Standardisation of the Supine Pelvic Radiograph Technique (STOPPAGE)

Study Protocol

Version 1.0

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Abbreviations and acronyms

AEC	Automatic exposure control
BMI	Body mass index
CoRIPS	College of Radiographers Industry Partnership Scheme
CRF	Case report form
DAP	Dose area product
DRL's	Diagnostic Reference Levels
ECR	European Congress of Radiology
EI	Exposure index
GCP	Good Clinical Practice
GP	General practice
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations 2017
IRR	Ionising Radiation Regulations 2017
kV	Kilovolts
mAs	Milliamps x second
MYH	Mid Yorkshire Hospitals NHS Trust
OP	Outpatient
PPI	Patient and Public Involvement
PACS	Picture Archive and Communication System
PIS	Participant information Sheet
SID	Source image distance
SOD	Source object distance
UKIO	United Kingdom Imaging and Oncology Congress
WHTH	Warrington and Halton Teaching Hospitals NHS Foundation Trust

Synopsis

Study Title	Standardisation of the Supine Pelvic Radiograph Technique
Short title	STOPPAGE
Protocol version and date	Version 1. 23rd March 2021
Study design	Multi-centre interventional study
Study participants	Patients referred for pelvic radiography
Planned study sample	Retrospective audit across two NHS sites (Mid Yorkshire Hospitals Trust (MYH) and Warrington and Halton Teaching Hospitals NHS Foundation Trust (WHTH) of existing pelvic radiographs obtained in the same time period in 2019 (June to October). Prospective convenience sample of patients attending either of the two NHS hospitals for supine pelvic radiography. The target sample size is n=314 across two NHS sites. Recruitment will be on a 1:1 basis
Planned study period	Recruitment July to October 2021. Data analysis, write up and dissemination November 2021 to March 2022
Primary objective	To standardise the acquisition of supine pelvic radiographs and determine the reliability of a different evidence based centring point with respect to sagittal axial and coronal rotation, image quality, and included anatomy.
Secondary objectives	To assess if the different centring point reduces the number of repeat radiographs required due to unacceptable technical quality To determine the average radiation dose of the different centring point compared with 'usual practice' To determine the perceptions of locating bony landmarks for both techniques amongst radiographers
Underlying hypothesis	The different centring point will reduce variability in pelvic radiograph measurements and be more acceptable to radiographers than the current standard of positioning

Summary

Radiographic projections should be standardised to enable consistent and accurate interpretation and measurements, but textbooks and clinical practice describe various methods.

This variation can lead to problems with measurements which determine patient outcomes, and this is particularly evident within pelvic radiography. This has implications for orthopaedic surgeons who need accurate measurements to plan hip replacements and assess the joints. In some instances, radiographers 'centre low' to demonstrate the hips, whereas others include iliac crests as a true 'pelvis'.

This research builds upon previous a previously funded project from the College of Radiographer's Industry Partnership Scheme (CoRIPS) project (IRAS 234096), and a recent retrospective image review study to determine the centring point for pelvic radiographs and will validate a standardised technique in the clinical setting (in press [1]).

This interventional study will use two clinical radiography sites based in two NHS hospitals to compare the use of the different standardised technique for pelvic radiography.

A retrospective audit will examine the quality of pelvic radiographs that were undertaken at both sites between July to October 2019 (to account for practice variation in 2020 due to CoVID-19). Any issues identified with quality will be addressed through a training package given to both sites and provided by the researchers.

Prospectively, one site will continue with current practice (the control site) and the other site will use the different technique which is based on the retrospective audit (the intervention site). Radiographers at the intervention site will undergo additional training to ensure adherence to the different procedure.

The prospective radiographs from both sites will be compared for variation in the following:

- Included anatomy (greater, lesser trochanters, and iliac crests)
- Axial, sagittal, coronal rotation
- Image quality

Radiographers undertaking the image acquisition will be asked to document any comments in relation to the examination including the ease of palpation of the anatomical reference point(s). This type of documentation is usual practice in radiography to document any challenges and therefore will not be considered as additional activity. The free text comments will be analysed at the end of the study.

Background

Radiography is an essential tool for diagnosing and monitoring hip and pelvic pathologies, such as dysplasia, impingement, and osteoarthritis, and they are essential for the investigation of pain, pre-operative planning and post-operative surveillance in joint replacement surgery [2].

Patient position contributes to variation in measurements taken from the radiographs, for instance the pelvis tilts differently when patients' knees are flexed, and the greater trochanters appear differently depending on the internal rotation of the feet [3], but there is little agreement within textbooks as to the optimum patient position [4-13]. Despite this there is a demand for standardised protocols from other professions (i.e. orthopaedic surgeons) who use radiographs for exact measurements and comparisons.

Some authors have proposed optimum positions [14] but agreement for this is absent and a recent study in UK hospital identified ten different centring points for pelvic radiographs [15]. Some radiographic texts agree a centring point based on readily visualised or palpated surface anatomy [5, 8, 9, 11], whilst others suggest alternatives [14, 16]. The centring point can impact on anatomic visualisation as a result of beam geometry [17] which is recognised by some surgeons [18].

To date no authors have established the suitability of their proposed positioning on a range of patient body habitus, or to the practitioner with respect to identifying the relevant bony landmarks, nor have they examined resultant radiographs to determine image quality and reliability of the measurements. In fact, acceptability criteria for pelvis radiographs demonstrate poor agreement [19-23]. Importantly there is evidence of radiographers choosing to replace the centring point by anatomy inclusion (field centring to include the iliac crests and collimating to the cassette size) [15]. Anecdotally some of this is driven by a reluctance to palpate sensitive anatomical regions in patients (i.e. symphysis pubis).

Comparison of successive pelvic examinations is essential for patient monitoring and therefore it is critical that the acquisition and quality of examinations is assured and standardised [14, 18, 24-29]. The evidence base behind pelvic image acquisition is limited and it is unclear how differences in technique impact on the quality of the subsequent radiographs, the accuracy of surgical planning, or treatment success. Literature studies repeatedly cite the exclusion of patients due to poor image quality [30, 31] and acceptability criteria are poorly articulated [20, 22, 32].

The different centring point being evaluated at the interventional site is based on features of the key anatomy being studied (the hips) and could be relevant regardless of patient body habitus, anatomical variation (pelvic tilt) and orientation (supine or standing). There is a clear gap in knowledge as to whether centring derived from different surface anatomy reference points result in the same image, radiation dose, and diagnostic quality and there is a need for greater standardisation in clinical practice and a robust underpinning evidence base.

The aim of this study is to provide evidence for a different centring point that has been developed from a previous image review study [1, 33] and determine its reliability and acceptability to radiographers. Providing evidence for optimum position is the first step to ensure radiography is evidence based and allows future development of an evidence base for other body parts. In addition, it provides a platform from which to consider changes to technique, such as the increasing requirement for weight-bearing images.

Principal aim of the study

To validate a different centring point for pelvic radiographs in a supine position.

Primary research question

What is the variability between the different pelvic centring point in a range of patient body habitus?

Secondary research questions

- Does the different centring point undertaken at the interventional site lower the number of X-ray repeats when compared to usual practice undertaken at the control site?
- What is the variability in pelvic radiographs (i.e. rotation and inclusion of anatomy) with the different method versus ‘usual practice’?
- What is the average radiation dose for the different centring point compared to usual practice?
- What are the perceptions of radiographers in the ease of using the different centring point?

Methods

This study will test the different centring point for reliability and acceptability. Two NHS clinical sites in England will be used with one undertaking pelvis radiography according to the different technique (intervention site) and the other continuing with standard practice (control site).

Retrospective audit: Pelvic radiographs from both sites obtained for the same time period in 2019 (June to September) will be assessed for image quality and to identify any recurrent issues (rotation, included anatomy, and image quality). Differences and similarities between the two retrospective cohorts will be assessed. An update on the retrospective audit will be provided to both sites as part of the prospective study training (see below).

Prospective data collection: All radiographers at the interventional site will undertake training on the different centring point, consisting of a video presentation and online Q&A session to embed the different technique. The training will be based on the literature, retrospective audit, and the findings of a recent unpublished evaluation [24] and article in press [1], which demonstrated high variability of centring points within pelvic radiographs and supported the proposal for a different centring point.

The control group will have a refresher update on pelvic positioning based on the retrospective audit. They will then continue with their usual practice and the technique used to position the patient (identified anatomical landmarks; field centring) will be documented on a case report form.

Sampling strategy

Patients presenting for pelvic radiography who fit the inclusion exclusion criteria will be sent a participant information sheet (PIS) with their appointment or given one in clinic and/or on arrival in radiology. Posters explaining the research will also be placed in each Department's waiting area.

A core group of study delivery radiographers, who have received GCP research awareness training will be responsible for obtaining informed written consent at both sites. Patients who agree to take part will sign a consent form agreeing to participation. The number of patients approached versus the number recruited will be recorded in a screening log.

Sample size

Based on unpublished pilot data, we would aim to reduce centring point variation with an effect size of 75%. This would require a total sample size, between the two study sites, of 314 (significance level 5%, power 80%) and would be achievable given the workload between the sites. Recruitment would be on a 1:1 basis.

Eligibility

Patients presenting for pelvic radiography who fit the inclusion exclusion criteria presenting to either of the clinical sites for pelvic radiography within the study period

Inclusion criteria

All adult patients referred for a pelvic radiograph from outpatient (OP) clinics and general practitioners (GPs).

Exclusion criteria

Patients referred for one or both hip radiographs (XHIPB). Anyone with a hip prosthesis as the anatomical measures will not be valid. Immobile patients who may need additional adjustments to techniques. Patients <18 years old or pregnant. Those unable to read the participant information leaflet (PIS) or unable to provide informed written consent due to a lack of capacity (Mental Capacity Act).

Withdrawals/declining to participate

Participants may decline to participate or withdraw from the prospective study at any time without providing an explanation and without any detriment to their care. A decision to decline to consent or to withdraw will not affect the standard of care that the patient receives, as all patients will follow the diagnosis and management pathway appropriate to their clinical and radiological findings regardless of inclusion. Where patients decline to participate, no routinely collected information will be sought from NHS hospital systems about their attendance.

Study processes

Retrospective audit

The audit will be registered with each hospital site (MYH and WHTH). As the data is anonymised at source the study team will not have access to patient details thus individual consent from patients will not be sought.

The retrospective audit will be conducted for the time period of July to October 2019 to reflect the same period of the prospective study, and avoid variation in attendance numbers which may have been due to COVID-19

Prospective study:

This is a prospective interventional two arm study. One site will undertake training and then use the different technique for pelvic radiography centring (the interventional arm) and the other site will continue with usual practice. Both sites will receive feedback on the results of the retrospective audit prior to data collection via a short presentation.

Patients presenting for pelvic radiography who fit the inclusion exclusion criteria will be sent a participant information sheet (PIS) (Appendix 1) with their appointment or given one in clinic or on arrival in radiology. Posters explaining the research will also be placed in each Department's waiting area.

Patients who are eligible will be approached by the 'study delivery radiographers' and provided with a full study information pack which will include the participant information sheet (PIS) and consent form (Appendix 2). The participant information sheet (PIS) clearly explains what the research is looking at, what the research would involve and the risks and benefits of taking part. Following a full explanation of the research and the implications of participation, the patient will be offered time to read the information again, discuss any points further for clarification and ask any questions.

Information regarding the prospective study will be prominently displayed in radiology waiting rooms (Appendix 6). A core group of study delivery radiographers, who have received research awareness training approved by the HRA and CRN, will be responsible for obtaining informed written consent at both sites

If patients choose to participate in the study, they will be recruited and formally consented in a private room for their agreement to share their anonymised images with the research team. Following written informed consent, the patient will be allocated a unique study ID number, which will be used on all non-public facing study documentation. Sufficient non-identifiable details will be logged by the research team using the EDGE research management system. This includes the patient's initials, date of birth, and eligibility checks.

The number of patients approached versus the number recruited will be recorded in a screening log.

Data collection

The retrospective audit will consist of data from existing pelvic radiographs from OP and GP clinics obtained from hospital PACS systems. This will be reviewed at a site level and compared to cross site data collated by the researchers. Images will be scrutinised for axial, sagittal, and coronal rotation; image quality, and missing anatomy. This will be recorded in a password protected Excel workbook.

Prospective data from both sites will include patient demographics (age, gender, height, and weight) and sagittal diameter at the centring point (Appendix 3). This will be recorded for each patient in the X-ray room to maintain dignity. The justification for imaging and the resultant radiograph, along with any repeats, will be collected by the research group and the resultant images will be scrutinised for axial, sagittal, and coronal rotation; image quality, and missing anatomy. This will be recorded in a password protected Excel workbook.

In the prospective cohort consented patients will undergo pelvic radiography based on the different technique or usual care, dependent upon which site they present to. The radiographer will record this, alongside the patient demographics detailed above, and justification for imaging, on a case report form (CRF – Appendix 3). The records will be anonymised and stored in a locked filing cabinet prior to analysis. The records sheet will be retained by the research team and anonymised data will be uploaded to the EDGE research management software to enable recruitment information to be collated by the NIHR portfolio and local CRN. Export of the data attributes from EDGE will be undertaken and the completely anonymised database shared with the research team for analysis. Anonymised images will be collected in DICOM format enabling analysis to be undertaken remotely. The radiation dose data will also be recorded.

Data management

Data security

The original versions of the screening logs, consent form, and CRFs will be stored in a locked filing cabinet within a locked research office at each study site. Only the research team will have access to this data. The electronic version of any data will password protected and stored on a secure drive only accessible to the direct research team. All patient identifiable information will be removed and transfer will be through encrypted devices or secure nhs.net email. All reports and dissemination of findings will only include anonymised data.

Quality control

The research team will incorporate a rigorous programme of quality control. At regular intervals, study data will be exported from EDGE into an Excel spreadsheet and validated by a member of the research team with any data queries checked against source data. The main trial site (MYH) has an established monitoring audit programme for research studies with sponsored studies guaranteed to be appraised as part of this process, the same processes will be established at the other site (WHTH). Missing data will be recorded as an empty value.

Outcome measures

Statistical evaluation and data analysis

The data from the retrospective audit from both sites will be evaluated to determine the variability of axial, sagittal and coronal rotation; image quality, and included anatomy.

Prospective data from both sites will be analysed with descriptive and inferential statistics ICC's and Bland Altman plots (if the data is normally distributed). Data will be stratified according to Body Mass Index (BMI) in the following categories:

- Underweight/Normal (BMI < 25)
- Overweight (BMI 26-30)
- Obese/morbidly obese (BMI >30)

Primary data analysis will determine the reliability of the centring point in the different technique versus usual care for sagittal, axial and coronal rotation; image quality, and included anatomy.

Secondary data analysis will compare results from within and between both sites to determine if the training and implementation of the different technique has any effect on the following:

- Obturator width left and right
- Axial pelvic rotation (degrees)
- Inter-acetabular line
- Pelvic outlet diameter
- Femoral head diameter left and right
- Inter-trochanter width
- Radiation dose
- Number of repeat radiographs
- Image quality as measured on the CRF form and from the exposure index
- Included anatomy from the iliac crests to the greater trochanters

For radiation dose data, and the number of repeats, the median and 75th percentiles will be compared.

The anonymised staff comments on the individual patient CRF's across both study arms will be descriptively analysed and a thematic analysis undertaken of any free text comments (see CRF Appendix 3).

Dose evaluation

The data collected at both sites will include the radiation dose, measured as Dose Area Product (DAP). This will be compared to both local and national Diagnostic Reference Levels (DRL's) 2019 [34]. If any radiographs require repeating due to inadequate technical quality then these will be recorded along with the DAP. All repeat radiographs will be stored on PACS locally and transferred to the research team anonymously, no study images will be 'rejected'.

The radiographs will be undertaken with the use of Automatic Exposure Controls (AEC's) which feedback to the control panel and deliver the optimum radiation dose to the patient based on patient thickness and density (attenuation). Patient thickness will be calculated by subtracting the source object distance (SOD) from the source image distance (SID). Participant height and weight will also be recorded to allow evaluation of the effect of BMI on the subsequent radiographic technical quality.

The exposure Index (E.I.) will also be recorded for each patient. The E.I. is the measure of the amount of exposure received by the image receptor (IR). It is dependent on mAs, total detector area irradiated, and beam attenuation. The exposure index is indicative of the receptor dose, hence inherent signal to noise ratio (a measure of image quality)

Study Management

Patient and Public Involvement (PPI)

This proposal was developed with the advice and contribution of two Patient and Public Involvement (PPI) representatives from one of the study sites. The research idea was presented to the representatives and their views sought on the relevance of the research and appropriateness of the

research methods proposed. The PPI were consulted on, and approved all patient facing documents, and the group gave an opinion regarding privacy and dignity issues relating to obtaining patient size characteristics and the palpation of pelvic landmarks. Advice was incorporated and aided in a refined study proposal. PPI involvement will continue during study monitoring and when disseminating study findings. The PPI team will formally continue to the publishing of a lay summary of research findings.

Study Support

The CoRIPS grant is providing the funding. They will have no intellectual property (IP) rights to the data or outcomes arising from this study. Local CRN support will be sought help with recruitment and site file monitoring.

Dissemination

Local dissemination will be led by the radiographers involved in the study delivery. It is also intended that these results will be presented at national and international conferences (UKIO and ECR). The radiographers will be supported in writing the abstract and presenting the research. The investigators will pursue publication of the results in relevant journals including Radiography and Clinical Orthopaedics. Open access will be preferred.

Use of social media and infographics (Twitter, LinkedIn and Facebook) will be used to publicise the research study and disseminate the results once the study has ended, the PPI group and participants will be encouraged to engage with these for feedback on the study.

Posters will be displayed at the participating NHS sites to feedback to patients and the radiography teams.

Ethical considerations

The key ethical consideration is identification of inadequate techniques in the retrospective audit and prospective study with respect to the pelvic radiographs.

To mitigate this and to provide quality assurance the radiographers at both sites will be provided with an overview of the main issues identified in the retrospective audit. All images will be assessed for quality throughout the study, providing opportunity for interventions if any variation from the protocol is identified.

No individual radiographer will be identified in the study.

Adverse Event Management

This study will be conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH-GCP) principles and guidelines, the Declaration of Helsinki, Mid Yorkshire Hospitals Standard Operating Procedures (SOPs), relevant UK legislation and this protocol. ICH-GCP trained personnel will conduct the study.

ICH- GCP definitions of Adverse Events (AE) and Serious Adverse Events (SAE) will be used. Pelvic radiographs and the imaging protocols are used in everyday practice and their safety profile is well established. The different technique introduced at the interventional site has been robustly tested with an existing study looking at retrospective images. It is not envisaged that the different centring technique will impact on the safety of patients or radiographers.

A member of the study team who is a senior and experienced radiographer will, at the first appropriate opportunity, consider the relatedness of any AE. Serious adverse events will be documented in the study site file with a copy of the SAE sent to the head of research or R&D at MYH.

All SAE/AE information will be emailed to midyorks.my.research@nhs.net (as lead clinical site) and the lead member of staff at the study site at the start of each calendar month as per local processes.

Dissemination strategy

Local dissemination will be led by the radiographers involved in the study delivery and presentation at national and international conferences (UKIO and ECR), The radiographers will be supported in writing the abstract and presenting the research. Publication of the results will be targeted to relevant journals including Radiography and Clinical Orthopaedics. Open access will be preferred.

Use of social media and infographics (Twitter, LinkedIn and Facebook) will be used to publicise the research study and results once published.

Impact statement

This is the first project undertaken by a group called Indication Driven Radiography (IDR). The aim is to develop evidence based standardised positioning protocols, starting with the pelvis as this is the technique most thought to demonstrate variability. There is also increasing demand from clinicians for weight-bearing images thought to better demonstrate biomechanics. The validation of a different centring point will lead to future work to demonstrate the transferability of this technique to weight-bearing postures. It will lead to future collaborations with other professions to standardise the views they most often require (i.e. collaborations with orthopaedic surgeons, physiotherapists and podiatrists).

At both clinical sites, radiographers will be trained in data collection and taking informed consent which increases the capacity of research active radiographers within the profession. These radiographers will also be supported in the dissemination of this research both locally and at national conferences.

End of Study

The end of the study will be defined as the collection of the last pelvic radiograph from either site.

Project timetable

Date From	**Date To**	**Task**
Sept 2020	Oct 2020	Preparation of, and submission of funding application to CoRIPS
March 2021	May 2021	Ethics and HRA approval
April 2021	May 2021	Retrospective audit data collection and analysis of pelvic radiographs undertaken between July to October 2019
June 2021	June 2021	Identification and training of radiographers at each clinical site to aid in recruitment, data collection and analysis
July 2021	October 2021	Recruitment of patients undergoing pelvis radiography (aided by local study radiographers)
November 2021	December 2021	Data analysis (aided by the local study radiographers)
January 2022	March 2022	Dissemination of results at conferences (UKIO, ECR) and in journals (Radiography, Clinical Orthopaedics)

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