Addis Ababa University School of Medicine and Health Science

Department of Orthopedics and Trauma Surgery

Effect of preoperative bowel preparation using cleansing enema on fluoroscopic pelvic image quality and Kerma area product radiation exposure during percutaneous sacroiliac screw fixation: randomized control trial

By: Dr. Binyam Dagnaw (OSRIV)

Advisor: Dr.Geletaw Tesema (Orthopedic trauma and arthroplasty surgeon)

October 2024

Acknowledgment

I am greatly thankful to my advisor, Dr. Geletaw Tesema for his sincere advice, comments, support in checklist preparation, and encouragement during the whole course of the study. My sincere thanks go to Dr. Gemechis R for initiating me to do this trial and collecting and recording intraoperative data. I would also like to extend my heartfelt thanks to Professor Biruk. L, head of the Department of Orthopedics and Trauma Surgery at TASH for his support and encouragement. I am also greatly thankful for Dr.Man Singh and his colleagues for their time and commitment to evaluate and score fluoroscopic and postoperative images. Last but not least, thanks to Gizew Dessie (MPH) for commenting on and guiding the design of the study proposal and Nurse Mequanent Antehunegn for his support during patient preparation and performing cleansing enema for the intervention group.

Acronyms

AAU=Addis Ababa University

AP=Anterior- Posterior

CT=Computerized Tomography

DAP=Dose Area Product

ESOT=Ethiopian Society of Orthopedics and Trauma Surgery

FMOH=Federal Ministry of Health

FPIQS=Fluoroscopic Pelvic Image Quality Score

ICRP= International Commission on Radiological Protection

KAP= Kerma Area Product

MSK= Musculo Skeletal

PRI= Pelvic Ring Injury

PSSF= Percutaneous Sacroiliac Screw Fixation

SD= Standard Deviation

SI= Sacro Iliac

SIJ= Sacroiliac Joint

TASH= Tikur Anbessa Specialized Hospital

WHO= World Health Organization

Contents

List of tables and figures

Abstract

Introduction: Unstable pelvic ring injuries present a high risk of morbidity and mortality, and early stabilization through percutaneous sacroiliac screw fixation (PSSF) offers pain relief and quicker mobilization. However, PSSF is technically challenging due to the complex pelvic anatomy and surrounding neurovascular structures, requiring precise fluoroscopic guidance. Issues such as poor visualization due to body habitus, bowel gas or fecal loading can prolong surgical time, increase radiation exposure, and increase the risk of nerve injury. This randomized controlled trial aimed to evaluate the effect of preoperative bowel preparation using a cleansing enema on fluoroscopic pelvic image quality and radiation exposure during PSSF.

Method: In this study, 50 patients were randomized into two groups: the intervention group (n=25) received preoperative bowel preparation with cleansing enema, while the non-intervention group (n=25) did not. Key outcomes assessed included fluoroscopic pelvic image quality score (FPIQS), radiation exposure (KAP), screw insertion time, number of irradiation events, postoperative reduction quality, and postoperative nerve injury. Data was analyzed using SPSS software, with significant results marked by a p-value of less than 0.05.

Result: The intervention group showed significantly better outcomes compared to the non-intervention group. The mean FPIQS was higher (25.16 vs. 16.96), radiation exposure was lower (4.88 Gycm² vs. 12.74 Gycm²), and screw insertion time was shorter (29.12 minutes vs. 49.28 minutes). Additionally, the intervention group had fewer irradiation events (86.92 vs. 151.8) and a higher rate of excellent postoperative reduction quality (56% vs. 20%). No cases of postoperative nerve injury were reported in either group**.**

Conclusion: The study concludes that preoperative bowel preparation with a cleansing enema significantly improves fluoroscopic visualization, reduces radiation exposure, and improves surgical outcomes during PSSF. Based on the findings it is highly recommended to use the method before PSSF. It can also be extended to pelvic and acetabular procedures as well.

Keywords: Unstable pelvic ring injury, percutaneous sacroiliac screw fixation (PSSF), fluoroscopic pelvic image quality score (FPIQS), radiation exposure (KAP), bowel preparation, cleansing enema, randomized controlled trial, screw insertion time, postoperative reduction quality, neurovascular injury.

1. Introduction

1.1 Background information

Pelvic stability relies on the integrity of the posterior sacroiliac complex, which is essential for withstanding the transfer of weight-bearing forces from the spine to the lower limbs. Injuries to the pelvic ring that result in instability are severe and linked to a high risk of complications and death. Minimally invasive surgical techniques, such as percutaneous sacroiliac screw fixation (PSSF), have become more widely used for early stabilization. This approach offers benefits such as reduced pain, shorter operative time, minimal blood loss, and quicker patient mobilization, ultimately supporting long-term functional recovery(1).

PSSF is indicated for complete sacral fractures, sacroiliac joint disruptions, or a combination of these posterior pelvic injuries after proper reduction. It can also be used to treat incomplete sacral fractures and sacroiliac joint disruptions that contribute to instability of the pelvic ring (2).

Percutaneous sacroiliac screw fixation (PSSF) can restore over 80% of pre-injury stability. However, it is technically challenging due to the complex bone structure and proximity to major neurovascular elements. To ensure accurate screw placement and prevent serious iatrogenic injuries, the surgeon must always maintain clear visualization of the 'safe corridors' for screw insertion. Poor fluoroscopic visualization can occur if there is significant bowel gas or fecal matter present (3).

Fluoroscopically guided procedures involving ionizing radiation pose two types of risks in medical care. The first is the stochastic risk, which includes the potential for cancer development and genetic mutations. The second involves deterministic risks, affecting superficial tissues such as the skin and the lens of the eye. Reducing radiation exposure for medical staff is crucial to enhance both immediate and long-term outcomes for patients and surgeons (4).

In our clinical practice, obtaining a clear view of the safe corridors during intraoperative fluoroscopy is often difficult due to factors such as body habitus, bowel gas, and fecal loading. This study aimed to evaluate the impact of preoperative bowel preparation with a cleansing enema on fluoroscopic pelvic image quality scores (FPIQS) and radiation exposure, measured by Kerma area product (KAP).

High-quality intraoperative fluoroscopic images are essential for visualizing safe corridors, ensuring accurate reduction, and avoiding injury to major neurovascular structures. Our trial aimed to fill the gap in scientific evidence regarding methods to improve fluoroscopic visualization of the pelvis during percutaneous sacroiliac screw fixation (PSSF). We randomly assigned 50 patients into two groups (intervention and no-intervention) using a randomized controlled trial (RCT) design. The trial was conducted between September 2023 and October 2024 at Tikur Anbessa Specialized Hospital's orthopedic and trauma surgery department.

1.2 Justification of the study

Pelvic fractures make up 3% of all skeletal fractures, with around 40% being unstable due to disruptions in the posterior ring. Achieving proper reduction of the sacroiliac (SI) joint and accurate screw placement without perforating the neural foramina is challenging, especially given the complexities of fluoroscopic imaging and variations in pelvic anatomy. Misplacement of SI screws can lead to iatrogenic neurovascular injuries, with screw malposition rates reported to be as high as 25% and neurologic injury occurring in up to 18% of cases. Even small deviations in screw trajectory can result in serious neurological and vascular complications. Therefore, successful SI screw placement relies on clear intraoperative imaging and precise reduction of the SI joint (5).

Localizing the screw's starting point can be challenging in patients with a larger body habitus, significant bowel gas, or after administering contrast media. Screw guidance primarily relies on inlet and outlet fluoroscopy, where the inlet view shows the anterior-posterior boundaries of the trajectory, and the outlet view helps guide the caudal-cranial trajectory. Potential risks during screw insertion include perforation of the spinal canal posteriorly, injury to the neural foramen affecting the exiting nerve root both caudally and cranially, as well as harm to the L5 root (6).

Currently, there is limited published data on patient radiation exposure during fluoroscopic procedures in orthopedic surgery. Reducing radiation dose from interventional procedures is crucial to enhance both the short- and long-term benefits for individual patients. Radiation management in relation to stochastic effects aims to improve overall medical care for the broader patient population. However, the impact on any single patient is less significant, as the immediate benefits of the procedure often outweigh the long-term risks associated with radiation exposure (4).

A thorough understanding of pelvic anatomy and safe bony corridors is essential for successful PSSF. Technologies like computer navigation and intraoperative CT scanning have improved accuracy; ensuring screws are correctly positioned within the bony tunnels without violating neural foramina. Unfortunately, these advanced tools are not always accessible, and many surgeons rely on C-arm imaging during surgery. Surgeons often face frustration when inadequate bowel preparation results in gas shadows, causing imaging artifacts that obscure the sacral foramina. This issue was frequently encountered by pelvic and spine surgeons, yet there was insufficient literature offering solutions to overcome these imaging challenges (7).

The study evaluated the impact of preoperative bowel preparation with a cleansing enema on fluoroscopic pelvic image quality scores (FPIQS) and radiation exposure, measured by Kerma area product (KAP), prior to percutaneous sacroiliac screw fixation (PSSF). Clear visualization of safe corridors aids surgeons in reducing the total number of irradiation events, radiation exposure, surgical time, and the risk of neurovascular complications from screw misplacement. This research also contributed valuable insights to the limited existing literature on improving imaging during PSSF .

2. Literature review

Unstable pelvic fractures make up 40% of all pelvic fractures and are responsible for approximately 8% of in-hospital deaths. PSSF has become the preferred method for surgically stabilizing acute unstable pelvic ring disruptions. Compared to traditional open surgery, this technique offers several benefits, including shorter operation time, reduced soft-tissue damage, and lower blood loss. It provides stability, reduces deformity, aids in patient mobility, and enhances the healing of posterior pelvic ring injuries. Proper inlet and outlet fluoroscopic imaging of the posterior pelvic ring is vital for the safe placement of SI screws. Poor fluoroscopic image quality can result in misinterpretation of the sacral anatomy, potentially leading to complications like screw misplacement or injury to nearby neurovascular structures. Therefore, obtaining clear C-arm images and accurately evaluating them is critical to preventing issues such as screw malposition and neurovascular damage (8).

The pelvic inlet, outlet, and lateral views are the standard radiographic images used to guide sacroiliac screw insertion. In the inlet view, the sacral promontory aligns with the anterior cortex of the first sacral vertebral body, providing optimal visualization of the anterior edge of the S1 body, ala, and canal. In the outlet view, the top of the pubic symphysis aligns with the second sacral body, offering the best view of the superior boundary of the S1 body, ala, and the upper bony surface of the S1 foramen. However, the slope of the superior surface of the sacral ala is not clearly visible in either the inlet or outlet views, making partial screw cut-out easy to miss in these images (9).

It has been demonstrated that long-term functional outcomes after pelvic injuries are closely linked to the anatomical alignment of the pelvic ring. Matta and Tornetta assessed vertical displacement by measuring the difference in height between the femoral heads using an AP pelvis x-ray. The vertical displacement was categorized as follows: Excellent: <4mm, Good: 4-10mm, Fair: 10-20mm, and Poor: >20mm (10).

A retrospective case-control study compared the outcomes of sacroiliac screw fixation with the use of bowel preparation in terms of obtaining adequate visualization by reviewing 74 cases. Intervention groups underwent preoperative bowel preparation using three liters of bowel preparation solution (Klean-Prep solution) orally the day before surgery. There were 37 patients in each group. The study showed a 10.8% revision rate, 5.4% nerve injury and two procedures abandoned for poor visualization in the intervention group. There was 2.2% revision rate, no nerve injury and no abandoned procedures for poor visualization in the non-intervention group. The study concluded that bowel preparation is not necessary to obtain adequate visualization for safe and accurate percutaneous sacroiliac screw insertion (3).

Adequate fluoroscopic visualization of the posterior pelvic ring is crucial for PSSF. Poor-quality fluoroscopic images can result in misinterpretation of bone anatomy, leading to issues such as screw malposition or injury to neurovascular injuries. A major drawback of the fluoroscopy technique is radiation exposure to both the surgical team and the patient, as multiple views are often required. Additionally, visualization of the pelvic bone can be obstructed by factors such as intestinal gas or obesity. Lateral fluoroscopic imaging is commonly recommended to locate the iliac cortical density, identify the procedure's entry point, and confirm that the screw has not penetrated the anterior cortical bone. However, obtaining clear lateral pelvic images can be technically challenging, particularly in obese patients, and interpreting the anatomical details may also be difficult. To mitigate these challenges, the inlet and outlet views have been proposed as alternative fluoroscopic approaches for guiding PSSF (8).

There was limited published data on patient radiation exposure during fluoroscopic procedures in orthopedic surgery. A study analyzing data from 492 patients who underwent fluoroscopic examinations during various orthopedic surgeries between 1997 and 1998 found that, in general, radiation exposure for limb and extremity procedures was relatively low. The median Kerma Area Product (KAP) ranged from 0.04 to 1.62 Gy·cm², with screening times between 0.2 and 2.0 minutes. In contrast, procedures involving the hips and spine had significantly higher median KAP values, ranging from 0.4 to 10.2 Gy·cm². Estimated effective doses indicated that radiation exposure for limb and extremity procedures was typically less than 10 microSv, while for hip and spine procedures, the effective dose could reach up to 1 mSv (11).

The radiation doses delivered to patients during most orthopedic procedures, under normal conditions, are generally insufficient to cause effects like skin injury, infertility, or cataracts. While the possibility of carcinogenic and genetic effects cannot be entirely ruled out, the likelihood of these effects is minimal and can be further reduced through appropriate measures. The typical radiation dose values, expressed in terms of Kerma Area Product (KAP), typically range from 0.02 to 20 Gy·cm². At this level of exposure, the potential radiation risks are much smaller compared to the clinical benefits gained from the procedure. KAP is a measurable dosimetric quantity that helps estimate radiation stochastic risks (such as cancer). It represents the product of the radiation dose and the area of the X-ray field at a particular plane. Since KAP is constant at any distance from the X-ray source, it reflects the total energy incident on the patient. By combining the KAP value with a specific coefficient (mSv/Gy·cm²), depending on the body part and protocol used, the effective dose (E) can be estimated, which helps gauge the overall radiation exposure to the patient (4).

In April 2011, the International Commission on Radiological Protection (ICRP) defined threshold value of absorbed dose limit of 0.5 Gy to the lens of the eye. For occupational exposure in planned settings, the ICRP now recommends an equivalent dose limit of 20 mSv per year for the lens of the eye, averaged over 5 years, with no single year exceeding 50 mSv. When performing several fluoroscopic procedures per week, each requiring less than 5 minutes of fluoroscopy time, adequate eye protection can be achieved by using a lead screen or wearing leaded eyewear. However, for procedures involving longer fluoroscopy times—more than 10 minutes per session—there is a considerable risk of lens opacity, which can lead to cataracts. Therefore, eye protection is critical during prolonged exposure to minimize the risk of radiation-induced lens damage (12).

3. Objectives

3.1 General objective

- To evaluate the effect of preoperative bowel preparation using cleansing enema on pelvic fluoroscopic image quality score and Kerma area product (KAP) radiation exposure during percutaneous sacroiliac screw fixation (PSSF) at Tikur Anbessa Specialized Hospital (TASH) from September 2023 to October 2024

3.2 Specific objectives

- ✓ To evaluate the effect of preoperative bowel preparation using cleansing enema on pelvic fluoroscopic image quality score (FPIQS) during PSSF at TASH from September 2023 – October 2024.
- ✓ To evaluate the effect of preoperative bowel preparation using cleansing enema on KAP radiation exposure during PSSF at TASH from September 2023 – October 2024
- ✓ To evaluate the effect of preoperative bowel preparation using cleansing enema on total number of irradiation events during PSSF at TASH from September 2023 – October 2024.
- ✓ To evaluate the effect of preoperative bowel preparation using cleansing enema on screw insertion time during PSSF at TASH from September 2023 – October 2024.
- ✓ To evaluate the effect of preoperative bowel preparation using cleansing enema on postoperative reduction quality using Matta and Tornetta criteria for vertical displacement of pelvis after PSSF at TASH from September 2023 – October 2024.
- ✓ To evaluate the effect of preoperative bowel preparation using cleansing enema on postoperative lower extremity nerve injury after during PSSF at TASH from September 2023 – October 2024.

4. Methods

4.1 Study design

A randomized control trial was conducted on 50 patients admitted with the diagnosis of unstable pelvic ring injury for percutaneous sacroiliac screw fixation at Tikur Anbessa specialized hospital from September 2023 to October 2024**.**

4.2 Study population

We followed the guidelines for reporting parallel group, randomized, controlled trials. We enrolled patients from a single major trauma center from September 2, 2023, through October 5, 2024. We enrolled 50 patients with Tile B and Tile C unstable pelvic ring injuries confirmed by a pelvic CT scan from a single orthopedic trauma center (Tikur Anbessa Specialized Hospital). Study participants were aged 18 or over and had unstable pelvic ring injury (Tile B & Tile C) scheduled for PSSF only. Patients were excluded if they presented more than two weeks after the injury, unfit for surgery, open pelvic injury, bilateral pelvic ring injury requiring more than two screw fixations, other injuries requiring anterior plating or acetabulum fixation, rectal injury, preoperative lower extremity nerve palsy, and pelvic dysmorphism. Eligibility for PSSF was determined by one of four experienced orthopedic trauma surgeons at Tikur Anbessa Specialized Hospital Orthopedic Trauma Center (Addis Ababa, Ethiopia).

4.3 Study Treatments

Patients scheduled for PSSF were randomly assigned using a lottery method in a 1:1 ratio to undergo preoperative bowel preparation using cleansing enema (Intervention group) or to undergo surgery without preoperative cleansing enema (No-intervention group). Both groups of patients were treated with similar techniques of PSSF using just 2 fluoroscopy views (inlet and outlet). The Patient was positioned under a supine position using a regular table. The approximate location of the entry point was identified by drawing a line from the anterior superior iliac spine directed perpendicularly to the floor and the second line with the femoral shaft. The intersection of the lines was formed in four quadrants. The poster superior quadrant represented the approximate entry point (8).

The number of screws used depends on the decision of the operating surgeon. Surgery was done by different surgeons and fellows using OEC Elite C-arm from GE healthcare used for all patients. Preoperative bowel preparation using cleansing enema was performed by an experienced ward nurse 4-6 hours before the surgery in accordance with standard methods, which was modified to local setup from Michigan Bowel Control Program cone enema protocol as follows (13).

Supplies: 1. slightly warm normal saline 2. Nasogastric tube 3. K-Y Jelly

Instruction;

1. Wash hands.

2. Use slightly warm normal saline.

3. Connect saline bag with nasogastric tube and hang saline bag above waist level.

4. Lubricate tip of nasogastric tube with K-Y Jelly.

5. Remove bottoms lay several folded towels or diapers or use dish with plastic cover applied under the bed

6. Insert tip of nasogastric tube about 7cm into rectum.

7. Open the clamp and allow 500-1000 mL saline flow into rectum or as much fluid as your rectum can handle.

8. Once most of the saline in the bag has been empty into the rectum, close the clamp.

9. Carefully and slowly slide the nasogastric tube tip out of your rectum

10. Hold the enema fluid in place as long as possible until you feel a strong urge to have a bowel movement. Allow at least five minutes of holding time. It's best to hold in the enema for about 15 minutes, but even waiting 5-10 minutes may be enough to help stimulate bowels.

11. Once unable to hold it any longer, expels stool and enema fluid.

12. Afterward, use a wet wipe to clean any remaining stool and lubricant from around the bottom

13. Dispose of the enema equipment.

4.4 Outcome measures

Patients' socio demographic characteristics affected side and length of stay before the surgery were self-reported after they consented to take part in the trial. **The primary outcome measures** were the fluoroscopic pelvic image quality score (FPIQS) out of 27 and radiation exposure using Kerma area product (KAP), recorded from the c-arm machine.

Fluoroscopic pelvic image quality score (FPIQS) was modified from European guidelines on quality criteria for diagnostic radiographic images of the pelvis (14). Fluoroscopic Pelvic Image Quality score (FPIQS) scores visibility of 9 important anatomic pelvic structures using a 3-point likert scale which ranges from 0 (not visible),1 (Barely visible),2(good or acceptable) and 3 (excellent or clearly visible) for each anatomic structure, making total score 27. These 9 structures included the sacral canal, anterior boundary of S1, posterior boundary of S1 on inlet view, S1 foramen, S2 foramen, superior endplate and inferior endplate of both S1 and S2 on outlet view. The image quality was assessed in a blind setting by two experienced orthopedic trauma surgeons on pelvic fractures. Both surgeons independently evaluated the visibility of 9 anatomic structures on the sacrum; the average score was taken as the final score out of 27.

Kerma area product (KAP or DAP) in Gycm2, record taken from c-arm machine is measured dosimetric quantity that can estimate the radiation risk. It represents the product of the dose (in mGy, cGy or Gy) at the center of a certain plane of the X-ray beam (e.g. the surface of the patient) multiplied by the area of the X-ray field at that plane (in cm2 or m2). KAP provides a good index for estimating stochastic risk. It is constant at any distance. KAP represents the total energy incident on the patent. Kerma-area-product (KAP) meters are wide-area output detectors that can only assess the average dose over the radiation beam area. Readout is provided in units of $Gy.cm^2$ (4).

The secondary outcome measures were screw insertion time in minutes, the total number of irradiation events, postoperative reduction quality assessed using Matta and Tornetta criteria for vertical displacement of the pelvis and postoperative lower extremity nerve injury.

- Screw insertion time is the time taken from the start of the surgery to completion of screw insertion measured in minutes recorded during the procedure.
- Total number of irradiation events is the total number of images taken during the procedure, which was taken from the final report of C-arm machine
- Postoperative reduction quality was assessed using Matta and Tornetta criteria for vertical displacement of hemi pelvis by measuring the difference in height of the femoral heads using postoperative AP pelvis x-ray (10)
- Postoperative lower extremity nerve injury was assessed clinically for sensation and motor activity of both lower extremities.

4.5 Randomization and Blinding

Considering few expected number of PSSF surgeries and cost restrictions, we planned a total sample size of 50 patients using 1:1 ratio (intervention group (n = 25) and non- intervention group (n = 25). 25 intervention group-labeled cards and 25 non-intervention group-labeled cards mixed together in a single box. After patient gave informed consent and scheduled for PSSF, the responsible nurse will pick one card randomly using lottery method from the box containing mix of all 50 cards and act based on the card picked either intervention or non-intervention.

All staff involved in scoring, checking, entering, and analyzing intraoperative questionnaire responses were blind to allocation. Orthopedic surgeons who assessed fluoroscopic pelvic image quality score and postoperative reduction quality were blinded for the allocation of fluoroscopic pelvic images given to them for analysis.

4.6 Ethical clearance

The study complied with the principles of the Declaration of Helsinki and was approved by the local ethics committee of department of orthopedics and trauma center at Tikur Anbessa Specialized Hospital. The first author takes responsibility for the integrity and accuracy of the reported data and for the fidelity of the study to the protocol.

4.7 Statistical Analysis

Data was collected using Kobo tool box application from September 2023 to October 2024. SPSS software, version 27.0, was used for statistical analysis. A two-sided P value of less than 0.05 (5% significance level) and 95% confidence interval were considered to indicate statistical significance. Descriptive statistics was used to summarize the data. Quantile-quantile (Q-Q) plot was used to assess the distribution of all scale variables. For scale variables with normal distribution, mean, standard deviation, range and unpaired t-tests were used. For scale variables with non-Gaussian distribution or unequal variance, Levene's test of t-statistics, Rank, sum of ranks and Mann-Whitney U test was performed. For ordinal variables, count, percentage and Wilcoxon rank-sum tests were used. Spearman's rank correlation coefficient was used to confirm the relationship between continuous variables.

5. Result

Randomization was performed on all 50 patients with unstable pelvic ring injuries scheduled for PSSF: 25 patients, or 50% of the total, were assigned to the non-intervention group, and 25 patients, or 50% of the total, were assigned to the preoperative bowel preparation group using cleansing enema (intervention group)(Figure 1).

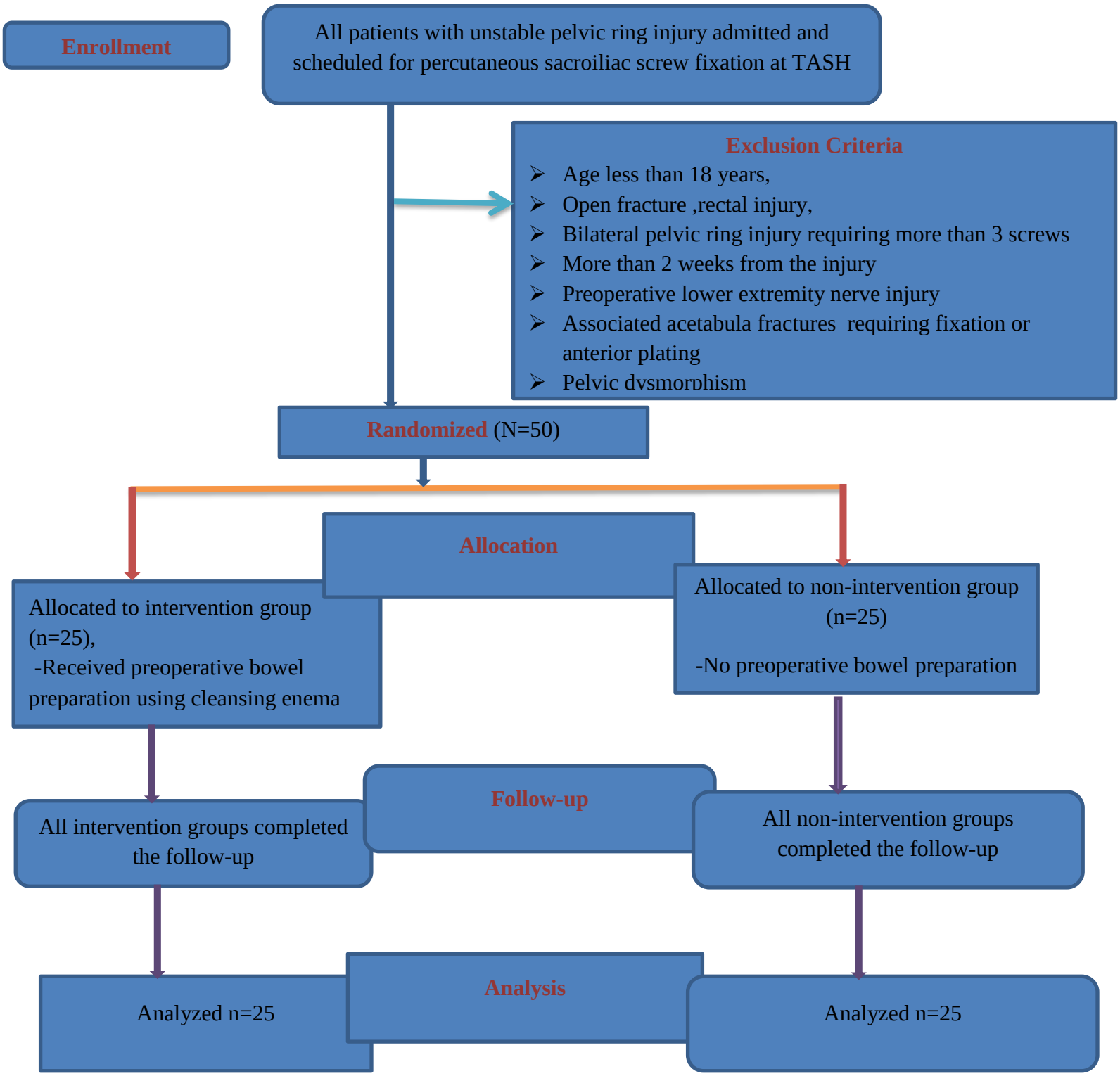


Figure 1.Flow diagram showing the process of enrollment, randomization, allocation, follow-up and analysis

From all 50 patients, 27 (54%) were male and 23 (46%) were female. The mean age of the intervention group was 33.52 years and 36.68 years for the non-intervention group. Intervention and non-intervention groups had mean body mass indexes of 21.37 kg/m2 and 22.15 kg/m2, respectively. The right side was the most affected 37 (74% of 50 patients). The mean waiting stay before surgery after the injury was 6.64 days for both groups. Tile C pelvic ring injury accounted for 26 (52%) of patients. More than half (27, 54%) of fixations were done on the S1 body (Table 1 and Figure 2).

Table 1.Sociodemographic and baseline characteristics of patients

Variables		**Intervention group(n=25)**	**Non Intervention group(n=25)**
Sex –no. (%)	Male	11(44%)	16(64%)
	Female	(14)56%	(9)36%
Age __year		33.52 ± 8.74	36.68±12.68
Body-mass index in kg/m^2		21.37 ±1.93	22.15±2.96
Affected side – no. (%)	Right	19(76%)	18(72%)
	Left	6(24%)	7(28%)
Length of stay before surgery in day		6.64±4.07	6.64±2.64
Tile classification of pelvis	Tile B	15(60%)	9(36%)
	Tile C	10(40%)	16(64%)
Body of Sacrum used for sacroiliac screw fixation	S1 sacral body	15(60%)	12(48%)
	Both S1 and S2	10(40%)	13(52%)

Plus–minus values are means ±SD. No significant differences between groups in the reported characteristics were found at baseline

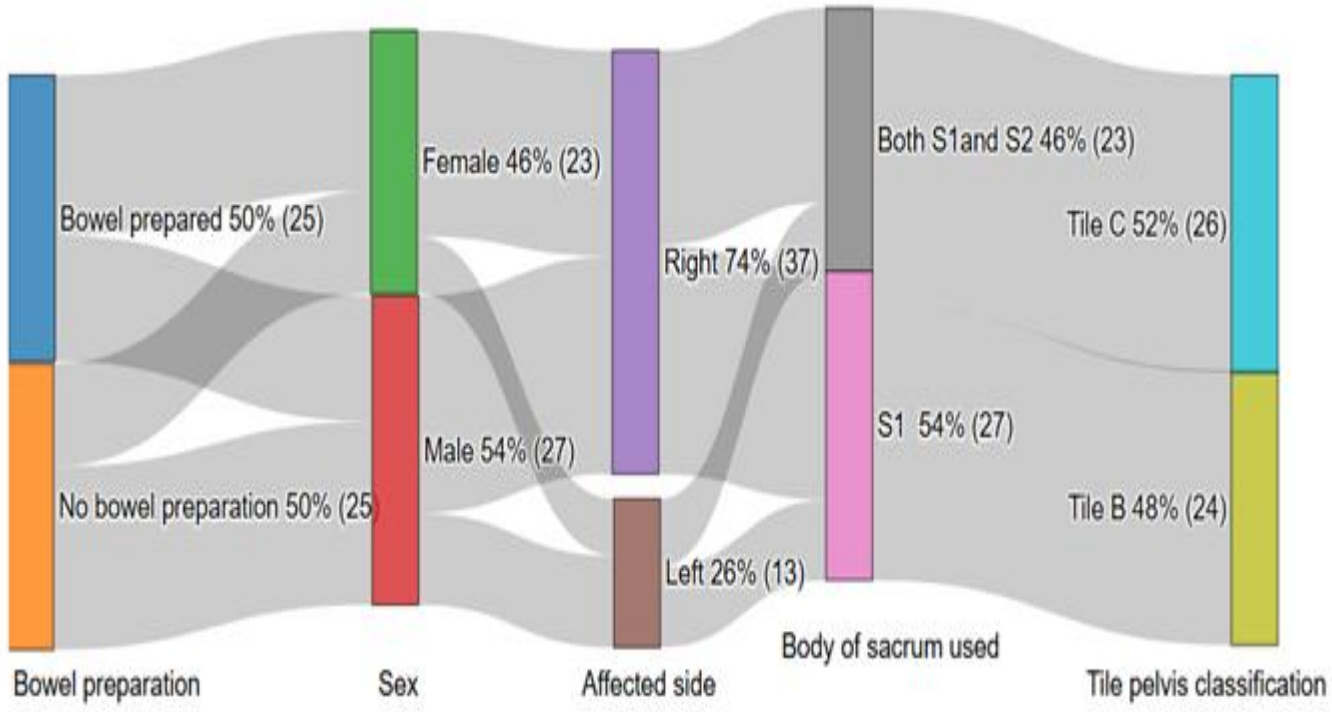


Figure 2 Sankey diagram showing socio demographic and baseline characteristics of patients

Descriptive statistics of intraoperative variables showed that the mean score of the fluoroscopic pelvic image quality score (FPIQS) out of 27 was 25.16 and 16.96 for the intervention and non-intervention groups, respectively. Radiation exposure using KAP in Gycm2 was 4.88 for the intervention group and 12.74 for the non-intervention group. The mean screw insertion time in minutes was 29.12 minutes for the intervention group and 49.28 minutes for the nonintervention group. The mean of the total number of irradiation events recorded from the C-arm machine for each procedure was 86.92 for the intervention group and 151.8 for the non-intervention group. Subgroup analysis also presented for Tile B and Tile C pelvic ring injury (Table 2).

Table 2. Descriptive Summary of intraoperative primary and secondary outcome measures										
Variable	**Intervention group**					**Non-Intervention group**				
	Frequency	**Mean**	**SD**	**95%CI**		**Frequency**	**Mean**	**SD**	**95%CI**	
				Lower	**Upper**				**Lower**	**Upper**
Fluoroscopic pelvic image quality score (FPIQS) out of 27	25	**25.16**	1.7	24.46	25.86	25	**16.96**	3.88	15.36	18.56
Radiation exposure measured with Kerma area product (KAP) in Gycm^2	25	**4.88**	2.46	3.87	5.9	25	**12.74**	9.74	8.72	16.76
Radiation exposure measured with Kerma area product (KAP) in Gycm^2 for Tile B pelvic ring injury(PRI)	15	**4.07**	2.36	2.76	5.37	9	**9.65**	7.35	4.0	15.3
Radiation exposure measured with Kerma area product (KAP) in Gycm^2 for Tile C PRI	10	**6.1**	2.17	4.55	7.65	16	**14.48**	10.68	8.79	20.17
Screw insertion time in minutes	25	**29.12**	10.87	24.63	33.61	25	**49.28**	12.9	43.96	54.6
Screw insertion time for Tile B PRI in minutes	15	**21**	3.12	19.27	22.73	9	**39.44**	8.82	32.67	46.22
Screw insertion time for Tile C PRI in minutes	10	**41.3**	5.03	37.7	44.9	16	**54.81**	11.57	48.65	60.98
Total number of irradiation events during the procedure	25	**86.92**	33.23	73.2	100.64	25	**151.8**	44.93	133.25	170.35
Total number of Irradiation events for Tile B PRI	15	**73.73**	26.89	58.84	88.63	9	**122.56**	51.14	83.24	161.87
Total number of Irradiation events for Tile C PRI	10	**106.7**	33.1	83.02	130.38	16	**168.25**	32.14	151.13	185.37

Postoperative reduction quality using vertical displacement of the pelvis was assessed based on Matta and Tornetta criteria using immediate postoperative AP pelvis x-ray. The trial showed excellent reduction (<4 mm) among 56% of intervention group and 20% of non-intervention group. There was no extended diarrhea related to the intervention. There was also no postoperative nerve injury on lower extremities for both groups of patients (Table 3).

Table 3.Summary of descriptive statics of postoperative variables

Postoperative variables		**Intervention group**	**Non-intervention group**
Post-operative vertical displacement using Matta criteria	Excellent	14(56%)	5(20%)
	Good	11(44%)	12(48%)
	Fair	0(0%)	8(32%)
Postoperative lower extremity nerve injury		0(0%)	0(0%)
Post enema extended diarrhea		0(0%)	0(0%)

Effect of preoperative bowel preparation using cleansing enema on primary and secondary outcome measures

The mean difference **of the fluoroscopic pelvic image quality score** of patients that had intervention (25.16) and without intervention (16.96) was 8.2 at 95% CI, normal distribution using Q-Q plot, and $P<0.001$ for the unequal variance assumption of Levene's test of T-statistics. The nonparametric test, the Mann-Whitney U test, showed that there was a significant difference in the image qualities between the two groups (mean rank 37.7 for the intervention group and 13.3 for the nonintervention group, $p<0.001$) with a large effect size ($r = 0.84$). The intervention group had a higher score of FPIQS than the nonintervention group (Table 4).

The mean difference of **radiation exposure using Kerma area product (KAP)** of patients that had intervention (4.88 Gycm2) and without intervention (12.74 Gycm2) was 7.86 at 95% CI, asymmetric distribution using a quantile-quantile plot, and P = 0.017 for the unequal variance assumption of Levene's test of T-statistics. The nonparametric test, Mann Whitney U test, showed that there was a significant difference in radiation exposure KAP using Gycm2 between the two groups (mean rank 15.88 for the intervention group and 35.12 for the non-intervention group, $p<0.001$) with a large effect size ($r = 0.66$). The test revealed intervention groups have significantly lower radiation exposure KAP than non-intervention groups (4). The results of subgroup analysis for both Tile B and Tile C pelvic ring injury patients also suggested the intervention group has significantly lower radiation exposure KAP than the non-intervention group.

The mean difference of total number of irradiation events was 64.88 among patients that had intervention (86.92) and non-intervention (151.8) at 95% CI with normal Q-Q plot, P = 0.049 for unequal variance assumption of Levene's test of t-statistics. Mann-Whitney U test showed that there was a significant difference of total number of irradiation events between the two groups (mean rank 16.16 for intervention group and 34.84 for non-intervention group, $p = <.001$ with a large effect size, $r = 0.64$) (Table 4). The test revealed intervention groups has significantly lower total number of irradiation events score than non-intervention group. Subgroup analysis on total number of irradiation events for Tile B and Tile C pelvic ring injury patients suggested intervention group has significantly lower total number of irradiation events than non-intervention group.

Postoperative vertical displacement of the hemi pelvis was assessed based on Matta and Torentta criteria using an immediate postoperative AP pelvis x-ray, which showed excellent reduction (<4 mm) among 56% of the intervention group and 20% of the non-intervention group. The non-parametric test, Mann Whitney U test, showed that there was a significant difference in postoperative vertical displacement of pelvis using Matta and Tornetta criteria between the two groups (mean rank 31.76 for the intervention group and 19.24 for the non-intervention group, $p = 0.003$) with medium effect size ($r = 0.47$) (Table 4).The test revealed intervention groups had more number of excellent postoperative reduction using Matta and Tornetta criteria than the non-intervention group.

Table 4 .Summary of analytical statics of intraoperative and postoperative variables using Mann-Whitney U-Test										
Variables	**Intervention group**			**Non-intervention group**			**Mann-Whitney U-Test**			**Effect size(r)**
	Frequency	Mean rank	Sum of mean rank	Frequency	Mean rank	Sum of mean rank	U-test	P	Z	
Fluoroscopic pelvic image quality score (FPIQS)	25	**37.7**	332.5	25	**13.3**	942.5	7.5	<0.001	-5.95	0.84
Screw insertion time for Tile B PRI	15	**8.2**	123	9	**19.67**	177	3	<.0.001	-3.91	0.8
Total number of irradiation events during the procedure	25	**16.16**	404	25	**34.84**	871	79	<0.001	-4.53	0.64
Radiation exposure measured with KAP in Gycm^2	25	**15.88**	397	25	**35.12**	878	72	<0.001	-4.67	0.66
Radiation exposure measured with KAP in Gycm^2 for Tile B pelvic ring injury	15	**9.4**	141	9	**17.67**	159	21	0.004	-2.77	0.57
Postoperative vertical displacement of pelvis using Matta and Tornetta criteria	25	**31.76**	794	25	**19.24**	481	156	0.003	-3.31	0.47

The mean duration of screw insertion time decreased by 20.16 minutes for the intervention group (M = 29.12, SD = 10.87) compared to the non-intervention group (M = 49.28, SD = 12.9) at 95% CI, normal distribution using a quantile-quantile plot, and p = 0.435 for the equal variance assumption of Levene's test of 2 tailed T-test statistics. The t-test revealed a significant difference between the two groups: t (48) = 5.98, p =<.001. The effect size for this difference was large, with Cohen's d equal to 1.69.The 95% confidence interval for the difference in means ranged from 13.37 to 26.95 (Table 5). The results for both Tile B and Tile C pelvic ring injury patients suggest the intervention group has significantly lower screw insertion time in minutes than the non-intervention group.

Table 5 .Summary of analytical statics of intraoperative variables using independent t-test											
Independent Samples Test											**Cohen's d**
Variables		**Levene's Test for Equality of Variances**		**T-test for equality of means**							
		F	**Sig.**	**T**	**Df**	**Sig. (2-tailed)**	**Mean Difference**	**Std. Error Difference**	**95% Confidence Interval of the Difference**		
									Lower	**Upper**	
Screw insertion time	Equal variances assumed	0.62	0.435	5.98	48	**<.001**	20.16	3.37	13.37	26.95	**1.69**
Screw insertion time for Tile C PRI	Equal variances assumed	2.87	0.103	3.47	24	**0.002**	13.51	3.89	5.48	21.54	**1.4**
Total number of Irradiation events for Tile B PRI	Equal variances assumed	3.16	0.089	3.08	22	**0.005**	48.82	15.84	15.97	81.68	**1.3**
Total number of Irradiation events for Tile C PRI	Equal variances assumed	0.03	0.874	4.7	24	**<0.001**	61.55	13.1	34.51	88.59	**1.89**
Radiation exposure measured with KAP in in $Gycm^2$ for Tile C PRI	Equal variances assumed	1.52	0.23	2.43	24	**0.023**	8.38	3.45	1.27	15.49	**0.98**

The result of the Spearman correlation showed that there was a significant correlation between fluoroscopic pelvic image quality score and screw insertion time, r (48) = -0.62, p = <.001. Spearman correlation showed that there was a significant correlation between fluoroscopic pelvic image quality score and Kerma area product in Gycm2, r (48) = -0.59, p = <.001. The result of the Spearman correlation showed that there was a significant correlation between fluoroscopic pelvic image quality score and total number of radiation events, r(48) = -0.54, p = <.001. Thus, there is a high, negative association between the fluoroscopic pelvic image quality score and screw insertion time, radiation exposure using KAP, and the number of irradiation events per procedure (Table 6).

Spearman correlation showed that there was no significant correlation between fluoroscopic pelvic image quality score and age (r (48) =-0.11, p=.432). The result of the Spearman correlation showed that there was no significant correlation between fluoroscopic pelvic image quality score and BMI, r (48) =-0.05, p=.735. The result of the Spearman correlation showed that there was no significant correlation between fluoroscopic pelvic image quality score and length of stay before surgery in days, r (48) = -0.17, p =.224. Thus, there was no association between fluoroscopic pelvic image quality score and age, BMI, or length of stay before surgery in days in our trial sample (Table 6).

Table 6. Spearman correlation between Fluoroscopic pelvic image score and Age, BMI, length of stay ,screw insertion time, KAP, and total number of irradiation events

Variables	**Spearman correlation**	
	R	**P**
Fluoroscopic pelvic image quality score and Age	-0.11	0.432
Fluoroscopic pelvic image quality score and BMI	-0.05	0.735
Fluoroscopic pelvic image quality score and length of stay before the surgery	-0.17	0.224
Fluoroscopic pelvic image quality score and screw insertion time	-0.62	**P<0.001**
Fluoroscopic pelvic image quality score and KAP radiation exposure	-0.59	**P<0.001**
Fluoroscopic pelvic image quality score and total number of irradiation events	-0.54	**P<0.001**

6. Discussion

The mean difference of fluoroscopic pelvic image quality score out of 27 between patients that had intervention (25.16), and no intervention (16.96) was 8.2. Mann Whitney U test showed that there was a significant difference in the image qualities between the two groups (mean rank 37.7 for the intervention group and 13.3 for non-intervention group, $p<0.001$) with large effect size ($r = 0.84$). The result was in contrast to the findings of H.Raza and his colleagues, a retrospective case control study on 74 patients to compare the outcomes of PSSF with and without the use of bowel preparation, using bowel preparation solution (Klean-Prep solution) orally a day before surgery. The study showed 10.8% revision rate, 5.4% nerve injury, and two abandoned procedures due to poor visualization among the bowel-prepared group. The study concluded that bowel preparation is not necessary to obtain adequate visualization for safe and accurate percutaneous sacroiliac screw insertion (3).

The discrepancy may be from the methods of bowel preparation; unlike any laxative, cleansing enema has the advantage of speed and certainty of action. It can also ensure that you will not lose any stool or stimulate the movement of bowel , which indirectly increases bowel gas and hinders adequate fluoroscopic visualization (13). Cleansing enema improves constipation and also doesn't need long NPO time before the surgery, unlike laxatives and bowel preparation solutions.

The mean difference of radiation exposure using the KAP record of the c-arm was 7.86 Gycm2 between the intervention (4.88 Gycm2) and non-intervention group (12.74 Gycm2). Mann-Whitney U test showed that there was a significant difference in KAP between the two groups (mean rank 15.88 for the intervention group and 35.12 for the non-intervention group, $p<0.001$). KAP is a measure of stochastic effects. Even at very low doses, it is possible that sufficient energy may be deposited into a critical volume within a cell to result in cellular changes or cell death. For occupational exposure, the limit should be an effective dose of 20 mSv per year, averaged over defined 5-year periods (100 mSv in 5 years), and should not exceed 50 mSv in any single year (15).

KAP of both groups in our trial was far below the recommended limit. The mean KAP of the non-intervention group was 12.74 $Gycm^2$. Using Dose Conversion Coefficient (DCCE) (mSv (Gy·cm2)–1] derived from Monte-Carlo simulations for orthopedic surgeries, 0.01 $mSv/Gy{\cdot}cm^2$ (16). The mean effective dose for no intervention group will be 0.000785 mSv and significantly lower than this value for intervention groups. Both intervention and no intervention group in our trial had occupational radiation exposure KAP below the recommended limit of 20 mSv effective dose per year.

Previous studies showed that effective dose, eye lens dose, and face skin dose to an orthopedic surgeon wearing a 0.5-mm lead-equivalent apron will not exceed the corresponding limits if the dose area product of the fluoroscopically guided procedure is <0.38 Gy m 2 (3800 Gycm2). When protective eye goggles are also worn, the maximum permissible dose area product increases to 0.70 Gym^2, while the additional use of a thyroid shield allows a workload of 1.20 Gy m 2. The effective dose to the orthopedic surgeon working tableside during a typical hip, spine, and kyphoplasty procedure was 5.1, 21, and 250 μSv, respectively, when a 0.5-mm lead-equivalent apron alone was used. Our results showed a lower effective dose for both groups compared to hip, spine, and kyphoplasty procedures (17).

During 41 procedures of intramedullary nailing of femoral and tibial fractures, the primary surgeon and the first assistant wore ring dosimeters on their dominant index fingers. The average dose of radiation to the dominant hand of the primary surgeon was 1.27 mSv and 1.19 mSv to the first assistant. The dose limit for the extremities is 500 mSv per year, as recommended by the International Commission on Radiological Protection. Extrapolation of the mean dose of the primary surgeon and first assistant per procedure of 1.23 mSv leads to the result that the recommended dose limit of 500 mSv would only be exceeded if more than 407 intramedullary nailing procedures are carried out per year. The duration of fluoroscopy time correlated with the radiation dose to the hands of the surgeons. Our results showed a by far lower level of effective dose on both groups in accordance with the recommended limit (18).

The mean duration of screw insertion time for both one and two screw fixations decreased by 20.16 minutes for the intervention group (M = 29.12, SD = 10.87) compared to the non-intervention group (M = 49.28, SD = 12.9) with p<.001 at 95% CI. The mean screw insertion time for a single sacroiliac screw at the S1 body of the sacrum was 39.44 minutes for the non-intervention group and 21 minutes for the intervention group. There was also a significant difference in the total number of irradiation events (mean of 86.92 for the intervention and 151.8 for the non-intervention group) between the two groups (mean rank 16.16 for the intervention group and 34.84 for the non-intervention group, p <.001). Our finding was comparable with the work of Mohammad Zarei and his colleagues on percutaneous sacroiliac screw insertion with only outlet and inlet fluoroscopic views for unstable pelvic ring injuries, which showed a mean operation time of 21.18 min (15-72 minutes per screw) (8).

Decreasing surgical and fluoroscopy time has been proven to be one of the most effective ways of reducing radiation dose substantial to the patient and staff during fluoroscopy. Reducing patient doses will lower staff doses too. Because X-rays involve ionizing radiation that can deposit energy in human cells and cause tissue changes, it is important to minimize any associated risk to the patient. This is done by limiting the radiation exposure to the minimum required to create the clinical images needed to answer the medical question (19).

Postoperative vertical displacement of the hemi pelvis was assessed based on Matta and Tornetta criteria using an immediate postoperative AP pelvis x-ray, which showed 56% of the intervention group and 20% of the non-intervention group, had excellent reduction (less than 4 mm). Mann-Whitney U test showed that there was a significant difference in postoperative vertical displacement of pelvis using Matta and Tornetta criteria using postoperative AP pelvis x-ray between the two groups (mean rank 31.76 for the intervention group and 19.24 for the non-intervention group, p = 0.003) with medium effect size (r = 0.47). The test revealed intervention groups had a higher number of excellent scores of postoperative vertical displacements of pelvis using Matta criteria than non-intervention groups. Comparable findings by El-Badawy and his colleagues using the Matta and Tornetta method for postoperative radiological evaluation showed 25% of patients had excellent results, 50% had good results, and 25% had fair results (1).

The result of the Spearman correlation showed that there was a high, negative association between FPIQS and screw insertion time, radiation exposure using KAP, and number of irradiation events per procedure with p = <.001. The Spearman correlation showed that there was no significant correlation between FPIQS and age (p =.432), BMI (P = 0.735), or length of stay before surgery (p = 0.224).

There was no postoperative nerve injury on lower extremities for both groups of patients. Similar finding with the work of Mohammad Zarei and his colleagues on PSSF only outlet and inlet fluoroscopic view for unstable pelvic ring injuries, which showed no evidence of iatrogenic neurovascular injury (8). Our finding was not comparable with Michael M. and his colleagues' findings which showed a 3.2% rate of iatrogenic nerve injuries (20). There was also no extended diarrhea related to our intervention.

Limitation

Our trial included a small number of patients due to the limited number of unstable pelvic ring injury and PSSF operations. We also used a single center trial using only one C-arm machine for the procedure. The patients were operated by four different Orthopedics and trauma surgeons.

Conclusion

Our trial result showed preoperative bowel preparation using cleansing enema before percutaneous sacroiliac screw fixation had significantly higher fluoroscopic pelvic image quality score (P<0.001).It also significantly decreased occupational radiation exposure KAP (P<0.001), screw insertion time (P<0.001) and total number of irradiation events (P<0.001) .Intervention group also had more number of an excellent score of postoperative vertical displacement of pelvis using Matta and Tornetta criteria than non-intervention group (P<0.003). No iatrogenic postoperative nerve injury was identified on both groups. We didn't encounter extended diarrhea related to our intervention. We recommend using preoperative bowel preparation using cleansing enema prior to percutaneous sacroiliac screw fixation. It can be extended for other fluoroscopic pelvic and acetabulum procedures. We also encourage researchers to do the trial at a multicenter level using different C-arm machines.

7. References

1. El-badawy ME sayed, Mohamed E sayed AM, Alalfy AT, El-aidy SM. Outcome of Percutaneous Iliosacral Screw Fixation of Sacroiliac Joint Disruptions.
2. Miller AN, Routt MLC. Variations in sacral morphology and implications for iliosacral screw fixation. J Am Acad Orthop Surg. 2012 Jan;20(1):8–16.
3. Raza H, Bowe A, Davarinos N, Leonard M. Bowel preparation prior to percutaneous ilio-sacral screw insertion: is it necessary? Eur J Trauma Emerg Surg Off Publ Eur Trauma Soc. 2018 Apr;44(2):211–4.
4. Agency IAE. Patient Dose Optimization in Fluoroscopically Guided Interventional Procedures [Internet]. Patient Dose Optimization in Fluoroscopically Guided Interventional Procedures. International Atomic Energy Agency; 2010 [cited 2024 Sep 26] p. 1–108.
5. Iorio JA, Jakoi AM, Rehman S. Percutaneous sacroiliac screw fixation of the posterior pelvic ring. Orthop Clin [Internet]. 2015 [cited 2024 Sep 26];46(4):511–21.
6. Banaszek D, Starr AJ, Lefaivre KA. Technical considerations and fluoroscopy in percutaneous fixation of the pelvis and acetabulum. JAAOS-J Am Acad Orthop Surg [Internet]. 2019 [cited 2024 Sep 26];27(24):899–908.
7. Patel S, Dhillon MS, Vashisht S, Kumar V. Pinhole effect and manual bowel gas displacement: Simple two tricks for better fluoroscopy imaging in iliosacral screw fixation. J Orthop Dis Traumatol [Internet]. 2020 [cited 2024 Sep 26];3(1):8–10.
8. Zarei M, Moosavi M, Saghebdoust S, Shafizadeh M, Rostami M. Percutaneous iliosacral screw insertion with only outlet and inlet fluoroscopic view for unstable pelvic ring injuries: Clinical and radiological outcomes. Surg Neurol Int [Internet]. 2022 [cited 2024 Sep 26];13.
9. Zhang J, Hamilton R, Li M, Ebraheim NA, He X, Liu J, et al. Evaluation of partial cutout of sacroiliac screws from the sacral ala slope via pelvic inlet and outlet view. Spine [Internet]. 2015 [cited 2024 Sep 26];40(24):E1264–8.
10. Matta JM, Tornetta III P. Internal fixation of unstable pelvic ring injuries. Clin Orthop Relat Res 1976-2007 [Internet]. 1996 [cited 2024 Sep 26];329:129–40.
11. Crawley MT, Rogers AT. Dose-area product measurements in a range of common orthopaedic procedures and their possible use in establishing local diagnostic reference levels. Br J Radiol [Internet]. 2000 [cited 2024 Sep 26];73(871):740–4.

12. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 2011. Statement on Tissue Reactions. ICRP ref 4825-3093-1464. Approved by the Commission on April 21, 2011.
13. ConeEnemas.pdf [Internet]. [cited 2024 Sep 26]. Available from: https://www.med.umich.edu/1libr/MBCP/ConeEnemas.pdf
14. European Commission: Directorate-General for Research and Innovation, Carmichael, J., Moores, B. and Maccia, C., European guidelines on quality criteria for diagnostic radiographic images, Publications Office, 1996,
15. ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).
16. NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, 2007. Ionizing Radiation Exposure of the Population of the United States, Report 160, Bethesda, MD (2009).
17. Theocharopoulos, Nicholas MSc; Perisinakis, Kostas PhD; Damilakis, John PhD; Papadokostakis, George MD; Hadjipavlou, Alexander MD; Gourtsoyiannis, Nicholas MD. Occupational Exposure from Common Fluoroscopic Projections Used in Orthopaedic Surgery. The Journal of Bone & Joint Surgery 85(9):p 1698-1703, September 2003.
18. Müller LP, Suffner J, Wenda K, Mohr W, Rommens PM. Radiation exposure to the hands and the thyroid of the surgeon during intramedullary nailing. Injury. 1998 Jul;29(6):461-8. doi: 10.1016/s0020-1383(98)00088-6. PMID: 9813705.
19.Https://www.iaea.org/resources/rpop/health-professionals/interventional-procedures/goodpractices-in-interventional-fluoroscopy
20. Michael M. Hadeed, David Woods, Jason Koerner, Katya E. Strage, Cyril Mauffrey, and Joshua A. Parry, Risk factors for screw breach and iatrogenic nerve injury in percutaneous posterior pelvic ring fixation, Journal of Clinical Orthopaedics and Trauma, Volume 33, 2022, 101994

8. Annex

8.1 Information sheet

Participant Information Sheet

(Randomized Controlled Trial)

Name of researchers: Dr.Binyam Dagnaw, Dr.Geletaw Tesema, Dr.Gemechis Regassa

We would like to invite you to take part in our research study. Before you decide whether you want to take part, it is important that you understand why the study is being done and what participating in the study entails. One of our team will go through this information sheet with you, to help you decide whether you would like to take part or not and answer any questions you may have.

It may take about 15 minutes. Please read the following information carefully. Feel free to ask us if there is anything that is not clear and do take time to decide whether you wish to take part.

This study aims to improve visualization of fluoroscopic pelvic image during percutaneous fixation of unstable pelvic ring injury by using preoperative bowel preparation using cleansing enema. Clear visualization of the complex pelvic anatomy during percutaneous sacroiliac screw fixation will improve anatomic reduction, screw insertion time and minimizes iatrogenic neurovascular injury. Preoperative Bowel preparation using cleansing enema will be done by experienced nurse 4-6 hours before the scheduled surgery. The procedure is commonly done for constipated patients. During the procedure slightly warm 500-1000 ml of normal saline will be flushed through the rectum using a lubricated nasogastric tube. You will be requested to hold the fluid as much as you can .Then you will release bowel and fluid .

This procedure will expel all the impacted stools and make your colon free from stool which enhances visualization of the complex sacral anatomy during the procedure.

We are inviting patients who expressed an interest, who have a diagnosis of unstable pelvic ring injury scheduled for percutaneous sacroiliac screw fixation. We are inviting up to 50 patients to take part in this study.

Participating in this study is voluntary. If you prefer not to take part in the study, this will not influence the current care you receive from doctors, nurses, or any other healthcare professionals.

If you agree to take part, we will then ask you to verbal a consent form. If you agree to take part but then change your mind you can withdraw from the study at any time without giving a reason. This would not affect the standard of care you receive.

Before taking part in the study a member of the research team will discuss the study in detail with you and give you time to ask any more questions that you may have. If you're eligible to take part in the study, you will then be asked to sign a consent form to confirm that you are happy to take part.

Taking part in the study will involve meeting with the research team on three separate events. The assessments are split into three phases: The first stage before surgery with a questionnaire booklet about your age, sex, weight and height used to calculate your body mass index, affected side and type of fracture you encountered. This will take around 10 minutes to complete and will be done by the researcher. The second stage involves intraoperative assessment of fluoroscopic pelvic image quality, radiation exposure KAP, screw insertion time and number of irradiation events. C-arm recording of dose summary and intraoperative fluoroscopic images will be utilized for analysis. The third stage involves postoperative nerve assessment of your lower extremities, reduction quality of fixation using postoperative x-ray and assessment of possible complications related to the intervention like extended diarrhea. This will be done by study researchers who will always provide you with clear instructions and takes up to 30 minutes. It is important for the study that you try to complete all the three phases. The assessments will take place at your hospital bed.

This study is a randomized control trial. This is a method where participants are put into groups and each group is given a different treatment and the results are compared to see if one is better. To try to make sure the groups are the same to start with, each person with unstable pelvic ring injury scheduled for percutaneous sacroiliac screw fixation will be allocated into a group by chance (randomly).

Therefore, half the people taking part will be allocated by chance to a group where they will be given preoperative bowel preparation using cleansing enema in addition to their usual surgical care. The other half will be allocated to a group that continues to receive their usual surgical care as normal but will not be prepared preoperative with cleansing enema.

If you are allocated to receive the intervention, an experienced trained nurse will support you and arrange necessary materials. We will not be changing your surgical treatment. The treatment you usually receive for your fracture will remain the same as it would if you were not taking part in the study.

There are minimal disadvantages in taking part in the study, but it will require a commitment of your time. If you don't feel happy at any point during the study, you can take breaks or stop completely. The researcher will work with you to ensure you get ongoing support.

This study does not involve taking any oral medications or any changes to your usual treatment. Cleansing enema may sometimes cause mild loosening of your stool for the first day.

If you are in the group that is allocated to receive preoperative bowel preparation, it is hoped that the cleansing enema before the surgery will improve visualization of your pelvis anatomy for the operating surgeon which will enhance anatomic reduction of your fracture, minimize your radiation exposure, decrease screw insertion time and avoids iatrogenic neurovascular injury. If it is well-effective in improving quality of fluoroscopic pelvic image, we hope that it could then be disseminated to other surgeons. It may be applied for acetabulum fractures. It may also be used as a model to develop better procedures to improve fluoroscopic pelvic image.

The study will not affect your usual surgical treatment and therefore, when the study is completed you will continue with your usual surgical care. We will be able to share the results of

the study with you and we hope the method will be helpful. If the information provided above has interested you and you are considering participation, please read the additional information below before making any decision.

You can withdraw from any aspects of the study at any time without giving a reason and without affecting the standard of care you receive. Every care will be taken during this study to ensure that your well-being is not compromised. If however you or your relatives have any concerns about any aspect of the way you have been approached or treated by members of staff during this study you can speak to a member of the research team who will do their best to answer any questions. Their contact details are at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the orthopedic and trauma surgery department head. The orthopedic and trauma surgery department head office is at first floor of orthopedic building. This is open from Monday to Friday from 8:00 Am to 5:00pm. Tel(+251115522995)

The unlikely event that something does go wrong, and you are harmed during the research due to someone's negligence then you have grounds for a legal action. The normal health Service complaints mechanisms will still be available to you.

We will be using information from you/ and your medical records to undertake this study. We are responsible for looking after your information and using it properly with confidentiality. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting study members listed at the end of this information sheet. The people who analyses the information will not be able to identify you and will not be able to find out your name, I-care number or contact details.

The scientific results of the study will be available after finished and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the participants involved in the study will be identified in any report or publication. Should you wish to see the results, or the publication, feel free to contact us at any time.

None of the doctors or researchers who are working on this study is being paid for including participants in the study, and there are no conflicts of interest.

The study is looked at by an independent group of people, called a Research Ethics Committee, of orthopedics and trauma surgery to protect your interests. This study has been reviewed and given favorable opinion by research Ethics Committee of orthopedics and trauma surgery department.

You are encouraged to ask any questions you wish, before, during or after the study. If you have any questions about the study, please speak to a member of the research team who will be able to provide you with up to date information. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

1. Dr.Binyam Dagnaw, binidagnaw@gmail.com , 09216382222

2. Dr.Gemechis Regassa , gemechisregasa100@gmail.com, 0944286295

8.2 Consent form

Thank you for taking the time to read, listen and ask questions on the above information sheet and for considering taking part in this study. You can have more time to think this over if you are at all unsure. You can also ask any unclear information about the study at any time. If you decide you would like to take part in this study we can proceed to the interview part. Your verbal agreement to take part on the study will be marked yes on the consent form. The date and person who interviewed will be mentioned on the consent form with signature. The consent form will be filed to the head of department of Orthopedics and trauma surgery.

Your agreement on this form means that: You understand the information given to you in the information sheet about the study on effect of preoperative bowel preparation using cleansing enema before percutaneous sacroiliac screw fixation, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by agreeing on this consent form.

Are you Volunteer to participate in this randomized control trial? Yes ☐ No ☐

Signature of Person Obtaining Consent **Date**

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE PLACED IN THE DEPARTMENT OF ORTHOPEDICS AND TRAUMA SURGERY .ONLY CONSENT FORMS THAT INCLUDE ADDIS ABABA UNIVERSITY LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS

8.3 Questionnaire

Participant unique code_____		
Part I PART I – Socio-demographic characteristics and injury of respondent(encircle the choice)		
No.	**Question**	**Choice**
1.1	Age in years	_____
1.2	Sex	1.Male 2.Female
1.3	Body mass index(Kg/m^2)	_____
1.4	Affected side	1.Right 2.Left 3.Both
1.5	Time from injury to surgery in days	_____Days
1.6	Injury classification based on Tile classification	1.Tile A 2.Tile B 3.Tile C

Part II Questions on quality of fluoroscopic pelvic image ,tick √ on your choice

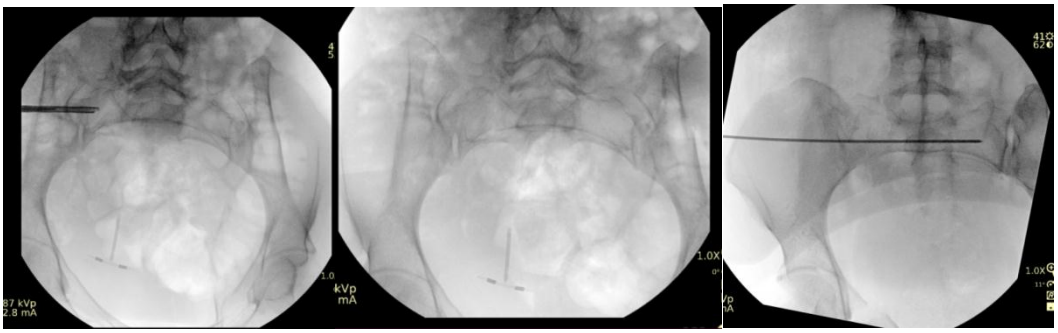
0 point =not visible, 1 point= barely acceptable, 2 points =Good/Acceptable 3 points=excellent(Clearly visible)

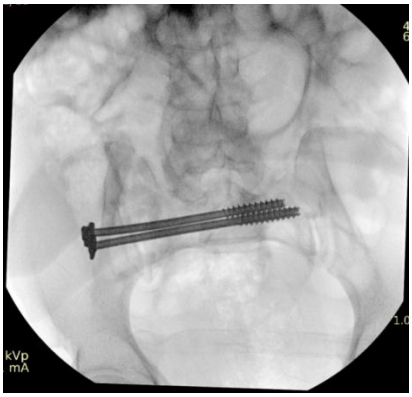
No.	Visibility of anatomic landmarks useful for the Sacroiliac screw fixation on pelvic fluoroscopic image	Not Visible	Barely visible	Good /Acceptable	Excellent (Clearly visible)
2.1	There is visually sharp reproduction of anterior boundary of S1 body and sacral ala on inlet view				
2.2	There is visually sharp reproduction of posterior boundary of S1 body and sacral ala on inlet view				
2.3	There is visually sharp reproduction of sacral canal on inlet view				
2.4	There is visually sharp reproduction of S1 foramen on out let view				
2.5	There is visually sharp reproduction of S2 foramen on outlet view				
2.6	There is visually sharp reproduction of superior endplate of the S1 body and ala on outlet view				
2.7	There is visually sharp reproduction of inferior endplate of S1 body and ala on outlet view				
2.8	There is visually sharp reproduction of superior endplate of the S2 body and ala on outlet view				
2.9	There is visually sharp reproduction of inferior endplate of S2 body and ala on outlet view				

Part III Questions on surgical report and postoperative reduction quality ,encircle your choice			
3.1	Body of sacrum used for sacroiliac screw insertion	Right side	1.S1 2.S2 3.Both
		Left side	1.S1 2.S2 3.Both
3.2	Screw insertion time in minutes	_____	
3.3	Amount of radiation exposure using kerma area product(KAP)	_____Gycm2	
3.4	Postoperative reduction quality measured by vertical displacement of hemi pelvis on postoperative AP pelvis x-ray based on Matta and Tornetta criteria	1. Excellent 2. Good 3. Fair 4. Poor	
3.5	Postoperative lower extremity nerve injury	1.Yes 2.No	
3.6	Extended diarrhea after cleansing enema	1.Yes 2.No	
Thank you			

8.4 Collections of intraoperative C-arm images

Figure 3; Gallery of some of intraoperative fluoroscopic pelvic images of intervention groups with preoperative cleansing enema





THANK YOU