Title page

The training value of a low fidelity cervical biopsy workshop: Technical Report.

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Running title: Training value of low fidelity cervical biopsy workshops

Abstract:

Introduction: Cervical biopsy increases diagnostic yield compared to cytology and reduces time between presentation with and diagnosis of cervical cancer. Procedural training however needs to evolve in line with legislated working time restrictions and patient safety concerns. This makes gynaecological procedures ideal for simulation training. To date, no studies have looked at the use of low fidelity simulation models to teach cervical punch biopsy.

Methods: A cervical punch biopsy model was created using home and departmental waste products. The simulation model was tested by expert colposcopists and used during a gynaecology trainee cervical study day. 21 trainees attended a lecture which showed photographs of normal and abnormal cervices and a workshop where colposcopists demonstrated the technique before direct hands-on training with the simulator. Participants were asked to complete a survey, using a 5-point Likert scale, outlining the educational value of the workshop.

Results: Five low fidelity cervical biopsy simulation models were created which cost nothing, took an hour to make and were easily transported. Of different 'cervix' materials tested, sponge provided the most realistic traction and the least fragmented biopsies (3-5mm). 18 trainees completed the survey of whom all strongly agreed that learning was enhanced compared to didactics alone. The mean score for the value of the simulation in preparing trainees to perform future cervical biopsies was 4.7 (SD 0.42; 95% CI 4.49-4.90).

Conclusion: Our low fidelity cervical biopsy models are easy to make, portable and low cost. Trainees have reported the significant educational value of this simulation model in teaching an outpatient gynaecological / colposcopy procedure in a non-clinical environment.

Keywords: cervical biopsy, low fidelity models, training

The training value of a low fidelity cervical biopsy workshop.

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Introduction:

Surgical training needs to evolve in line with the legislated restriction of trainee doctors' working hours and patient safety concerns. Medical regulatory bodies have identified a reduction in exposure to clinical procedures following these working time restrictions and have highlighted the importance of innovative methods of training.[1] Evidence suggests that procedural skills can be learnt through the use of simulation models[2-5] but the fidelity or 'realism' of the models can vary widely depending on cost and ethical implications. These repercussions have led to the development of low fidelity models.[6-7] Grober *et al*, 2004 undertook a randomised control trial of 50 novice surgical residents who had hands-on training with either high or low fidelity models and found no significant difference ($t_{38} = 1.16$, $P = 0.25$) in acquisition of technical skill when objectively assessed on the high fidelity models.[2]

Cervical biopsy is a diagnostic technique which should be undertaken when a recognisably atypical cervical lesion is visualised.[8] Positive Predictive Value (PPV) for invasion following cervical punch biopsy has been quoted at 83%[9] whilst cytology has a PPV of 56%.[10] Undertaking a cervical biopsy in a gynaecology outpatient setting will therefore improve diagnostic yield and reduce time between presentation and treatment of a cervical cancer.

The World Health Organisation reports that worldwide cervical cancer is the second commonest female cancer[11] and all grades of gynaecology trainees will review referrals for 'a suspicious cervix' or irregular bleeding patterns. Major complications such as inpatient admission for bleeding are rare consequences of cervical biopsy but an understanding and application of haemostatic measures is required, particularly in cases of frank malignancy. A prospective observational study[12] found that 79% of women reported bleeding, of whom 21.4% described severe bleeding, following the procedure. Learning this procedure is therefore a valuable use of training time as correct technique is vital for completing the biopsy and managing complications.

Training for gynaecology residents to undertake minor cervical procedures follows the old adage of 'learning by doing', which due to the invasiveness of the procedure is becoming less acceptable to women.[13.14] The use of a simulation model to teach cervical biopsy will optimise patient safety by obtaining this basic skill away from the clinical environment, thereby improving patient safety and experience.

Studies looked at the learning curve and training aspects of colposcopy using high fidelity models compared to clinical performance in the colposcopy setting and found competence levels were comparable, as was educational value.[3,15] However, no studies to date have looked at low fidelity models to teach cervical punch biopsies. Low fidelity sourcing could provide a cost-effective training alternative which will help achieve educational competencies without compromising patients.

This study describes the construction of a low fidelity cervical biopsy model and its value as an educational training model.

Method:

1. Construction of the Model:

We constructed five models using cardboard boxes (25cm x 15cm x 8cm), toilet rolls, brown paper, stones, sponge backing from discarded suturing sets, sticky tape and a permanent marker (Figure 1). Qualitative data was gathered from expert colposcopists who subjectively rated different materials for authenticity including foam, plasticine and rubber.

A hole to fit the toilet roll was cut half way up the box, stones were placed in the bottom to weight it and it was wrapped in brown paper. The sponge was cut to fit inside the back of the toilet toll, a central 5mm core was removed to represent the cervical os and a 'transformation zone' was painted onto the sponge (Figures 2 & 3). This sponge was then taped just inside the back of the toilet roll. The models were easily portable.

2. Workshop training:

21 Obstetric and Gynaecology Doctors attended a regional study day of whom 18 (86%) were eligible for enrolment. Certified colposcopists were excluded from the study. All trainees undertook a cervical biopsy workshop but only those who had signed a consent form prior to the day were enroled. Participants completed a baseline questionnaire which detailed level of training, prior experience with cervical biopsies and colposcopy.

Knowledge phase: Two hours of interactive lectures included anatomy, physiology, pictures of normal and abnormal cervices but no procedural based information. The photographs demonstrated gross abnormalities viewed without the aid of acetic acid or iodine as noncolposcopy trainees would not have access to this. This provided the gynaecology trainees with a basic understanding of recognition of an abnormal transformation zone and where to take a biopsy from.

Orientation phase: The participants were divided into five groups of four trainees and certified colposcopists demonstrated the instruments and procedure over twenty minutes. Equipment provided included the training model, a Cusco's speculum, Eppendorpher and Tischler biopsy forceps, silver nitrate sticks, swabs with Monsell's solution and a haemostatic tampon (Figure 4). A Crib sheet was given to all demonstrators outlining the learning objectives to be covered so that training could be standardised. These included:

- Patient Safety & dignity (Gain consent, chaperone, hygiene).
- Set up of equipment prior to beginning procedure.
- Biopsy forceps (eppendorfer, tischlers): illustrate the benefits and disadvantages of different forceps such as size and fragmentation of the tissue samples.
- Visualise the cervix and transformation zone
- Undertake biopsy from most abnormal area – use cervical atlas pictures from the lectures as a guide.
- Check biopsy for fragmentation and size
- Application of silver nitrate and Monsell's solution.
- Description of additional haemostatic measures such as diathermy or sutures in the event of continuing blood loss
- Post-procedural advice.

Training phase: All participants were given direct and then indirect hands-on model training and demonstrators were asked to ensure that all trainees completed each of the learning objectives on the Crib sheet. Each group was given one hour to practice the skill (Figure 5). Application of knowledge learnt in the orientation phase was applied in the training phase: if the transformation zone was not visible trainees were encouraged to take a smear with a broom and brush to sample a potential endocervical lesion. Endocervical curettage is not routinely undertaken by general gynaecologists or colposcopists in the UK so this was not a learning objective for the workshop.

Participants completed a course evaluation form detailing the learning value of the workshop: a five point Likert scale (strongly disagree = 1 to Strongly agree = 5) documented confidence in performing a cervical biopsy and the usefulness of the workshop in acquiring this skill. Participants completed a pre- and post- multiple choice test which assessed knowledge of site of biopsy, instruments used, haemostatic measures and post-procedural advice. A maximum of 15 points could be scored and a team of certified colposcopists composed the questions from national guidelines.[8] The aim of this test (see e-appendix) was to assess whether the workshop improved trainee's knowledge of the procedural steps.

Statistical Analysis

Participant numbers were used so that pre- and post- questionnaires could be paired for statistical analysis. Statistical analysis was undertaken using Graphpad Prism 6 software. A t-test assessed the paired, parametric continuous data. Descriptive statistics looked at the mean, range and standard deviation. A multivariate regression model was computed to assess whether the training effect was independent of participant's previous experience or level of training.

Details of Ethics Approval

Ethical approval for NHS staff is no longer required under NRES regulations (GAfREC - changes to the REC, v 1.1, March 2012 from www.nres.nhs.uk). Approval for the study was given by the Severn School of Obstetrics and Gynaecology who had organised the Colposcopy Study Day. In concordance with the WMA Declaration of Helsinki, the health of patients was safeguarded by training on bench models. The research participants' confidentiality was protected by adherence to the Caldicott Principles, Data Protection Act and the Human Rights Act. Information leaflets sent prior to the study provided contact details and outlined the benefits of enrolment. Participants submitted consent forms giving permission to take part in the study and store their data two weeks prior to the study day. Participants could withdraw at any point.

Results:

The total time for construction of the five models was approximately one hour. There was no cost for the reusable items which were easily sourced from household waste. The remaining materials (tape, pens, sponge) were easily accessible from the department and cost nothing.

Of the 18 eligible participants, ten (55%) were in Years one to two of their speciality training, six (34%) were in Years three to five and two (11%) were in Years six to seven. Eleven (61%) had undertaken 0-3 cervical biopsies, four (22%) had completed 4-6 biopsies, one (5.5%) had undertaken 7-9 biopsies and two (11.5%) had undertaken more than ten biopsies (Table 1 for Baseline characteristics).

100% of trainees completed the course evaluation. All participants strongly agreed that ‘a cervical punch biopsy simulation model is a useful teaching tool’ and ‘learning was enhanced compared to didactic lectures alone’. 95% of participants strongly agreed their procedural learning needs were met; one participant stated they would have liked to practice suturing as a haemostatic measure. Participants graded the value of the training in preparing them to perform cervical biopsies from no relevance (1) to highly relevant (5). The mean score was 4.7 out of five (SD 0.42; 95% CI 4.49-4.90) with 100% of participants expecting to undertake cervical punch biopsies in the future. Table 2 includes the questions asked of the participants relating to their confidence and subsequent results. Multivariate analysis revealed that the confidence effect was dependent upon the participant’s previous level of training (p=0.02).

Qualitative analysis revealed which aspects of the training participants considered the most valuable such as ‘discussing and practising haemostatic measures before undertaking on a real patient has decreased my anxiety in undertaking this in an outpatient environment’ and ‘learning the technique on a model and becoming familiar with the instruments, I feel more prepared to undertake on a patient now’.

Six expert colposcopists evaluated the model. The foam was the most difficult to biopsy, a tearing motion / technique was required which led to a small (1-2mm), crushed or fragmented sample. Experts felt this would increase patient discomfort and reduce histological adequacy. The plasticine was also difficult to biopsy – it was tricky to gain traction with the forceps, in a warm room in became too maleable and the biopsy became fragmented (~1mm). The sponge provided the most realistic traction and the least fragmented biopsies (3-5mm). One reviewer felt that the lack of bleeding from the biopsy site was a limitation to the realism and suggested partially soaking the sponge in red dye.

Scores for knowledge of the procedural steps were significantly higher following the workshop ($p < 0.0001$). Mean scores prior were 7.33 / 15 (48%; SD 1.23, 95% CI 6.71 – 7.94) versus a mean of 11.9 following the workshop (79%; SD 1.79, 95% CI 11.0 – 12.7). Mean scores and range are shown in Figure 4. Effect size was calculated and showed a strong positive linear relationship, $r = 0.83$ (95% CI = 0.74 – 0.92). Multivariate analysis revealed that the training effect was independent of participant's previous experience (P = .648) and level of training (P = .968).

Discussion:

This study has illustrated the significant educational value of a low fidelity simulation workshop in teaching an outpatient gynaecological procedure. Multivariate analysis suggested this training effect was independent of level of training or experience and therefore could be used for continuing clinical development, as well as with novice trainees.

Current evidence has reported the reliability and validity of bench model training for surgical techniques. In a gynaecology setting, studies have focused on laparoscopic and hysteroscopic techniques.[4-7,16,17] Educational studies have shown that exposure to clinical procedures have been reduced following working time restrictions and with ever increasing capacity of patients in clinics, clinical effectiveness (safety and efficiency) can be affected by trainee's poor confidence in undertaking outpatient procedures. Proficiency and confidence, gained through a simulation training scheme, can then be consolidated by the transference of these skills to a clinical setting.

Indeed, the qualitative component of the survey gave a greater depth of understanding to the value of the training. Following the publication of the Francis Report, patient safety is at the forefront of clinicians' clinical practise. The informal environment allowed participants to learn a procedural skill without compromising patients or causing embarrassment to the trainee or woman. Responses from the formal structured feedback by the Severn Deanery indicated all participants felt the workshop was a valuable educational experience and the combination of aural, visual and kinaesthetic stimuli that the workshop provided appealed to all types of learners.

By essentially using waste products to make the models, no cost was incurred by the training faculty. This has led to the development of an environmentally friendly product which can reduce concerns over patient safety, high costs and rigid training scheduling. Some sacrifice of realism will be made with low fidelity models but this is replaced by reproducibility, portability and multiple training opportunities. With 85% of cervical cancer deaths in the developing world resulting from limited access to any form of effective screening and or training[11], unskilled health care workers could be trained to take biopsies with the use of a colposcopy atlas and a low fidelity model.

Evidence is poor with regards to whether bench model training leads to maintenance of these skills or an improvement in clinical outcomes. Preferably a randomised control trial should be undertaken as a small sample size can generate type 1 errors and makes the generalizability of the study harder to determine, but this has proven difficult as formal teaching of cervical punch biopsies for gynaecology trainees is undertaken on an ad hoc basis.

Conclusion:

This novel low fidelity cervical biopsy model is easy to construct, can be easily transported and is low cost which would be of particular use in low resource countries. Trainees reported significant educational value in practising this technique before patient contact. Future research should focus on whether low fidelity cervical punch biopsy models improve performance in the clinical setting by, for example, reducing time between referral and diagnosis of a cervical cancer.

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Figure Legends:

Table 1: Baseline Demographics

Table 2: Usefulness of the workshop in improving confidence in taking cervical biopsies unsupervised.

Figure 1: The equipment before construction

Figure 2: The 'Cervix' with transformation zone and biopsy marks.

Figure 3: The completed model

Figure 4: The training equipment

Figure 5: Direct, hands on training

Table 1: Baseline Demographics.

Characteristic	Eligible Participants (n = 18)
Cervical Biopsies 0-3	11 (61%) Five = 0 / Six 1-3
Cervical Biopsies 4-6	4 (22%)
Cervical Biopsies 7-9	1 (5.5%)
Cervical Biopsies >10	2 (11.5%)
Colposcopy Trainee	1
Certified Colposcopist	0
Specialist Trainee Yr 1-2	10 (55%)
Specialist Trainee 3-5	6 (34%)
Specialist Trainee 6-7	2 (11%)

Table 2: Usefulness of the workshop in improving confidence in taking cervical biopsies unsupervised.

	Pre-workshop scores		Post-workshop scores	
Do you expect to perform colposcopy in your future practice?	***Yes***	***No***	***Yes***	***No***
	2	16	2	16
Do you expect to perform punch biopsies in your future practice?	***Yes***	***No***	***Yes***	***No***
	18	0	18	0
I am confident to undertake cervical punch biopsies unsupervised.	7 scored 1 (strongly disagree) 5 scored 2 (disagree) 4 scored 3 (neutral) 2 scored 4 (agree)		1 scored 3 (neutral) 3 scored 4 (agree) 14 scored 5 (strongly agree)	
This workshop has increased my confidence in performing cervical punch biopsies.			6 scored 4 (agree) 12 scored 5 (strongly agree)	
How useful was this low fidelity workshop in teaching cervical biopsies?			3 scored 4 (agree) 15 scored 5 (strongly agree)	

Multivariate analysis revealed that the confidence effect was dependent upon participant's previous level of training (p=0.02).

Figure 2: The 'Cervix' with transformation zone and biopsy marks.

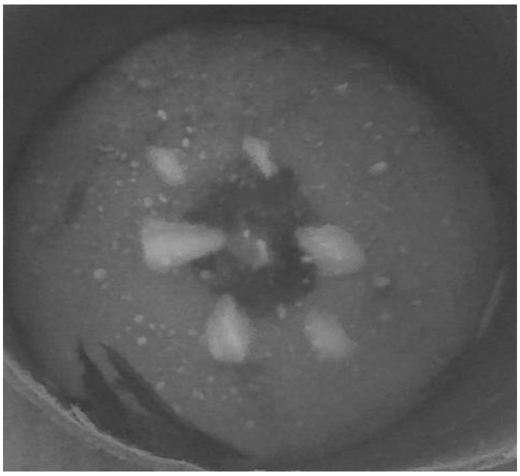

Figure 3: The completed model

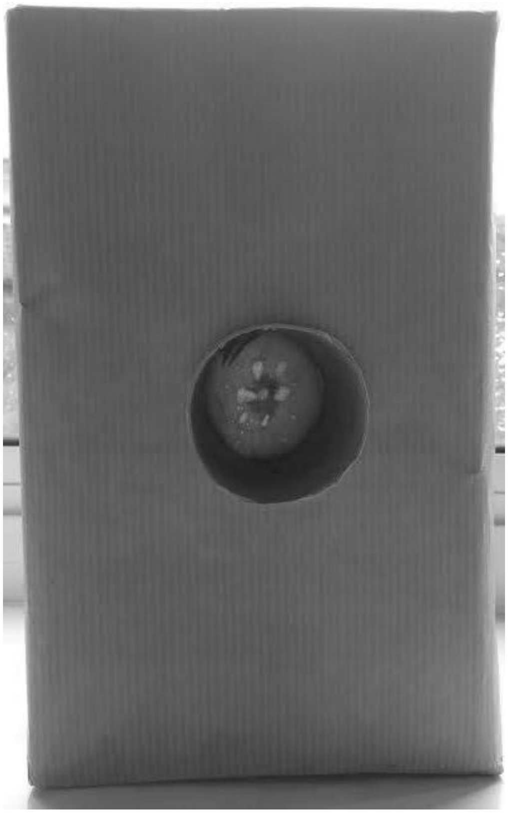

Figure 4: Training Equipment

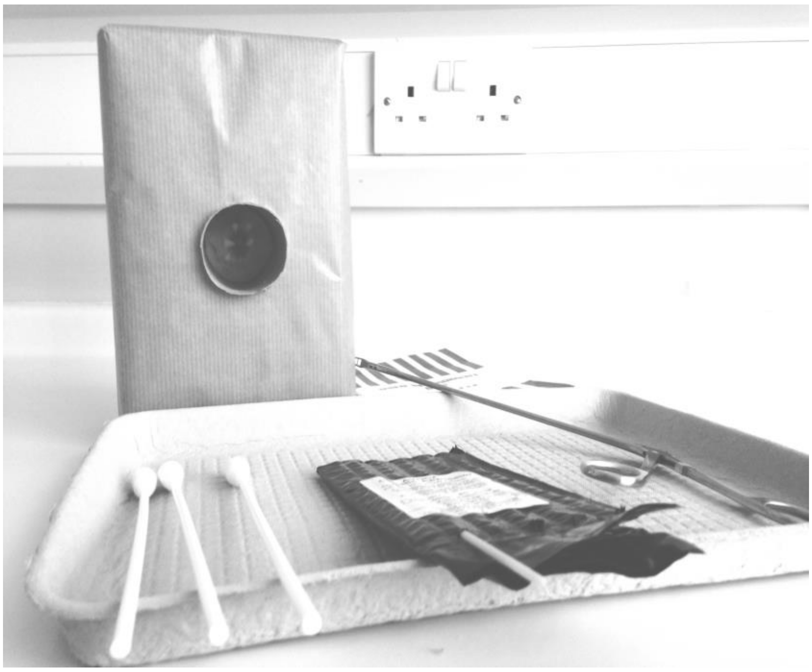

Figure 5: Direct, hands-on training