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COMPARING ACTIVE PHASE ASSESSMENT OF CERVICAL DILATATION BY OBSTETRIC CLINICIANS USING FOAM MODELS

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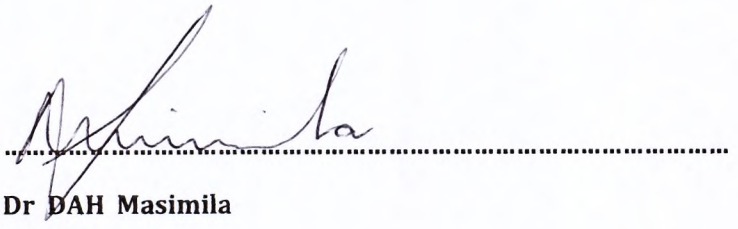
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DECLARATION

I, Davinia Alpharita Helene Masimila, declare that this research report is my own work. I am submitting this research dissertation for the degree of Masters of Medicine at the University of the Witwatersrand, Johannesburg.



Dr DAH Masimila

01 Day of February 2017

DEDICATION and ACKNOWLEDGEMENTS

This work is dedicated and written in honour and memory of my grandfather, Willem Masimila. I stand tall because of your character of courage and to never give up for what you believe in ....and for that I thank you.

I would like to thank my supervisor, Prof Eckhart Buchmann , for his supervision and unfailing support and assisting me for making this research report possible.

I also want to thank the medical staff and my colleagues in the Obstetrics and Gynaecology department of the University of the Witwatersrand for taking the time to be part of this research study. It' is appreciated.

Lastly I want to thank my husband, Henry Alexander and especially my parents, David and Lena Masimila, for their support and prayers as well as constant guidance. I am forever thankful.

TABLE OF CONTENTS PAGE

DECLARATION 2

DEDICATION & ACKNOWLEDGEMENTS 3

LIST OF TABLES AND FIGURES 6

ABSTRACT 7

1. INTRODUCTION 9

2. LITERATURE REVIEW

2.1 The cervix and uterus during pregnancy and labour 10

2.2 Technique of vaginal examination during labour 10

2.3 Clinical indications for and frequency of cervical assessment in labour 12

2.4 Accuracy of digital assessment of cervical dilatation 13

2.5 Other clinical methods for clinical estimation of cervical dilatation 14

2.6 The use of partogram during labour 16

2.7 Technology in assessment of cervical dilatation

2.7.1 Cervimeters 17

2.7.2 Position tracking systems 18

2.7.3 Devices to measure cervical length 19

2.7.4 Ultrasound 19

2.7.5 Computerized sensor system devices to monitor labour progress 21

2.7.6 Training to improve the skill of cervical assessment 22

3. MOTIVATION FOR THE STUDY

3.1. Problem Statement

3.1.1 Aim of the study 25

3.1.2 Objective 26

4. METHODS

4.1 Study design and study population 27

4.2 Sampling and recruitment 27

4.3 Conduct of the experiment 27

4.4 Data collection 31

4.5 Ethics 32

5. RESULTS 33

6. DISCUSSION 39

7. REFERENCES 42

8. APPENDICES

8.1. Data Sheet 46

8.2. Ethics Clearance Certificate 47

LIST OF TABLES AND FIGURES PAGE

Table 1	Characteristics of participants who estimated cervical dilatation on the models (n=81)	33
Table 2	Cervical dilatation of models, with mean error and standard deviation of each centimetre measure of dilatation. Negative mean error indicates underestimation of models cervical dilatation	34
Table 3	Mean error, with standard deviation of the models, for each of the professional ranks (n=81). Negative mean error indicates underestimation of the model cervical dilatation.	36
Table 4	Proportions with percentages of exactly correct estimates and estimates correct to within 1cm, by professional ranks of the participants.	37
Table 5	Comparison of proportions of estimates exactly correct and correct within 1cm of model cervical dilatation, between medical students or interns, and registrars (p values obtained using Chi squared test).	37
Table 6	Comparison of proportions of estimates exactly correct and correct within 1 cm of model cervical dilatation, between registrars and consultants (p values obtained using Chi-squared test).	37
Table 7	Univariate logistic regression for possible predictors of exactly correct estimation of cervical dilatation in the models.	38
Table 8	Univariate logistic regression for possible predictors of model cervical dilatation estimates correct to within 1 cm.	38
Figure 1	PVC simulation models with cervical dilatations ranging from 3- 6 cm.	28
Figure 2	PVC simulation models with cervical dilatations ranging from 7 - 9 cm.	29
Figure 3	Frequency distribution of mean error in cervical dilatation estimation (n=81).	35
Figure 4	Brown blanket with a hole in the centre covering the artificial introitus of the PVC simulation models.	29
Figure 5	Top view of a PVC simulation model covered with a brown blanket with a hole in the centre covering the artificial introitus.	30
Figure 6	Each PVC simulation models marked with the correct dilatation in centimetres to the side of the researcher to compare with the participant's findings.	30

ABSTRACT

Introduction

Digital vaginal examination is the gold standard to assess cervical changes during labour and accurate cervical estimation plays an important role to monitor labour progress. This study was done to determine how the level of experience amongst medical students, interns, registrars and consultants influences accuracy in estimating cervical dilatation by using foam models. The objectives for this study were: 1) determining accuracy of cervical dilatation estimation, with respect to predetermined dilatations of foam models; and 2) to compare accuracy of cervical dilatation between clinicians with different levels of experience by using the foam models.

Methodology

Medical 6th year students, interns, registrars (1st to 4th year) and consultants were involved in this cross sectional analytic study. Participants estimated cervical dilatation in foam models of the cervix covering a plaster of Paris mould of the fetal head, which was encased in a PVC pipe of 10 cm diameter. Seven models with fully effaced simulated cervices were used at exact different dilatations of 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm and 9 cm respectively.

Results

Of the 81 participants, 35% (28/81) provided exactly correct model cervical dilatation estimates while 15% (12/81) underestimated by 1 cm and 21% (17/81) overestimated by 1 cm. The overall accuracy improved to 70% when an error of ±1cm was allowed. Medical students and interns (n=23) underestimated cervical dilatation by a mean of 0.27 cm, while registrars and consultants overestimated by a mean of 0.27 cm (p=0.13). Registrars (n=33) were significantly more frequently correct to within 1 cm (85% of examinations) than consultants (n=15) (53%; p=0.019) and medical students or interns (n=33) (64%; p=0.049). The study showed no other statistically significant differences between groups and could not identify any factors to account for differences in over- or underestimation, or accuracy.

Conclusion

Cervical dilatation estimation obtained by digital examination are precise when an error within ± 1 cm is allowed. Simulation training can be a valuable addition in the routine training of junior staff to improve clinical skills to master accuracy of cervical dilatation measurements.

1.INTRODUCTION

Estimating cervical dilatation plays a pivotal role in monitoring the progress of normal labour. Digital vaginal examination is the current gold standard for assessing cervical changes during labour. Cervical dilatation is assessed manually by obstetricians and midwives. To an extent, such assessment is subjective with several limitations, which is of concern when making decisions to ensure successful delivery. The invasive and discomforting nature of vaginal examination demands that assessment of vaginal examination is done correctly, and only when necessary. These concerns have brought some technological advances to improve the accuracy and objectivity of cervical dilatation assessment. Ultrasonic, electronic and other devices have been developed with the purpose of providing user-friendly bedside methods to replace or augment traditional digital assessment.

For as long as digital cervical assessment remains the method of choice, its limitations need to be recognised and clinical training needs to consider sources of inaccuracy. Clinical experience is likely to be an important predictor of accuracy. This study was done to determine how clinical experience influences accuracy in estimating cervical dilatation.

2.LITERATURE REVIEW

2.1. The cervix and uterus during pregnancy and labour

The trigger of labour is thought to be the fetus. The mature fetal brain provokes the release of corticotrophin from the fetal pituitary gland. This in turn stimulates the fetal adrenal glands to release cortisol and dehydroepiandrosterone sulphate (DHEAS). The cortisol indirectly stimulates the release of prostaglandin E2 from the amnion. This has a direct influence on the cervix, especially the internal os, which is close to the fetal membranes.[1]

The myometrium drives human labour through a co-ordinated set of forces. The aim is to efface and dilate the cervix. There is a close interaction between the uterine corpus and cervix during labour. During labour the uterus contracts while the cervix yields. Before delivery of the fetus, the cervix softens, shortens and dilates. The cervix is generally 3 cm long and 2.5 cm in diameter, but these dimensions vary depending on the woman's age, parity and menstrual cycle. Magnetic resonance imaging and ultrasound studies suggest that the internal os of the cervix is essential to normal cervical function. Close to labour onset, the internal os undergoes ripening to initiate effacement. DHEAS is metabolized in the placenta to enhance oestradiol levels. This provokes the release of prostaglandin F2-alpha from the decidua, which initiates myometrial contractions.[1]

2.2. Technique of vaginal examination during labour

Vaginal examination is done digitally, usually with the right index and middle fingers, using an antiseptic vaginal cream or lubricant. The examiner should take time to explain the procedure to the labouring woman and warn that it might be an uncomfortable experience. The woman should only be exposed once the examination will be performed. The vaginal examination during labour not only involves assessment of the cervical status, but also examination of the

vulva and vagina. Information regarding the membranes, presenting part and pelvic adequacy should also be provided. The abdominal examination of the gravid uterus, together with the vaginal examination, completes the obstetric clinical assessment.[2]

When examining the cervix, the most important information recorded is the length and dilatation. The length is the distance from the internal os of the cervix to the external os, estimated in centimetres. Indirect estimation from the lateral vaginal fornix may be necessary if the external os does not admit a finger. Dilatation of the cervix is also estimated in centimetres, as the diameter from rim to rim. This is theoretically easy in the active phase of labour, when the cervix is fully effaced. In the researcher's experience, two mistakes are often made by examiners: 1) when the cervix is thin or fully effaced, it might be difficult to feel and the uterine wall will be mistaken for the cervical rims, thus overestimating cervical dilatation; and 2) the cervical rim may be stretched by the examiner, also with overestimation of cervical dilatation. It is likely that these errors occur more frequently with inexperienced examiners.

In a recent midwifery text book by Chapman and Charles, common pitfalls or limitations that can occur when doing a digital vaginal examination in labour include:[3]

- In multigravid women, cervical assessment is not always reliable
- Cervical assessment may be affected by a full bladder
- A thickened anterior lip of the cervix may be present at full dilatation of the cervix, leading to incorrect assessment
- An oedematous cervix may result in underestimation of effacement and dilatation, while itself being a possible indication of premature bearing down or obstructed labour
- A shrinking or collapsed cervix may transiently follow artificial rupture of membranes, and may also be observed in occipito-posterior positions. Dilatation may be underestimated.

2.3. Clinical indications for and frequency of cervical assessment in labour

Vaginal examinations are invasive and uncomfortable, and the benefit gained from cervical assessment should make up for the discomfort caused. Shepherd and Cheyne[4] investigated the frequency and reasons for vaginal examinations performed by midwives in labouring women. This prospective study recruited 144 pregnant women either in spontaneous labour or admitted for induction of labour. The number of vaginal examinations per woman ranged from one to seven with a mean of 2.9; 70% of the women had more vaginal examinations carried out than expected. The reasons provided for performing multiple vaginal examinations included assessment of labour progress (51%), clinical assessment of labour onset (29%) and assessments prior to induction of labour and administration of analgesia (20%). Not surprisingly, the number of vaginal examinations was directly proportional to the length of the labour.

A literature review by Muliira et al.[5] showed that vaginal examinations were conducted too frequently during labour, with the concern that women in labour were assessed by different birth attendants at a time. The review also revealed that most labouring women experience pain, discomfort and embarrassment when frequent vaginal examinations are performed. When examined by a male health professional, women reported that the opportunity to refuse vaginal examinations was limited or not granted. This added to their experience of embarrassment and discomfort.[6] Muliira et al.[5] made several suggestions. These include judging the need to do a vaginal examination and ensuring correct and comprehensive assessments to avoid multiple or repeat examinations; also adopting effective communication skills between the health care provider and the woman, and respecting privacy, to reduce unnecessary distress associated with vaginal examination. The woman's fears and anxieties during the labour process should also be addressed. Specific non-verbal communication skills,

for example keeping eye contact, while performing a vaginal examination, can help to decrease the feeling of vulnerability. An important point made in this review was the ideal that the same health care provider should perform all vaginal examinations on the same patient wherever possible, not only to reduce discomfort, but also to reduce inter-observer variability and inaccuracy of cervical assessments.

Current national guidelines for maternity care in South Africa recommend four-hourly cervical assessments in the latent phase, and two-hourly assessments in the active phase of labour.[7] Therefore, midwives in South Africa are directed more by guidelines than by their own discretion on when to repeat a vaginal examination. The shift system in hospital midwifery care in South Africa also renders it impossible at times for the same midwife to do every vaginal examination in the same labouring woman.

2.4. Accuracy of digital assessment of cervical dilatation

Incorrect estimation of cervical dilatation can clearly lead to inappropriate clinical management decisions. Over-estimation of cervical dilatation may produce a false impression of good progress, and under-estimation may lead to inappropriate intervention when poor progress is falsely suspected. The importance of accurate assessment was shown in a recent study involving 500 low risk women in labour in Tanzania.[8] Misclassification of women between latent and active phase of labour resulted in higher neonatal unit admission rates.

During the 1990s, various studies were done to evaluate error in cervical dilatation assessment. Letic reviewed this topic and concluded that almost 90% of examiners' assessments would be correct when an error within 1 cm was allowed, but that only 50% would be exact to the cm.[9] Letic also highlighted that a shorter assessment interval time (2 hours instead of 4 hours), could more easily provide an incorrect conclusion on the dilatation

rate, resulting in unnecessary obstetric interventions. It has been pointed out, with some merit, that prolonged intervals between cervical assessments reduce the opportunity for incorrect vaginal assessments, but in turn have the disadvantage of delaying necessary interventions.[10]

Buchmann and Libhaber conducted a study at the Chris Hani Baragwanath Maternity Hospital in Soweto to assess the accuracy and inter-observer agreement of cervical assessments in about 500 women.[11] They found, as did Letic above,[9] that there was agreement in cervical dilatation measurement to within 1 cm or less in 90% of the assessments amongst registrars and consultants. However, junior staff (registrars with less than 2 years of experience) frequently overestimated cervical dilatation. The results suggested that cervical assessment is a skill that develops with training and experience, and that errors of inexperienced staff mostly involved overestimation.

The study was limited by the absence of a gold standard measurement, and also by assessing only specialist staff (obstetric and gynaecologic registrars) and not junior staff such as medical officers, interns or students.

2.5. Other clinical methods for clinical estimation of cervical dilatation

Rectal examination is an alternative way to assess cervical dilatation but it is no longer routinely used. Reis and Kroenig were the first clinicians to independently advocate rectal examinations during labour to assess progress.[12] Kroenig believed that the rectal approach provided a more accurate measure of cervical dilatation. Reis recommended that vaginal examinations in the labouring woman should only be reserved for operative vaginal deliveries. The risk of maternal and fetal infection was believed to be decreased when doing a rectal rather than a vaginal examination.[12]During the 1960s this concept of possible contamination

with vaginal examination was re-evaluated and no increased risk of infection was found.[13] By the 1980s rectal examination for cervical assessment was largely abandoned worldwide.

The 'purple line' is an anatomically-based observation frequently used by experienced midwives, and is considered to be a reliable non-invasive measure of labour progress. It arises from the anal margin and extends between the buttocks reaching below the sacrococcygeal joint, and is reported as being most visible at the onset of the second stage of labour. In 2010, Shepherd et al.[14] reported on a study involving 144 women to assess the presence of the purple line and to determine the relationship between the length of the purple line and cervical dilatation or descent of the fetal head. The authors reported that the line was present in 56% of labours, and that it lengthened on average from 5.3 cm in the latent phase of labour to 9.6 cm at 9-10 cm cervical dilatation. The appearance of the purple line is most likely the result of venous vasocongestion at the base of the sacrum caused by intrapelvic pressure as the fetal head descends. A recent study by Kordi et al. from Iran suggested that the purple line could be a useful adjunct to monitoring labour progress.[15] Authors reported that the purple line was present in 75% of labours, and that it had modest sensitivity and specificity in predicting labour progress and the second stage of labour.[15]

The purple line has obvious limitations as it only gives indirect information on cervical dilatation, and assumes a correlation between dilatation and venous vasocongestion. It also does not provide information regarding presentation and position of the fetus, effacement of the cervix and status of the membranes. The two studies that investigated the purple line were also limited by the subjective assessments of the birth attendants when digital vaginal examinations were done.

2.6. The use of the partogram during labour

The partogram is an inexpensive paper tool used in obstetrics to record labour information. It is widely believed that use of the partogram can improve labour outcomes.[16] The partogram is a graphic representation of labour that helps to identify complications, especially poor progress, that need intervention during labour.[17] Cervical dilatation is the main parameter used to record the progress of labour on the partogram labour graph. The partogram has even been referred to as the cervicograph by Philpott et al, who first described its use from Zimbabwe in the 1970s.[18]

The alert line on the cervicograph helps to detect the earliest signs of abnormal labour. The purpose of the alert line is to allow for transfer from a remote clinic to a hospital. The action line is drawn 4 hours to the right of the alert line and gives guidance for professionals to intervene, by labour augmentation or caesarean section, to improve labour progress. Correct placement of information on the partogram requires correct assessment of cervical dilatation. A cervical dilatation of 4 cm or more, is classified as active phase of labour, and is expected to progress at 1 cm dilatation increase per hour. Misclassification of labour phase as latent (3 cm or less) when it is truly active may result in incorrect management, such as prolonged observation and inaction when progress was truly expected. The opposite, when misclassifying latent phase as active phase, will result in unnecessary interventions. The skill of accurate cervical dilatation is a prerequisite for managing labour correctly.[19,20]

2.7. Technology in assessment of cervical dilatation

2.7.1. Cervimeters

Van Dessel et al.[21] in 1991 reviewed the history of methods for assessing cervical dilatation in labour. From 1956-1968 mechanical cervimeters were introduced in the form of callipers or string-type cervimeters. The callipers were equipped with a centimetre ruler at the distal end of the device to measure the distance between the cervical rims. The disadvantage of this calliper method was the use of heavy mechanical instruments, for example Kelly clamps, as they also caused obstruction making cervical assessment difficult. This led to the invention of electro-mechanical low weight cervimeters. These clips with potentiometers were attached to the cervix, and as the callipers moved during dilatation, an electrical signal was generated and recorded on a polygraph.

The string-type cervimeters cause change in the length of the strings as the cervix dilates and the signal is transmitted to a kymograph via a mechanical pulley-guided system. Another type of device discussed by Van Dessel et al. is an electromagnetic cervimeter used in the 1950s. This device works by attaching small induction coils to the opposing cervical rims, allowing cervical dilatation to be recorded via electrical currents sent from one coil to the other.

These historical methods of cervical dilatation assessment proved not feasible for clinical use. Some devices interfered with the actual cervical dilatation as well as increasing the risk of infection. The cervimeters were not practical for continuous monitoring of cervical dilatation and metal devices caused local injury to the cervix.[22]

2.7.2. Position tracking systems

Because of the potential for honest errors and bias in digital examination of cervical dilatation, focus has shifted to the use of more sophisticated technology to assess cervical dilatation and even fetal head descent. In 2009, Nizard et al. reported the use of a position tracking system in comparison with standard digital examination in 188 women in active phase labour.[23] The system uses a sensor attached to the examiner's gloved fingers and during the examination the device records the distance between the cervical rims in centimetres.

Given the precision of the technology, the position tracking system acted as a gold standard against which digital cervical dilatation estimates could be compared. In the study, the clinical digital assessment of cervical dilatation without the use of the position-tracking device was least accurate when the cervix was dilated from 6-8 cm. A possible limitation with the tracking system was dependence on the examiner touching the correct landmarks of the cervix when assessing dilatation. The system differs from previous devices in that it does not rely on sensor clips attached to the cervical rims, which may cause discomfort to the labouring woman. The position-tracking system still needs further evaluation for general clinical use. The authors suggested that it could at least serve as a teaching tool for digital cervical assessment.

The cervical dilatometer is a newly invented mechanical cervimeter that may help to improve inter-observer agreement of measurements and reduce the number of actual digital vaginal examinations. Taghizadeh et al.[24] tested this device using midwives as participants. The midwives put the rings of the cervimeter device on their gloved index and middle fingers and performed simulated cervical assessments on models. The study showed precise measurements at 4-5 cm dilatation, with the least precision from 8-10 cm. The authors claimed

that the device is an affordable, non-contact design which will not cause harm to cervical tissue. However, as with Nizard et al.'s cervimeter,[23] correct cervical assessment still depends on correct placement of the fingers at the cervical rim. Although the devices are considered 'affordable', they will certainly be more expensive than current clinical digital assessment. Real benefit will have to be shown in clinical trials before money can be spent on adopting such technologies at scale.

2.7.3. Devices to measure cervical length

Cervical length may be measured with another type of cervimeter known as the Cervilenz, a low cost disposable device that measures cervical length in women with preterm labour. Richard et al. compared cervical length findings between standard digital vaginal examination and Cervilenz. The aim of the study was to identify preterm labour in women with suggestive symptoms by making accurate cervical measurements. They found that digital cervical length findings were mostly underestimated and correlated poorly with the Cervilenz findings. In 36% of cases, the digital cervical length was measured 1 cm shorter compared with the Cervilenz. As described, the Cervilenz is easy to use and needs minimal training. It also has a movable flange to measure the distance in length from the lateral fornix to the distal end of the cervix under direct vision using a speculum. Cervilenz is currently available for use in clinical practice but not in South Africa.[25]

2.7.4. Ultrasound

Intrapartum ultrasound use is a complementary tool in obstetrics to supplement the clinical skills of obstetricians and midwives. Ultrasound can be used during labour to monitor progress and reduce the numbers of digital vaginal examinations.[26] Various studies have looked at the use of intrapartum ultrasound for estimating cervical dilatation. Hassen et al. investigated two-

dimensional trans-perineal ultrasound to measure cervical dilatation during labour.[27] The transducer was placed at the level of the posterior fourchette in a sagittal plane. A view of the anterior lip of the cervix was obtained, and by rotating the transducer 90 degrees a diameter section of the cervix was seen. The cervical dilatation was then measured in an anteroposterior plane. A similar prospective study from Sweden compared two-dimensional trans-perineal ultrasound assessment of cervical dilatation with digital vaginal examination. The ultrasound cervical dilatation was obtained by measuring anterior to posterior as well as transverse diameters. The mean value of the two measurements was taken as the cervical dilatation.

Cervical dilatation was successfully assessed in 61 out of 86 cases (71%) using ultrasound. The mean difference between clinical cervical dilatation and ultrasound measurements was 0.9 cm. Women reported less discomfort when examination was done with the trans-perineal ultrasound compared with digital examination.[28]

Khalil et al.[29] assessed the role of intrapartum translabial ultrasound to accurately and objectively monitor the progress of labour by predicting successful vaginal delivery. Digital vaginal examination was performed, followed by ultrasound measurement of cervical dilatation in a transverse plane. Statistically significant correlation was found ($p<0.001$) when cervical dilatation was assessed by digital vaginal assessment and the translabial ultrasound.

Zimmerman et al.[30] used three-dimensional ultrasound as a non-invasive method to measure cervical dilatation during both latent and active phases of labour. They compared their findings with digital vaginal examination and also assessed intra-observer and inter-observer agreement. Three-dimensional ultrasound was used to measure the mean cervical diameter, maximal cervical diameter as well as the inner cervical area. These measurements showed a positive correlation with digital examinations ($p<0.001$). The intra-observer mean difference was less than 0.5 cm, similar to digital vaginal examinations if ±1 cm error is accepted.

The authors concluded that three-dimensional ultrasound to assess cervical dilatation during labour is similar to, if not more accurate than, digital vaginal examination. An advantage of the three-dimensional ultrasound is the maintenance of the cervix in its natural application to the presenting part or membranes, unlike the disturbance and stretching that occurs during digital vaginal assessments. The disadvantage of three-dimensional ultrasound for this purpose is in cost and convenience.

Ultrasound has other uses in assessment of labour progress. Studies involving the use of intrapartum ultrasound have reported successful assessment of fetal head descent as well as fetal head rotation.[31-34]

2.7.5. Computerized sensor system devices used to monitor labour progress

Ofer et al.[35] described computerized labour monitoring during the active phase of labour. This ultrasonic technique uses pulses transmitted by three external abdominal transducers. The pulses are received by three internal sensors, two on opposite sides of the cervix, and the other on the fetal scalp. The times from the transmission of pulses from the abdominal transducers to reception of the pulses by the internal sensors are measured and converted to distances. Ofer et al. studied the relationship between head station and cervical dilatation during individual active phase contractions.

The findings showed that these two variables are affected differently by the same contraction. The fetal head station increases while cervical dilatation starts by increasing and then decreasing again, before it is eventually complete at full dilation.

Huck et al.[36] reported the effectiveness of an electronic sensor system in 2008, to continuously monitor cervical dilatation without the need for hospital admission. The sensor with two terminals is attached to the cervix and as it dilates the sensor stretches and produces a voltage

proportional to the distance between the two sensor terminals. This information is sent to a remote data-processing agency, allowing communication between the attending doctor and the labouring woman without them having to meet. The development of this device is incomplete as the authors did not test it on any human subjects. It appears to be a sophisticated upgrade of 20th-century cervimeters.

2.7.6. Training to improve the skill of cervical assessment

Obstetric simulation training is a teaching tool for doctors and midwives. Various studies have focused on cervical dilatation assessment using simulation devices. Ideally, simulation devices should realistically represent the original tissue or body part that is to be manipulated. Lueng[37] discussed the texture of cervical tissue in artificial models and stated that cervical simulators do not represent the actual texture of the cervix. Lueng suggested that trainees should be taught to recognize the appropriate textures of the cervix by comparing it to the mouth. Lueng describes sublingual folds and caruncles as similar to the soft vaginal epithelium, while the smooth buccal epithelium has the texture of the surface of the dilating cervix. The mouth edges, which is formed by the tensed orbicularis oris muscle is similar to the cervical os. By applying this approach, junior clinicians can learn to identify the cervix and appreciate its rim and measure its opening.

During the 1980s, Tuffnell et al.[38] designed simulators representing cervical effacement and dilatation. They tested the inter- and intra-observer variability among 24 obstetricians and 36 midwives, and found that obstetricians made more accurate assessments compared to midwives and that there was also smaller variability within the obstetrician group.

Phelps et al.[39] also assessed accuracy and intra-observer variability among midwives, obstetric residents and specialists by using polyvinyl chloride pipe models embedded in polysterene

plastic blocks representing different cervical dilatations. The exact accuracy of cervical dilatation among the examiners was 56.3% but increased to 89.5% if an error of ±1 cm was allowed. There was a tendency among the participants to overestimate dilatation for dilatations at 1-3 cm and underestimate at more than 4 cm. A significant difference was found between residents and specialists with more than 10 years of experience, favouring those with more experience.

Knutson et al.[40] described findings from a workshop where family medicine residents were trained for three hours in assessment of cervical dilatation by using hard models made of clay and soft models made from crocheted caps. These hard and soft simulated models represented different dilatations ranging from 0 cm to 10 cm. Pre-training results found that 18.5% of measurements were more than 1 cm different from the actual measurement, and this improved to 6.1% after the training. The study showed that trainees benefit from simulation training workshops to assess cervical dilatation, at least in models.

In India at the nursing college of Karad in 2011, midwives estimated diameters of various size holes representing dilated cervices, by visual impression and palpation.[41] The 88 participants were divided into a study group (n=43) and control group (n=45). The study group received routine training (without the simulated devices) as well as training on the simulated devices, while the control group received only routine training. After the training, the participants from the study group had a better ability to identify the correct dilatation of all the models by visual impression and palpation. The study also found that inaccurate assessments were mostly made at more than 5 cm cervical dilatation.

Various studies have looked at cervical evaluations using both hard and soft simulation models. Huhn et al.[42] found that participants made more accurate estimations with hard models in comparison to soft models. It had been assumed that soft models provided a more realistic

copy of the cervix than hard models. However, only 19% of participants showed accurate results with soft models compared to 54% correct assessments with hard models. But with advancing cervical dilatation in the hard models, participants tend to be less accurate. Overall, there was no significant difference regarding accurate assessment with soft models (49%) versus hard models (58%). The researchers concluded from their findings that trainees should first be trained by using the hard models to master their skills to assess cervical dilatation and effacement accurately, followed by soft simulation models to appreciate the texture of the human cervix.

3. MOTIVATION FOR THE STUDY

3.1. Problem Statement

Cervical dilatation remains the most important parameter for measuring progress of labour. Despite efforts by researchers to come up with non-invasive technologies to obtain accurate measures of cervical dilatation, no such methods can as yet replace traditional cervical assessment using the fingers of a gloved hand. Erroneous cervical dilatation estimates can result in incorrect clinical decisions. In addition, varying results by different examiners can lead to a lack of trust between the labouring woman and her clinician or caregivers. It is thus important that effective and appropriate assessments be made to assess progress of labour. The priority is to encourage correct assessment to inform correct clinical management. Training doctors and midwives in measuring cervical dilatation therefore needs to continue and needs improvement. Knowledge of the limitations of digital vaginal examinations, including pitfalls in estimating dilatation, will assist in designing training for future clinicians. A method of studying error is to compare experienced staff with novice staff, assuming that experienced staff will be more frequently correct than the novices.

3.1.1. Aim of the study

This aim of the study was to determine and compare accuracy of cervical assessment among different grades of obstetric clinicians in the estimation of cervical dilatation using foam models with predetermined cervical dilatation on plaster-of-paris moulds of the fetal head.

3.1.2. Objectives

The objectives of the study were:

1. To determine accuracy of cervical dilatation estimation, with respect to predetermined dilatations of foam models, in obstetric clinicians in the Department of Obstetrics and Gynaecology at the University of the Witwatersrand.
2. To compare accuracy of cervical dilatation in foam models between clinicians with different levels of experience.

4. METHODS

4.1. Study design and study population

This was a cross sectional analytic study. The participants included final year medical students (sixth year medical students who had all completed their 6-week obstetric training clerkship in the fifth year of study), medical interns, registrars, and specialists (who have completed four years of registrar training) in the three teaching hospitals attached to the University of the Witwatersrand in Johannesburg (Charlotte Maxeke Johannesburg Academic Hospital, Rahima Moosa Mother and Child Hospital, Chris Hani Baragwanath Academic Hospital). Participants excluded were interns with less than 28 days of experience, pre-registrar medical officers, and community service medical officers. The staff complement, excluding students, consisted of 47 consultants, 59 registrars and 30 interns (n=136).

4.2. Sampling and recruitment

The researcher approached eligible participants at convenient times to do the simulation cervical dilatation assessment. A participant checklist was kept to prevent duplication of participants during the process. Each participant made one assessment.

4.3. Conduct of the experiment

Participants were asked to estimate cervical dilatation in a foam model using an ungloved hand. The foam model of the cervix covered a plaster of paris mould of the fetal head and was encased in a PVC pipe of 10 cm diameter (Figures1 & 2). The cervical dilatation was not disclosed to the participant before estimation of dilatation, and could not be seen as a blanket

with a hole in the centre covered the artificial introitus. The researcher had seven such models with fully effaced simulated cervices at exactly 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm and 9 cm. Each participant was asked to estimate the cervical dilatation of one of the foam model by using one or two fingers, and decide on the cervical dilatation to the nearest 1 cm. The researcher held the model firmly at table top level while the participant estimated the cervical dilatation.

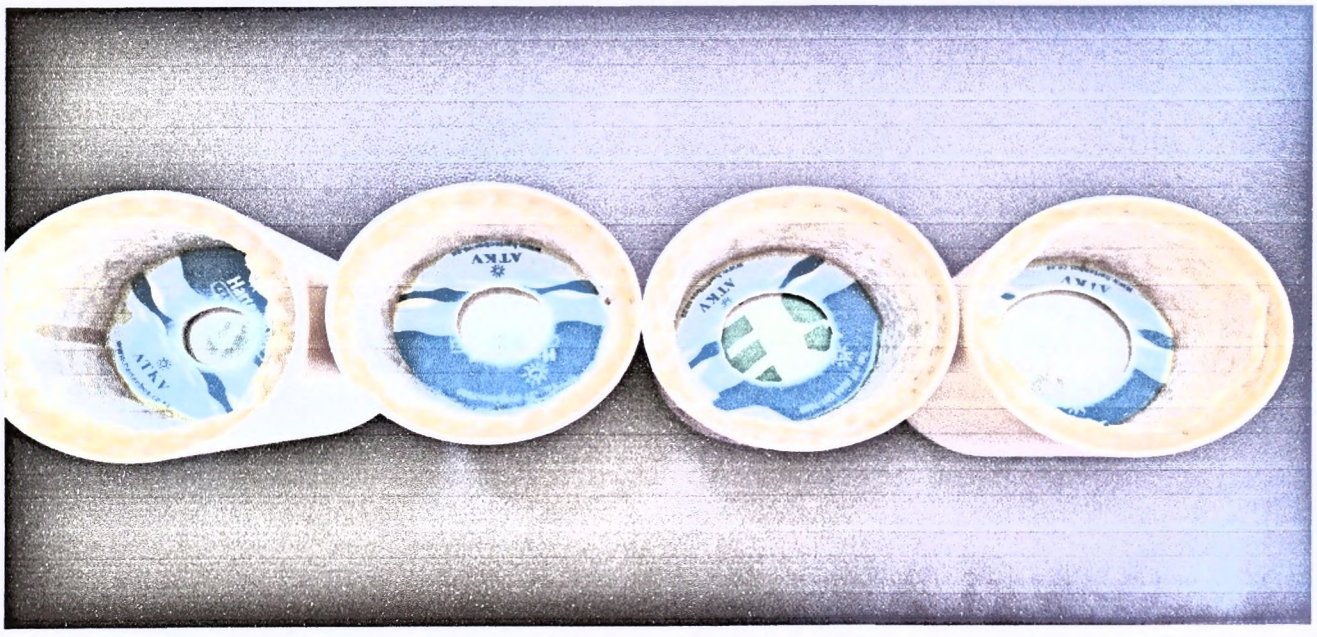


Figure 1. PVC simulation models with different cervical dilatation ranging from 3 – 6 cm (left to right)

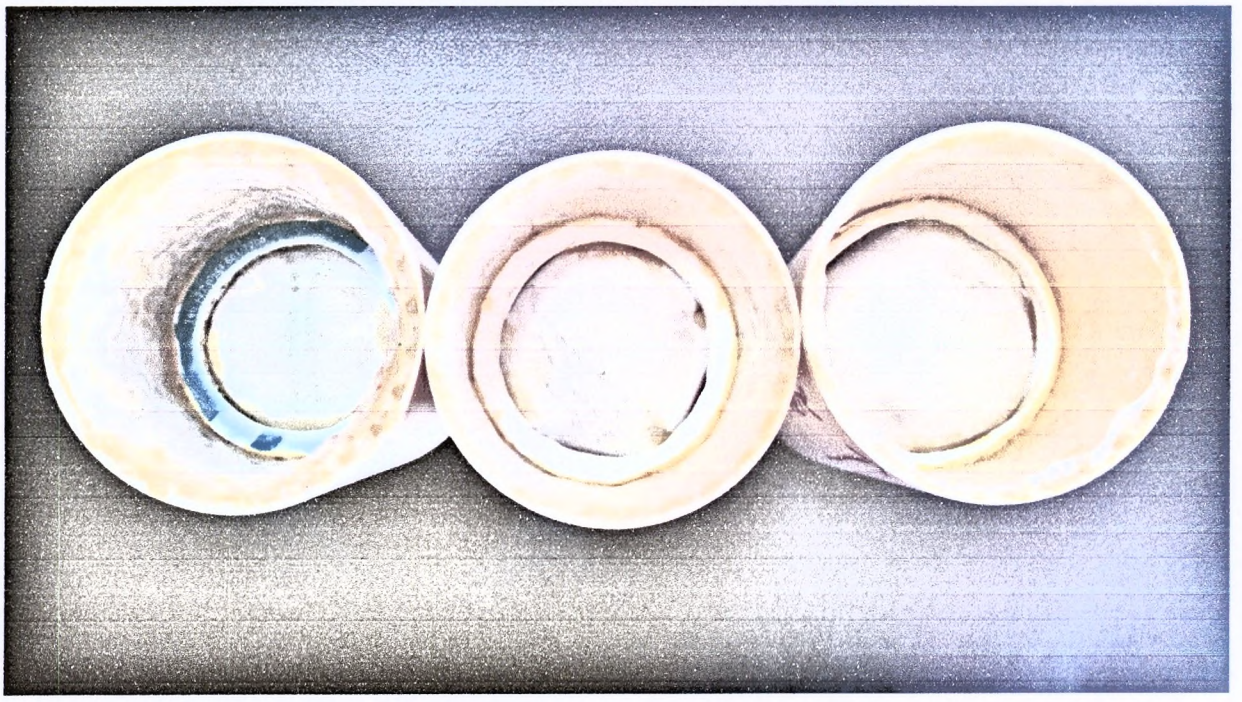


Figure 2. PVC simulation models with cervical dilatation ranging from 7- 9 cm(left to right)



Figure 4. Brown blanket with hole in the centre covering the artificial introitus of the PVC simulation model.

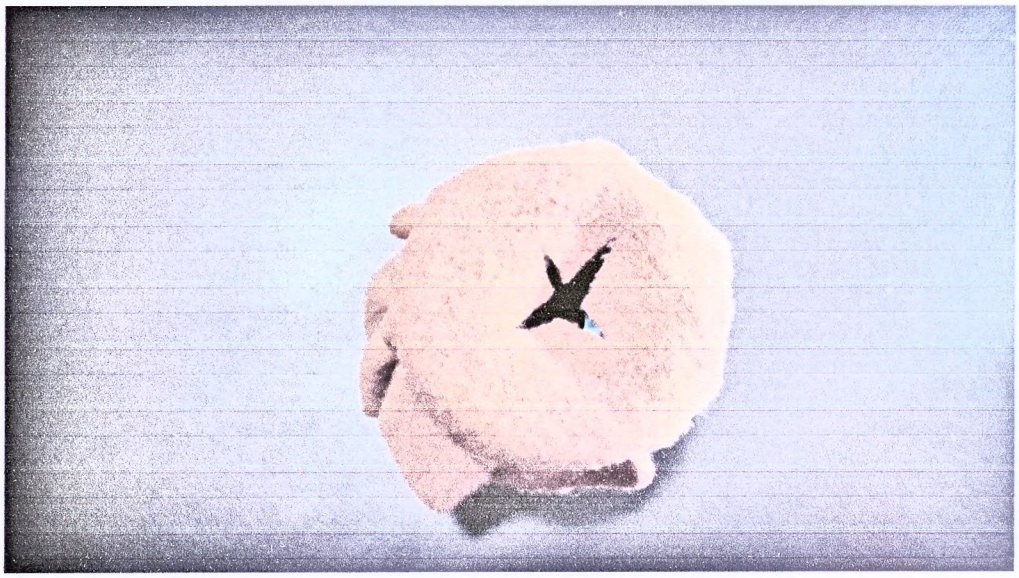


Figure 5. Top view of brown blanket with hole in the centre covering the artificial introitus of the PVC simulation model.



Figure 6. Each simulation PVC model marked with the correct dilatation in centimetres to the side of the researcher to compare with the participant's findings.

4.4. Data collection

All the findings of the cervical estimations were entered by the researcher onto a datasheet (Appendix 8.1). The datasheet included the participants' demographics details including age, sex, right and left-handedness and clinical experience/rank, as well as the correct dilatation and the participant's estimate.

The data were entered into Microsoft Excel software, and then imported into Stata software for statistical analysis. Descriptive statistical methods used were proportions and percentages. Errors in cervical dilatation assessment were calculated by subtracting the actual diameter of the model from the participants' estimates from the actual diameters of the models in cm.

Errors with a negative sign (<0), indicates underestimation and those with a positive sign (>0) overestimation. The errors were expressed as means ± standard deviations (SDs). P-values for differences in means ± SDs were calculated using Student's t-test. Proportions of correct estimates were expressed as percentages. P-values for differences in frequencies were calculated using the Chi-squared test. Univariate logistic regression was applied to examine odds ratios for correct estimation for various predictors. P-values <0.2 merited inclusion into multivariable logistic regression models. Statistical significance for all tests was accepted as $p<0.05$

4.5. Ethics

The privacy of the participants was respected. No names or any form of identification were used or entered onto the datasheet to identify participants. The participants were told the correct cervical dilatation after the simulation and had the opportunity to re-examine the models when requested.

Each participant had the choice to participate in the study and this was reflected by signing a consent form. The aim of the study was explained to each participant in full detail. No one was affected negatively by being part of the study, even if they declined. None of staff members or students who were approached declined to participate. No patients were examined in this study. Ethical approval was obtained for this study from the Human Research Ethics Committee (Appendix 8.3) and approval to use both undergraduate students and staff of the Obstetrics and Gynaecology department, including interns, registrars and consultants was also obtained.

5. RESULTS

A total of 81 participants performed digital examinations on PVC simulation models. Of the 81 participants in this study, 12 were medical students, 21 were medical interns, 33 were registrars and 15 were consultants (Table 1). The majority of the participants were right-handed and of the six left-handed participants, four performed the cervical assessment with their right hands.

Characteristic	Total of participants	Per cent
Age in years:		
<30	39	48
30-39	34	42
40-49	5	6
50-59	3	4
Gender:		
Male	29	36
Female	52	64
Professional rank:		
Medical student	12	15
Medical intern	21	26
Registrar - year 1	8	10
year 2	9	11
year 3	7	9
year 4	9	11
Consultant	15	19
Dominant hand:		
Right	75	9
Left	6	7

Table 1. Characteristics of participants who estimated cervical dilatation on the models (n=81)

The models examined had cervical dilatations ranging from 3 cm to 9 cm. On average, overestimation was observed with the cervices at 3,4 and 6 cm, and underestimation at 5, 7, 8 and 9 cm (Table 2). The mean error at 3-6 cm (n=52) was 0.37±1.34 cm compared to the mean error at 7-9 cm (n=39) of -0.52±1.86 cm (Student's t-test; p=0.02).

Cervical dilatation (cm)	Total of partcipants	Mean error ± standard deviation (cm)
3	13	0.85±0.80
4	10	0.60±1.35
5	16	-0.69±0.79
6	13	1.00±1.63
7	11	-0.27±1.56
8	10	-0.60±2.37
9	8	-0.75±1.75
All	81	0.05±1.60

Table 2. Cervical dilatation of the models, with mean error and standard deviation at each cm measure of dilatation. Negative mean error indicates underestimation of the model cervical dilatation.

The assessment of cervical dilatation was exactly correct for 28 of the 81 participants (35%), with 12 underestimates by 1 cm (15%) and 17 overestimates by 1 cm (21%). Fifty-seven estimates (70%) were therefore correct within 1 cm (Figure 1). There were no statistically significant differences for correct estimates found for the age of the participants, as well as for the lower versus higher models cervical dilatations (data not shown). However, there was a non-significant trend towards greater accuracy correct to within 1 cm cervical dilatation for male participants (24/29; 83%) versus female participants (33/52; 63%)(Chi-squared test, p=0.07).

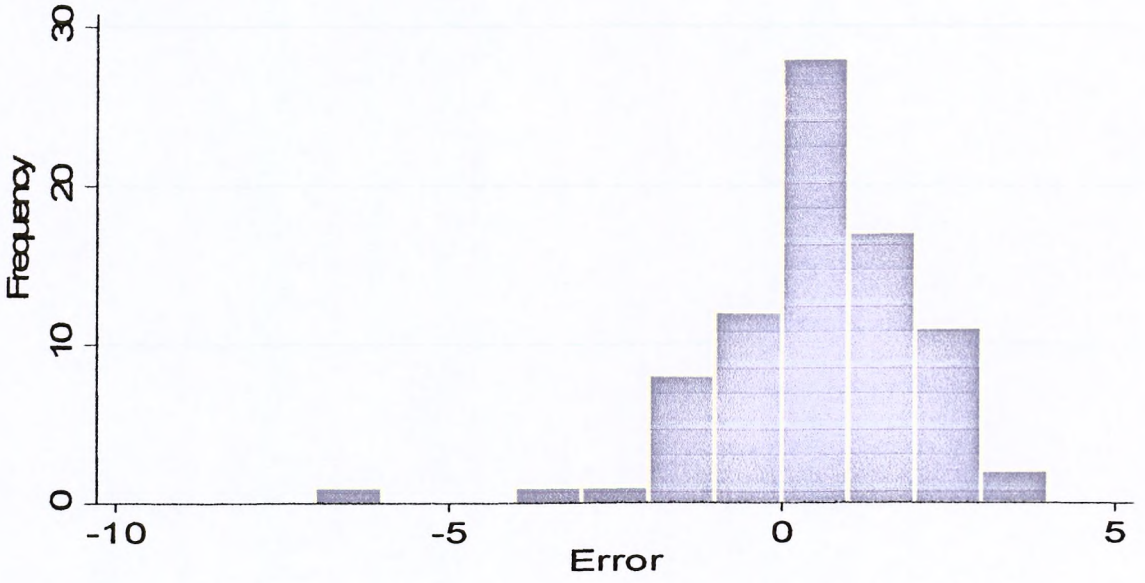


Figure 3. Frequency distribution of mean error in cervical dilatation estimation (n=81).

There was no discernible trend in under- or over-estimation of cervical dilatation when professional ranks of the participants was compared (Table 3). The underestimation by medical students and interns (mean of -0.27±1.25 cm) versus the overestimation by registrars and consultants (mean of 0.27±1.97 cm) showed no statistical significance (Student's t-test, p=0.13)

Professional rank	Total of participants	Mean error ± standard deviation (cm)
Medical student	12	-0.17±2.86
Medical intern	21	-0.33±1.32
Registrar year 1	8	0.50±1.31
Registrar year 2	9	-0.11±1.05
Registrar year 3	7	0.00±0.00
Registrar year 4	9	0.11±1.05
Consultant	15	0.60±1.68

Table 3. Mean error, with standard deviation, for cervical dilatation of the models, for each of the professional ranks (n=81). Negative mean error indicates underestimation of the model cervical dilatation.

Sixteen of the 33 registrars (49%) were exactly correct with their estimates, more than medical students and interns combined (9/33; 27%) and consultants (3/15; 20%)(Table 4). The accuracy of medical students and interns versus registrars to within 1 cm showed statistical significance (p=0.049)(Table 5). Also, registrars had 85% correct estimates within 1 cm, significantly better than the consultants (53%) (Chi-squared test, p=0.019) (Table 6).

Professional rank	Total of participants	Exactly correct, n (%)	Correct within 1 cm, n (%)
Medical student	12	2 (17)	6 (50)
Medical intern	21	7 (33)	15 (71)
Registrar year 1	8	3 (38)	5 (63)
Registrar year 2	9	3 (33)	8 (89)
Registrar year 3	7	7 (100)	7 (100)
Registrar year 4	9	3 (33)	8 (89)

Table 4. Proportions with percentages of exactly correct estimates and estimates correct to with 1 cm, by professional rank of participants

Professional rank	Total of participants	Exactly correct, n (%)	P value	Correct within 1 cm, n (%)	P value
Medical student or intern	33	9 (27)	0.076	21 (64)	0.049
Registrar	33	16 (48)		28 (85)	

Table 5. Comparison of proportions of estimates exactly correct and correct within 1 cm of model cervical dilatation, between medical students or interns, and registrars (p values obtained using Chi-squared test).

Professional rank	Total of participants	Exactly correct, n (%)	P value	Correct within 1 cm, n (%)	P value
Registrar	33	16 (48)	0.06	28 (85)	0.019
Consultant	15	3 (25)		8 (53)	

Table 6. Comparison of proportions of estimates exactly correct and correct within 1 cm of model cervical dilatation, between registrars and consultants (p values obtained using Chi-squared test).

Univariable logistic regression analysis was performed to determine possible predictors for exact estimation of cervical dilatation. There was no association regarding professional ranking, gender and age of participants, as well as dilatation of the models <7 cm or >6 cm, for exact cervical dilatation measurements (Table 7). A multivariable model was therefore not applicable. For estimates correct to within 1 cm, only one predictor (participant gender) showed a p-value <0.2, so a multivariable model could not be applied (Table 8).

Predictor	Referent	Odds ratio	95% confidence interval	P value
Medical student or intern	Registrar or consultant	0.57	0.22; 1.49	0.26
Female gender	Male gender	0.63	0.24; 1.62	0.34
Age <30 years	Age ≥30 years	0.72	0.29; 1.82	0.49
Model dilatation <7 cm	Model dilatation >6 cm	1.01	0.39; 2.61	0.99

Table 7. Univariate logistic regression for possible predictors of exactly correct estimation of cervical dilatation in the models.

Predictor	Referent	Odds ratio	95% confidence interval	P value
Medical student or intern	Registrar or consultant	0.58	0.22; 1.53	0.27
Female gender	Male gender	0.36	0.12; 1.11	0.07
Age <30 years	Age ≥30 years	0.71	0.27; 1.85	0.48
Model dilatation <7 cm	Model dilatation >6 cm	0.86	0.31; 2.34	0.76

Table 8. Univariate logistic regression for possible predictors of model cervical dilatation estimates correct to within 1 cm.

6. DISCUSSION:

Successful labour management is based on accurate estimation of the cervical dilatation. Therefore, correct technique to estimate cervical dilatation and effacement is important to limit errors. The concern with overestimation and underestimation of cervical dilatation is the resultant false impression of labour progress, leading to premature or inappropriate decision making to expedite labour through unnecessary obstetric interventions, or, conversely, failure to act in situations of poor progress.

This study looked at the accuracy of cervical dilatation among obstetric clinicians ranging from junior clinicians including medical students and interns to the more senior clinicians, namely the registrars and consultants. The exact accuracy of cervical assessments among the clinicians in this study was 35% but increased to 70% when an error of ±1cm was allowed. It was interesting to find that the registrars were more accurate with their cervical assessment compared to the consultants. Previous studies have shown that the more experienced the clinician is, the more accurate cervical assessments will be. The relatively poor accuracy of the consultants could be a chance finding (type 1 statistical error) related to a small sample size. One could also speculate that consultants in the teaching hospitals spend less time in the labour ward than registrars and may have lost accuracy through lack of regular practice. The possibility that the registrars have been previously exposed to these models, and are therefore more accurate, can be discounted as the models have only been used for midwife training in the district primary care services. It is possible that finer points in estimation, such as tissue texture and application of the head, not included in the foam models, are not available to consultants who may rely on experience-related complex pattern recognition for their dilatation estimations. Regarding the medical students and interns, their lesser accuracy

compared to registrars was expected. A study by Buchmann and Libhaber on humans in labour showed that almost 90% of examiners would be correct when an error within 1 cm was allowed for cervical dilatation[11] .The equivalent figure in this study was 70%. They also found that overestimation of cervical dilatation was evident amongst junior participants. However, in this study, the opposite was the case, although the mean underestimation by medical students and interns (-0.27 ±1.25) versus the overestimation by registrars and consultants (0.27 ±1.97) showed no statistically significant difference (p=0.13). It is possible that the obvious differences between human cervixes in labour and foam models play in a role in this unexpected finding.

There were no other statistically significant findings in terms of seniority or demographics of the participants. The finding that overestimation was more likely with low dilatations was perhaps expected, as the guesswork element in the estimation would likely shift estimates towards the middle ground.

The unexpected findings in terms of lack of significance and counter-intuitive results with the consultants, suggest that the foam models may be less realistic than they appear, and that they do not approximate to true cervical assessment in humans. Simulation training in cervical assessment therefore needs to consider the types of models used. Knutson et al[40] demonstrated the importance of simulation training for junior clinicians to improve accuracy. Their study showed that results from pre-test cervical dilatation had a mean error of 38.2% but improved to a mean error of 15.7% with the post-test assessment. Obstetric simulation training can be beneficial to allow junior clinicians to master accurate assessments of the cervix during labour and therefore contribute to improve clinical care. But all of this potential benefit may not apply if the simulation models are not realistic copies of the human tissue that is being examined or manipulated.

Problems with different models have been previously reported. Studies looked at cervical evaluations by using both hard and soft models. It is an assumption that soft models will provide more accurate results as they provides more realistic copies of the cervix compared to hard models. However, most studies showed that accurate results were obtained with hard models as suggested in studies by Phelps et al,[39] and Huhn et al[42]. It seems that hard models, which are the least realistic in terms of texture and pliability, give the most reassuring results. But as such, they may be least desirable for simulation training.

Recent advances in ultrasound-based cervical assessment may make it possible for examiners to learn cervical dilatation assessment at the labour ward bedside using the ultrasound, or even new electronic technologies, as the gold standard [26-34,35,36] .This may provide confirmation to those learning cervical assessment, as well as more objective tool to assist in labour management. However, the availability of resources and time committed to train junior staff and registrars to use the ultrasound intrapartum in our setting, will not allow replacement of digital vaginal examination, at least not in the foreseeable future.

Limitations inherent in this study are the small and different sample sizes in each professional group, leading to possible type 1 and type 2 statistical errors. The researcher, being a full-time registrar, had limited opportunities to approach sufficient staff and students. The possible limitations of foam models have already been discussed. Future studies of this type should consider more realistic stretchable models for simulation training, to allow field-testing before uncritical adoption in clinician training programmes.

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8.APPENDICES:

8.1. Data Sheet

✓ the correct one please (only 1-5):

1. Level of training:
   - 6th year student ☐
   - Intern ☐
   - Registrar 1st 2nd 3rd 4th year ☐
   - Specialists/consultant ☐

2. Sex: Male ☐ Female ☐

3. Age of the participant
   - < 30years ☐
   - 30 – 39 years ☐
   - 40 – 49 years ☐
   - 50 -59 years ☐
   - > 60 years ☐

4. Are you Left handed or Right handed? .....

5. Did you use your left or right hand to do the simulated PV?
   .....

For the researcher:

6. Simulated cervix dilatation model:
   - 3 cm ☐
   - 4 cm ☐
   - 5 cm ☐
   - 6 cm ☐
   - 7 cm ☐
   - 8 cm ☐
   - 9 cm ☐

7. Participant's cervical dilatation estimate:

1 cm	☐	6 cm	☐
2 cm	☐	7 cm	☐
3 cm	☐	8 cm	☐
4 cm	☐	9 cm	☐
5 cm	☐	10 cm	☐

8.2. ETHICS CLEARANCE CERTIFICATE

R14/49 Dr. Davinia Masimila

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150535

NAME: (Principal Investigator)	Dr. Davinia Masimila
DEPARTMENT:	Obstetrics and Gynaecology
PROJECT TITLE:	Comparing Active Phase Assessment Cervical Dilatation by Obstetric Clinicians using Foam Models
DATE CONSIDERED:	29 May 2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof. Eckhart Buchmann
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2015/06/24

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be *completed in duplicate and* ***ONE COPY*** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES