an independent examiner. **Results:** A strong correlation was demonstrated between both the Cobb angle and the Flexicurve angle (r=0.96) and the Cobb angle and manual inclinometer angle (r=0.86). On observation of the Bland-Altman plots, the inclinometer showed good agreement to the Cobb angle (mean difference 4.8°±8.9°). However, the Flexicurve angle was systematically smaller than the Cobb angle (mean difference 20.3°±6.1°), which reduces its validity. **Conclusion:** The manual inclinometer is recommended as a valid instrument for measuring thoracic kyphosis, with good agreement with the gold standard. While the Flexicurve is highly correlated to the gold standard, they have poor agreement. Therefore, physiotherapists should take caution when interpreting its results.

INTRODUCTION

Thoracic hyperkyphosis is a curvature of the thoracic spine of greater than 40º in the sagittal plane (Bansal et al., 2014). It is commonly observed among individuals of all age groups and has been implicated in a range of negative health consequences. Thoracic kyphosis generally appears to increase with age (Fon et al., 1980) and is estimated to affect 20-40% of older adults (Takahashi et al., 2005). An increase in thoracic kyphosis may be the visible manifestation of a pathological process such as Scheuermann’s disease during adolescence, it can result from postural habit (Gravina et al., 2012) or it may be a normal physiological response to aging (Willner, 1981).

An extensive array of impairments have been associated with thoracic hyperkyphosis, which include a slowing of gait, reduction in balance and increased risk of falls (Sinaki et al., 2004). Increases in thoracic kyphosis has also been associated with impairments in the musculoskeletal system including cervical pain (Griegel-Morris et al., 1992), shoulder pain (Gumina et al., 2008) and lower back pain (Ensrud et al., 1997). These are all commonly encountered in physiotherapy practice.

These negative health consequences place importance on the measurement of thoracic kyphosis by physiotherapists. It drives the need for valid and reliable measurement tools for the purposes of screening, monitoring and assessing intervention in patient populations. The gold standard measurement for thoracic kyphosis is the Cobb angle, calculated from a sagittal plane spinal radiograph (Harrison et al., 2001). However, the limitations of radiographic measurement, including expense (de Oliveira et al., 2012), limited portability, time-consumption and exposure to ionising radiation (Briggs et al., 2007; Teixeira and Carvalho, 2007), make it unsuitable for use in physiotherapy practice.

A previous systematic review highlights the diverse range of non-invasive measurement devices which facilitate the measurement of thoracic kyphosis in clinical practice (Barrett et al., 2014). This review identified the Flexicurve and manual inclinometer as cheap, simple tools which permit a quick clinical measurement of thoracic kyphosis. Both tools have previously demonstrated excellent levels of intra-rater and inter-rater reliability (Teixeira et al., 2007; Barrett et al., 2013; Lewis and Valentine, 2010; van Blommestein et al., 2012). However, the validity of the manual inclinometer has not been investigated to date.

The primary output of the Flexicurve is a kyphosis index. Attempts have been made to translate the Flexicurve index into a corresponding Flexicurve angle, to aid comparison with the radiographic Cobb angle (Greendale et al., 2011; Teixeira and Carvalho, 2007; Azadinia et al., 2014). Greendale and colleagues proposed a simple translation formula which provides an approximate angle of thoracic kyphosis without the need for specialised software and have demonstrated its correlation with the Cobb angle in older adults with thoracic hyperkyphosis (Greendale et al., 2011). However, the level of correlation and agreement in a younger, healthier population has yet to be established.

Therefore, the aim of the present study was to determine the concurrent validity of the Flexicurve and manual inclinometer as a measure of thoracic kyphosis by comparison with the gold standard.

METHODS

Subjects

A cross-sectional study design was carried out. The study sample was patients attending a spinal orthopaedic clinic for the purpose of a spinal radiograph and orthopaedic consultation. The exclusion criteria were as follows: (i) under the age of 18 years, (ii) not referred for a lateral spine radiograph, (iii) unable to stand independently and (iv) a documented history of vertebral compression fracture. Ethical approval was granted by the University Hospital Limerick Research Ethics Committee. All subjects provided written informed consent.

Instrumentation

Two gravity-dependent inclinometers (Isomed, Inc., 975 SE Sandy Boulevard, Portland, OR, USA) were used. The feet of the inclinometers were 2.5 cm apart, which remained constant for all subjects. The Flexicurve (TridentR) is a flexible plastic-covered metal ruler, 60 cm in length, marked at 1 mm intervals.

Preparation

Initial preparation included the identification of the spinal landmarks required for skin-surface thoracic kyphosis measurement. For this, the subject was positioned in relaxed standing and the spinous processes of C7, T1, T2, T12 and L1 were identified by palpation and marked with an erasable pen. The interspinous space of L3/4 was identified at the level of the iliac crests (Chakraverty et al., 2007) and the L1 and T12 spinous processes were marked by palpating superiorly from this reference point (Palastanga et al., 2007). The 7th cervical vertebra was designated to have the most prominent spinous process (Palastanga et al., 2007). Palpating inferiorly from this reference point, the T1 and T2 spinous processes were identified and marked (Lewis and Valentine, 2010).

Radiographic measurement

The radiographic assessment was performed by a radiographer using a device made by *Siemens*, X-ray film from *Fuji Films* and a processor from *Kodak*. The same radiographer took all of the radiographic images. For the thoracic spine the focus was maintained on the seventh costal arch. In order to avoid the thoracic spine image being overlapped by the upper limbs, the shoulder and elbow were positioned at 90º flexion by the participant holding onto a bar in front of them. As the radiograph was being taken, the subject was instructed to stand in their normal relaxed posture and to hold their breath.

Afterwards, an experienced orthopaedic consultant, who was not involved in taking the radiographic images, calculated the Cobb angle using the digital radiographic images. The two-line Cobb method was used to obtain the thoracic kyphosis angles. This method consists of tracing two straight lines, one extending from the T4 upper endplate and the other extending from the T12 lower endplate, respecting the inclination of the vertebrae. The Cobb angle is formed where these lines meet (Harrison et al., 2001; Goh et al., 1999).

Flexicurve and manual inclinometer measurement

Non-invasive measurement of thoracic kyphosis was carried out by a physiotherapist with three years of experience using these tools for research purposes. The order between the Flexicurve and manual inclinometer measurement was determined for each subject individually by a coin toss. Both were measured directly after the X-ray, before the subject moved out of position. The tip of the Flexicurve was placed at C7 and was moulded to the contour of the thoracic spine in a caudal direction. The Flexicurve was then carefully transferred to paper and the curve was outlined. This process was repeated three times, being flattened between each measurement. Both the kyphosis index and Flexicurve angle were later calculated using the formulae, as described in Figure 1.

For the inclinometer measurement, the feet of the inclinometers were placed over the spinous processes of T1/T2 and T12/L1. The readings were read directly from the inclinometers and recorded. Inclinometer measurements were performed three times in succession and an average was used for analysis (Lewis and Valentine, 2010; van Blommestein et al., 2012). These protocols for both the Flexicurve and manual inclinometer measurement of thoracic kyphosis were previously shown to have excellent levels of inter-rater and intra-rater reliability (Barrett et al., 2013).

Data analysis

Data were analysed using SPSS software, version 22.0 for Windows (SPSS, Inc., Chicago, IL, USA). Data were non-normally distributed (Shapiro-Wilks, $p<0.05$). Spearman's rank correlation coefficient (r_S) was used to establish the linear relationship between the Cobb angle and both the Flexicurve angle and inclinometer angle. The values of r_S were classified as: strong (>0.5), medium (from 0.3 to 0.5), small (from 0.1 to 0.3) and none (<0.1) (Cohen, 1988). Bland-Altman analysis was carried out to graphically display the level of agreement between the measures. In the Bland-Altman plot, the mean of the two paired angles are plotted on the x-axis and their differences are plotted on the y-axis (Bland and Altman, 1986). These plots include approximate 95% confidence intervals.

RESULTS

Eleven subjects (seven male, four female), with a mean±SD age of 40.9±20.1 years and body mass index of 24.4±5.4 kg/m^2 participated in the study. Six participants presented with a primary complaint of low back pain, four with thoracic pain and one with inter-scapular pain. Table 1 displays a description of thoracic kyphosis values obtained from the Cobb angle, inclinometer angle, Flexicurve angle and Flexicurve index. The mean±SD Cobb angle was 52±15.2°. The mean±SD inclinometer angle was comparable to the actual Cobb angle (47.2±17.7°). As demonstrated previously in older, hyperkyphotic patients (Greendale et al., 2011), the Flexicurve angle averaged about 21° less than the Cobb angle (31.7±19.2°). Both the manual inclinometer and the Flexicurve demonstrated strong levels of correlation to the Cobb angle (Cobb and inclinometer angles r_s=0.86, p=0.001; Cobb and Flexicurve angles r_s=0.96, $p<0.001$).

Figure 2 (a) and (b) displays Bland-Altman plots for the Cobb angle with both the manual inclinometer angle and the Flexicurve angle respectively. The differences were normally distributed (Shapiro-Wilks $p>0.05$) and so the assumptions of the Bland-Altman plot were satisfied. Both plots demonstrated wide 95% confidence intervals, which may be principally related to the small sample size used. Neither plot demonstrated proportional bias (Cobb and inclinometer angles p=0.60; Cobb and Flexicurve angles p=0.67) and the spread of the differences remained relatively consistent across the range of thoracic kyphosis magnitude. The Bland-Altman plots demonstrated that the manual inclinometer had good agreement with the Cobb angle (mean difference±SD = 4.8±8.9°), unlike the poor agreement between the Flexicurve angle and Cobb angle (mean difference±SD 20.2±6.1°). Figure 3 displays a graphical comparison of the Cobb angle and the paired manual inclinometer angle and Flexicurve angle obtained for each subject.

DISCUSSION

Main findings

This study established the level of validity of two commonly used physiotherapy tools, the Flexicurve and manual inclinometer, for measuring thoracic kyphosis in reference to the gold standard method, using both correlation and agreement. The manual inclinometer demonstrated a strong correlation and good level of agreement with the gold standard. Although there was a mean difference of 4.8º between the manual inclinometer and the Cobb angle, the clinical importance of this difference should be judged according to the purposes of the measurement. This mean difference is larger than the standard error of measurement for the inclinometer, which was previously demonstrated to be 2.2º (Barrett et al., 2013). This indicates sources of error beyond measurement error. The mean difference between the manual inclinometer angle and Cobb angle observed in this study is similar to the differences reported for other clinical measurement devices. Previous studies have reported mean differences from the Cobb angle measurements of 1.4º-2.9º for the arcometer (D'Osualdo et al., 1997; Chaise et al., 2011), 5º for stereovideography (Leroux et al., 2000) and 2.3º -2.8º for the Debrunner kyphometer (Greendale et al., 2011; Korovessis et al., 2001). The observed discrepancy between the radiographic and skin-surface measurements could be attributed to the distortion of the contour of the thoracic spine by intervening soft tissue. Additionally, the Cobb angle itself is not without error, as intrinsic error associated with the Cobb measurement technique has been accepted to be approximately 5º (Morrissy et al., 1990) and individual differences can be as large as 30º (Carman et al., 1990). The primary source of error in calculating the Cobb angle appears to be the difficulty in identifying the bony landmarks accurately on the radiographic image (Carman et al., 1990). However, the Cobb angle is still accepted as the gold standard due to its simplicity and clinical meaningfulness.

This is the first study to report an estimate of the validity of the manual inclinometer. However, one previous study demonstrated that the digital inclinometer had acceptable validity in individuals with thoracic hyperkyphosis who are less than 30 years (ICC= 0.89) and greater than 50 years old (ICC= 0.81) (Azadinia et al., 2014). However, measures of agreement were not provided in that study (Azadinia et al., 2014). Therefore, direct comparison between these results and the present study cannot be made as different statistical methods and study populations were used. However, it is reassuring that the manual inclinometer showed comparable levels of validity to the digital inclinometer even though judging the reading from the manual inclinometer may serve as an additional potential source of error.

The method of Flexicurve angle calculation used in this study was strongly correlated with the Cobb angle. Importantly, correlation quantifies the degree to which two variables are related but a high correlation does not imply that there is good agreement between the two methods (Geravarina, 2015). When the measure of agreement was graphically displayed using a Bland-Altman plot, it was evident that large mean differences existed. The method of Flexicurve angle calculation used in this study produced angles which were systematically smaller than the radiographic Cobb angles. This finding is in agreement with a previous study which used an older, hyperkyphotic sample (Greendale et al., 2011). In contrast, Greendale et al.,. (2011) demonstrated lower correlation of the Flexicurve angle with the Cobb angle, which varied from r=0.67 to r=0.76. One explanation of the higher correlation coefficient demonstrated in this study might be the fact that the measurement of thoracic kyphosis using the non-invasive tools directly followed the radiographic procedure, before the subject moved from position. This is in contrast to the previous study which took all measurements within a

4 hour window (Greendale et al., 2011). This leaves the potential for variability in resting standing posture between measurement times.

Other methods of Flexicurve angle calculation have also been suggested. Two studies followed a method using a third degree polynomial formula (Teixeira and Carvalho, 2007; Azadinia et al., 2014). One of these studies reported strong validity (ICC=0.91) and mean differences of 0.8º, when the mean of two measurements was used for the analysis in a healthy population (Teixeira and Carvalho, 2007). However, a subsequent study demonstrated a much lower ICC of 0.50-0.51 when comparing this third degree polynomial formula to the Cobb angle in older adults and children with hyperkyphosis (Azadinia et al., 2014). Therefore, the validity of this technique in people with thoracic hyperkyphosis is questionable. One study which used a Cartesian coordinate system to calculate a Flexicurve angle reported high correlation (r=0.7) and an absolute mean difference of 6.5º ±4.7º (de Oliveira et al., 2012). This mean difference between the Flexicurve and Cobb angle is smaller than demonstrated in the present study. However, as this method requires advanced calculations and specialised software, it may not be appropriate for everyday clinical use.

At present, there is no method which allows for the accurate translation of the Flexicurve index into a corresponding Cobb angle with close agreement. The reason for this is that the Flexicurve is designed to measure spinal curve using the contour of full thoracic spine, whereas the Cobb angle depends on the vertebrae at the limits of the curve. The Flexicurve may show higher agreement with the centroid angle, which computes thoracic kyphosis using the midpoints of all vertebral bodies from T1–T12. Further research is required to investigate this.

Implications for practice

The strong validity of the manual inclinometer demonstrates that it is an appropriate tool to aid physiotherapists in monitoring thoracic kyphosis over time and when determining the effectiveness of intervention strategies. Further, it is readily accessible to physiotherapists, relatively cheap and has high reliability. As the inclinometer angle relies totally on the two selected vertebral levels, deformities at these selected endplates may overestimate the degree of thoracic kyphosis. Therefore, the manual inclinometer may potentially be more suitable for use in healthy populations. Future research should consider establishing the validity of the manual inclinometer specifically in people with osteoporosis.

The Flexicurve allows for the provision of visual feedback to the patient which enables a qualitative evaluation of postural deviation. This attribute of the Flexicurve can aid postural retraining in patient populations. It can also permit the longitudinal study of change in thoracic kyphosis induced by disease progression or therapeutic intervention. However, physiotherapists should be aware that the method used in this study to calculate a Flexicurve angle is not in agreement with the gold standard.

Limitations

This study has strengths including the skin-surface measurements directly after the radiographic procedure and the consideration of both correlation and agreement to provide an accurate reflection of validity. However, similar to other validation studies of thoracic kyphosis measurement devices (Perriman et al., 2010; Ripani et al., 2008), the number of participants in this study was small due to ethical considerations regarding radiation exposure. Although the method of Flexicurve and manual inclinometer measurement described here reflects how the tools are used clinically, the reliability of skin-surface palpation of bony landmarks has been debated in the literature (Lewis et al., 2002).

CONCLUSION

In summary, the manual inclinometer has been demonstrated to have strong concurrent validity when compared to the gold standard Cobb angle technique. This is an important finding for physiotherapists who require a simple, cost-effective, reliable and valid tool for use in clinical practice as either a screening tool or for longitudinal assessment of thoracic spine posture. The Flexicurve angle has a strong correlation with the Cobb angle but demonstrates poor agreement. Therefore, the Flexicurve angle, as calculated here, cannot be regarded as a valid measurement of thoracic kyphosis.

Declaration of interest

The authors report no declarations of interest.

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