AMERICAN UNIVERSITY OF BEIRUT

SYSTEMATIC INTERVENTION TO REDUCE RADIATION DOSE FROM FLUOROSCOPIC GUIDED PROCEDURES IN THE RADIOLOGY DEPARTMENT

by
MIKHAEL GEORGES SEBAALY

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ABSTRACT
OF THE THESIS OF

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Title: Systematic Intervention to Reduce Radiation Dose from Fluoroscopic Guided Procedures in the Radiology Department

Background: Radiation effects are one of the pillars that determines how radiologists, radiology technologists and radiology trainees practice radiology and take decisions related to patient care and management. Although the risk of cancer increases with the ionizing radiation dose, the severity of the stochastic effects does not; the patients will either develop cancer or will not. Hence, the principle "as low as reasonably achievable" (ALARA) of radioprotection became fundamental to the principles of radiation protection. Fluoroscopic guided lumbar puncture to retrieve CSF is an example of a radiological procedure that may potentially result in a significant radiation dose. We developed a 3-point systematic approach with checklist for fluoroscopic guided lumbar puncture, with the aim to decrease the radiation dose/fluoroscopy time of the procedure.

Objectives: In this study we aim to check if our developed 3-point systematic approach with checklist for the fluoroscopic guided lumbar puncture will reduce the fluoroscopic time of the procedure with similar or improved complications and failure rates compared to the standard technique.

Methods: We did a retrospective review of patients that underwent fluoroscopic guided lumbar puncture (LP) in the department of Radiology, at the University of Iowa Hospitals and Clinic, Iowa City, IA, USA between 2019 and 2021. 145 cases performed using the developed 3-point systematic approach with checklist and 226 cases performed using the standard technique were included in our study. We collected data on relevant patient demographics, date of procedure, type of procedure, fluoroscopy time, immediate complications, CSF color, physician performing the procedure and procedure technical success rate. The chi-squared test was used to compare categorical variables and the independent t-test was used to compare continuous variables between the two age groups. Univariate and multivariate linear regression models were conducted to investigate the effect of different patient and procedural factors on fluoroscopy time. Statistical analyses were carried out with the use of IBM SPSS software package version 28.0, level of significance of $p < 0.05$.

Results: There is significant reduction in radiation dose and fluoroscopy time in the group where the 3-point systematic approach with checklist was used (2.03 sec) compared to the group where only the standard technique was used (25.62 sec). This significant dose reduction remained statistically significant when adjusting for several potential confounders: type of the procedure (lumbar puncture with or without myelogram), age, BMI, date of the study (first vs second half of the academic year), gender and staff performing the procedure. Furthermore, there is statistically significantly higher success rate of the fluoroscopic guided lumbar puncture in the group where the 3-point systematic approach with checklist was used (99.3%) compared to the group where only the standard technique was used (95.6%). There was no statistically significant difference in the complication rate and traumatic tap rate between the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. In our linear regression model, doing a myelogram, increased patient age and doing the procedure in the first half of the year are factors contributing to a statistically significant increase in fluoroscopy time.

Conclusion: The 3-point systematic approach with checklist was associated with 1162% decrease in fluoroscopy time/radiation dose of fluoroscopic guided lumbar punctures and statistically significantly increase in success rate reaching more than 99% compared to the standard technique. No difference in traumatic tap rates and complication rates was noted between the two groups. We believe that our study will provide a cornerstone for future research on effective interventions and approach for dose reduction in fluoroscopy guided procedures.

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ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACR	American College of Radiology
ALARA	As Low as Reasonably Achievable
ASRT	American Society of Radiation Technologists
AY	Academic Year
BMI	Body Mass Index
CSF	Cerebrospinal Fluid
CT	Computed Tomography
Cm	Centimeters
DNA	Deoxyribonucleic Acid
EHR	Electronic Health Record
FDA	Food and Drug Administration
FL	Fluoroscopy
FOV	Field of View
FPS	Frames per Second
GI	Gastrointestinal
Gy	Gray
HIT	Heparin-Induced Thrombocytopenia
I.E.	Id Est (that is)
INR	International Normalized Ratio
IRB	Institutional Review Board
KeV	Kiloelectron Volts
Kg/m^2	Kilograms Per Meters Squared

LET	Linear Energy Transfer
LP	Lumbar Puncture
MRI	Magnetic Resonance Imaging
MRN	Medical Record Number
mSv	Millisievert
min	Minutes
M phase	Mitosis Phase
OER	Oxygen Enhancement Ratio
PACS	Picture Archiving and Communication System
PT	Prothrombin Time
PTT	Partial Thromboplastin Time
RBE	Relative Biologic Effectiveness
RSNA	Radiological Society of North America
Sec	Seconds
SIR	Society of Interventional Radiology
S phase	Synthesis Phase
SPR	Society of Pediatric Radiology
SPSS	Statistical Package for the Social Sciences
SSD	Source-to-Skin Distance
U	Units
UIHC	University of Iowa Hospitals and Clinics
UK	United Kingdom
US	Ultrasound
U.S.	United States

/L	Per Liter
YO	Years Old

CHAPTER I

BACKGROUND

A. Radiation Safety

1. ALARA

Radiation is energy moving in the form of particles or waves. Familiar radiations that we encounter in our daily life are heat, light, radio waves and microwaves. Radiations with higher frequency and energy are used in radiology to image patients for diagnostic and therapeutic purposes. Ionizing radiation is a form of electromagnetic radiation with energies much higher than visible light. X-rays and gamma rays have enough energy to remove electrons from the atoms when they interact with them causing the atom to become ionized or charged. Hence, X-rays and gamma rays are considered ionizing radiation [1]. Ionization is a unique property of radiation with lower frequency/higher energy. Ionized atoms seek to get to a more stable state where they have a good balance of neutrons and protons. To get to the more stable state, atoms expel energy from the nucleus in the form of a particle of X-ray which is called radioactive decay [2]. ALARA – As Low as Reasonably Achievable is the guiding principle of radiation safety in Radiology [3]. It means avoiding exposure to ionizing radiation that does not have a direct benefit to the patient even if the dose is minimal. Examples of ionizing radiation modalities in radiology include computed tomography (CT), radiography (X-ray), fluoroscopy and nuclear medicine examinations [4].

2. Time

Time simply refers to the amount of time an individual spends exposed to radiation. Hence, the target should be to minimalize the radiation time during a radiologic examination which will respectively reduce the radiation dose to the patient and to the team in the examination room. The radiation dose delivered during a procedure is highly operator dependent [5]. During Fluoroscopic procedures, there are several techniques to decrease the radiation exposure time. Controlling the pulse rate reduces the radiation dose. Pulse rate is the number of fluoroscopic images taken per second by the machine. Continuous fluoroscopy is defined as pulse rate of 30 pulses per second which leads to the highest radiation dose per second for a fluoroscopic study. However, pulsed fluoroscopy at a reduced acquisition rate, typically 15 pulses per second or less is proposed to reduce radiation dose in interventional procedures [6]. The fluoroscopy pulse rate to be chosen by the operator depends on the aim of the study. The operator should choose the lowest fluoroscopy pulse rate possible and complete the work as quickly as possible while getting diagnostic study that addresses the clinical concern. It is like spending a day at the beach, if you stay in the sun the entire day, you will likely get sunburned. However, if you are there for just a short period of time, you are less likely to get sunburned. In short, the amount of time you are in there makes a difference. It should be a balance between the risks and benefits for each study.

3. Distance

Distance refers to how close a patient or a health care provider is to a radiation source. Maximize your distance from a radiation source to decrease your dose is the basic idea behind limiting radiation exposure. The dose is inversely proportional to the square of the distance from the source of radiation. It is like sitting very close to a fireplace, you can feel the heat and may even be uncomfortable. However, if you go to the other side of the room, you would be more comfortable as the intensity decreases. To minimize the patient's dose, the fluoroscopy image detector which is above the patient should be close to the patient to detect the maximum possible number of the x rays. Furthermore, to minimize the operators' dose, the tube should be under the table and the operator and patient should be at a maximum possible distance from the fluoroscopy tube. The inverse square law states that the intensity of radiation is inversely proportional to the square of the distance from the ionizing radiation source. This means that if the distance is doubled, the intensity decreases by 4-fold; in other words, the intensity is one fourth the intensity if the distance is doubled [7].

4. Shielding

To shield a patient and at the same time the healthcare providers from unnecessary radiation exposure, several techniques can be used. Coning the radiation beam is used to shield the patient from unnecessary radiation. Coning works by limiting the field of view of radiation exposure on the patient to the area of interest, thereby decreasing the radiation dose. In addition, there is shielding to the medical team which simply is putting a radiation barrier between the radiation source and the operator. The most effective shielding depends on the kind of radiation the source is emitting. For fluoroscopic studies, a lead apron is used to protect the medical team performing the procedure from excessive radiation. The percentage of radiation transmitted through a 0.5 mm thick lead apron ranges from 0.9% to 6.8% depending on the energy of the radiation being emitted with higher transmission percentage as the energy of the radiation increases [8].

B. Radiation Biology

1. Radiation Effect

Ionizing radiation has enough energy to cause changes in DNA of cells and affect the cell function when it falls on a normal cell. This radiation damage to the cells and tissues as well as the effect of radiation on the human body is called "Biologic effect of Radiation". The severity of the damage caused by radiation is dependent on several variables including quality of radiation, quantity of radiation, received dose of radiation and exposure condition [9]. Primary variables that determine the biologic effect of radiation include those inherent to the cells and the condition of the cells at the time of irradiation. Damage to biologic systems occurs in the order of molecular, then cellular then organic. Molecular damage is always first. The ionized atoms do not bind properly to the other molecules which leads to loss of function in the molecule and ultimately loss of the cellular function.

When radiation interacts with a biologic material, energy is deposited along the tract and the pattern of this deposited energy depends on the type of radiation involved. Linear energy transfer (LET) refers to the average amount of energy deposited per unit path length of the incident radiation. LET is important in assessing the potential for soft tissue damage. For instance, X-rays and gamma rays' ionization density is low along the track. Whereas neutrons, protons and alpha particles lead to much more frequent ionization events. Therefore, neutrons, protons, alpha particles, and other heavy ions are said to have higher LET (much more damaging) compared to photons, gamma rays, electrons and positrons which have lower LET (less damaging).

Relative biologic effectiveness (RBE) refers to the relative capability of radiation with differing LETs to produce a particular biologic reaction. So Relative biologic effectiveness increases with increasing linear energy transfer to a certain point. Above 100 keV/micrometer of tissue, RBE decreases with increasing LET because the maximum potential damage has been done and the cells are dead. This is called the "kill effect". Oxygen enhancement ratio (OER) is the relative effectiveness of radiation to produce damage at different oxygen levels. The idea behind it is that biologic tissue is more sensitive to radiation in an oxygenated state, however, this is only valid for low LET because with high LET, the OER is 1 where biologic damage with oxygen is equal to biologic damage without oxygen.

The radiation effects on the DNA include single strand break, double strand break and mutation. The single strand break is the least damaging since the repair enzymes can move in and fix the damage. The double strand break causes a break in multiple chemical bonds and is harder to fix. The mutation in the DNA chain is transferred when the cell divides if the cell did not die from radiation. Besides, the sensitivity of the cells to radiation depends on the cell cycle phase where cells are most sensitive to radiation in the M phase and least sensitive to radiation in the S phase. Therefore, rapidly dividing cells, like in the gastrointestinal tract (GI) and lymphocytes, are more sensitive to radiation. Radiation can cause immediate effect on the body or long-term effect which may appear in years or several generations later. Biological effects of radiation are of two types: deterministic effect and stochastic effect.

2. Deterministic Effect

Deterministic effect comes from tissue injury derived from death of its stem cells induced by the acute high dose radiation and leads to sterility in germ line and organ disorders in somatic cells [10]. Deterministic effect which is also referred to as nonstochastic effect depends on the time of exposure, dose of radiation and type of radiation. Deterministic effect has a threshold of doses below which the effect does not occur. The threshold varies from person to person. However, deterministic effect is dose related and severity increases with increasing dose. All early effect and most tissue late effect are considered deterministic effects. The mechanism is related to radiation effect on many cells and although the severity of effect is related to dose of radiation, there is cell killing in all people when the radiation dose is large enough. Deterministic effect includes acute radiation sickness and chronic radiation sickness.

a. Acute Radiation Sickness

Acute radiation sickness happens when a large radiation dose has been delivered in a short period of time. The symptoms appear just after the radiation exposure or within 24 hours. The symptoms include nausea, vomiting, headache, fever, skin and tissue burns. The earlier the symptoms appear, the worse the prognosis. First symptoms to appear are the GI flu like symptoms (nausea, vomiting and diarrhea), then the patient feels better “latent phase”, then the syndrome subtype manifests which is related to the damaged organ system, and the last phase is death or recovery.

b. Chronic Radiation Sickness

Chronic radiation sickness occurs after a month or year of high radiation exposure. These are after the “latent phase” and take a month or year for the symptoms to manifest. The symptoms depend on the dose of radiation and hence the organ that is affected. For example: lymphocytes are the most radiosensitive blood cells, hence lymphocytopenia is one of the common signs of chronic radiation sickness affecting the blood cells. These effects are dangerous and difficult to cure, hence may lead to death. In some situations, a small dose of radiation continuously or over many years cause chronic effect. This includes the patient's exposure as well as the team's performing the procedure exposure to radiation. Chronic radiation sickness effects are not immediately observable and include long term effect such as cataract, cancer, genetic mutation, temporary or permanent sterility.

3. Stochastic Effect

Stochastic effect is an effect that occurs when a person receives a high dose of radiation. There is no dose threshold relationship with stochastic effect. The risk of stochastic effect increases with increasing radiation dose. However, the severity of the effect does not depend on the magnitude of the absorbed dose, and it occurs by chance. Classic examples of stochastic effect are somatic stochastic effect such as malignant disease and genetic or hereditary effect. Somatic effect affects the individuals exposed to radiation during their lifetime. Whereas genetic effect is a result of damage to the genetic material in the reproductive cell which is transmitted to the descendants causing birth defects or diseases related to individual gene mutation.

Keeping the radiation dose as low as possible will not only decrease the likelihood of somatic and genetic stochastic effects for the patient but also for the healthcare team (radiologist, radiology technician…) that are doing these procedures all day for years throughout their career. Establishing cause effect relationship between the exposure to small dose of radiation for a long time among radiologist and radiologic technologists is tricky, however, early studies showed increased mortality due to leukemia in early radiology departments workers [11]. In addition, the leukemia cluster near Sellafield

Nuclear Plant is another example of the stochastic radiation effects [12]. Finally, the radiation effect on offspring of irradiated parents could be higher that currently predicted with higher risk of acquiring cancer over their lifetime [13].

4. Limiting the Effect of Ionizing Radiation Damage

Why should we keep radiation dose to the minimum? The survival curve best describes the Quasi-threshold dose relationship between the radiation dose and cell survival (figure 1) [14]. The rationale behind radiation safety and ALARA is to keep the radiation dose as low as possible to stay in the part of the graph where the cell repair mechanisms (repair shoulder) are trying to hold the ship together and repair the damage to the cell. It is a measure of the sub-lethal damage to the cell. The linear part of the curve which represents the radio-sensitivity of the cell population is 1/Slope (D_0); where the higher (D_0), the more radio-resistant the cell is.

C. National and International Entities Recommendations and Resources on Decreasing Patients' Radiation exposure

Since 1895, when William Roentgen discovered X-ray radiation, radiology has been booming. The number of diagnostic imaging facilities have been growing in recent year and became more modern as the demand for radiological examination has increased [15, 16, 17]. Besides, imaging not only facilitates the diagnosis, but it is being used for treatment as is the case with fluoroscopic guided lumbar puncture and intrathecal medication administration. However, the increased availability and the easier access to imaging studies increased the risk of the population-based exposure to ionizing radiation in the medical setting. The background and natural radiation dose is approximately 1-3 mSv per year, however the average radiation dose for a single CT scan is around 10-30 mSv [18, 19]. Given that studies demonstrated that the risk of cancer increases with radiation exposure, more so in the pediatric population where the tissues are growing and hence more sensitive to radiation, it is estimated that medical procedures using ionizing radiation are responsible for 0.6% to 3% of cancers worldwide [20, 21, 22]. Therefore, the ALARA principle that has been introduced into radiological practice is justified with no doubt [23]. The almost logarithmic increase in the number of examinations prompted the governing bodies in healthcare to come up with new principles to decrease radiation during radiologic procedure. This resulted in the formation of the alliance for radiation safety in pediatric imaging in 2007 which included the Society of Pediatric Radiology (SPR), the American College of Radiology (ACR), the American Association of Physicist in Medicine (AAPM), and the American Society of Radiologic Technologists (ASRT) which launched the Image Gently campaign. In addition, an American College of Radiology (ACR)/Radiological Society of North America (RSNA) coalition was formed joined by the American Association of Physicist in Medicine (AAPM), and the American Society of Radiologic Technologists (ASRT) launched the Image Wisely campaign directed towards the adult population. These campaigns shared a common goal of developing and sharing educational resources with providers and consumers to curb unnecessary imaging and reduce radiation exposure [24, 25].

1. Image Gently

The image gently mission statement is to improve safe and effective imaging care of children worldwide through advocacy. The alliance goal is to change practice by raising awareness of the opportunities to lower radiation dose in the imaging of children.

The strategy to reach the goal is straightforward: providing information and free educational materials to every member of the care team.

The image gently pledge states [25]:

> "Yes, I want to image gently.
> Recognizing that every member of the healthcare team plays a vital role in caring for the patient and wants to provide the best care, I pledge:
> • To make the image gently message a priority in staff communications this year
> • To review the protocol recommendations and, where necessary, implement adjustments to our processes
> • To respect and listen to suggestions from every member of the imaging team on ways to ensure changes are made
> • To communicate openly with parents "

For instance, in an academic multihospital health care system, a comprehensive campaign was implemented at all sites in 2010 in concordance with the objective of Image Gently campaign. The pediatric radiology department, which has a close working relationship with the division of pediatrics, provided a monthly radiology conference to the department of pediatric house staff in which, on the basis of case studies, the use of imaging and alternative imaging was discussed. In addition, these discussions were incorporated into the joint weekly pediatric radiology and pediatric surgery conference [26]. Furthermore, pediatric dosing/low-dose technique was used when appropriate. This resulted in the decrease in the CT examinations (ionizing radiation) from 55.5% in 2004 to 29% in 2014, while MRI examinations increased from 23.1% in 2004 to 31.5% in 2014 and ultrasound examinations increased from 21.3% in 2004 to 39.5% in 2014 as a percentage of all imaging performed in the pediatric population [26]. This proves that we can reduce radiation exposure through education.

2. Image Wisely

The image wisely taskforce mission was to raise awareness of opportunities to eliminate unnecessary imaging examinations and to lower the amount of radiation used in necessary imaging examinations to only that needed to acquire appropriate medical images [24]. Hence the taskforce was charged to develop educational resources for radiologists, medical physicists, and technologists who provide medical imaging care within the United States and for consumers of medical imaging care, including referring physicians, patients, and the public which were released in 2009 as the image wisely campaign. An online pledge was developed summarizing the approach and practice that should be adopted by each member of the health care team.

The image wisely pledge for imaging professionals states [24]:

> "I wish to optimize the use of radiation in imaging patients and thereby pledge:
>
> - To put my patients' safety, health and welfare first by optimizing imaging examinations to use only the radiation necessary to produce diagnostic-quality images.
> - To convey the principles of the Image Wisely program to the imaging team in order to ensure that my facility optimizes its use of radiation when imaging patients.
> - To communicate optimal patient imaging strategies to referring physicians, and to be available for consultation.
> - To routinely review imaging protocols to ensure that the least radiation necessary to acquire a diagnostic-quality image is used for each examination.
> - To monitor examination radiation dose indices to enable comparison to established diagnostic reference levels."

The image wisely pledge for referring practitioners states [24]:

> "I have reviewed the Image Wisely webpage for Referring Practitioners and pledge to the following:
>
> - I will educate myself regarding the relative radiation exposures for the various imaging exams which use ionizing radiation (plain X-rays, fluoroscopic studies, CT scans, and nuclear medicine studies). In my practice, I will balance the medical benefit to my patients for any of these imaging exams I order against any potential radiation risk associated with that exam.
> - I will consult, as needed, with professionals specializing in medical imaging (radiology, nuclear medicine, ultrasound, and magnetic resonance

imaging) in order to choose the most appropriate imaging examinations for my patients."

For instance, in an academic multihospital health care system, a comprehensive campaign was implemented at all sites in 2010 in concordance with the objective of Image Wisely campaign. A lecture series was developed that emphasized the potential risks of medical ionizing radiation, the appropriate indication for examinations that expose patients to ionizing radiation such as CT scans and the alternative imaging strategies for common conditions. The lectures were provided to the board of trustees, department chairs, attending radiologists, trainees, medical students, CT technologists, and all incoming house staff members. In addition, the lectures were presented at grand rounds, divisional meetings, and house staff orientation on annual and semiannual basis. Medical students also received a dedicated lecture in their mandatory radiology clerkship. This resulted in the decrease in the percentage of CT examinations (ionizing radiation) in patients above 20 years of age, with proportional increase in the percentage of MRI and ultrasound examinations between 2004 and 2014 as a percentage of all imaging performed in this patient population [26].

3. U.S Food and Drug Administration (FDA)

The U.S. Food and Drug Administration's (FDA) mission is to protect and promote the public health [27]. Hence, the FDA has been concerned with minimizing unnecessary radiation exposure of people for more than 50 years since the passage of Radiation Control for Health and Safety Act of 1968 [28, 29]. Recently, the FDA's concerns regarding unnecessary medical imaging related radiation exposure were expressed in the 2010 white paper [26] as well as the FDA's activities related to the Bonn Call for Action [31, 32]. Therefore, FDA works closely with manufacturers and other stakeholders to regulate medical X-ray imaging systems both as medical devices and as electronic products by developing guidance documents, assisting in maintaining and updating national and international voluntary consensus standards, holding public meetings, publishing safety notices, public health advisories and other public communications [33]. The aim of the FDA approach in this matter is to decrease radiation and promote public health. The FDA recommends that medical x-ray imaging exams, which include computed tomography (CT), fluoroscopy, and conventional X-rays, use the lowest radiation dose necessary, considering the size and age of the patient. Whether grouped by age or by size, an x-ray image should always be adjusted to meet the needs of the specific type of pediatric or adult patient receiving the exam.

gD. Fluoroscopy

1. Fluoroscopy technique

Fluoroscopy is an imaging modality that allows real time X-ray viewing of a patient with high temporal resolution. It was based in the old days on X-ray image intensifier coupled to a still/video camera. However, in recent years with the more advanced systems, it is based on flat panel detectors which are similar to the digital radiography. The fluoroscopy machine uses lower current for continuous or near continuous X-ray exposures that results in images with low signal to noise ratio but are of sufficient quality for patient positioning and certain diagnostic/therapeutic procedures. There are 2 basic modes of operation of fluoroscopy systems. First, fluoroscopy, which provides real time imaging for positioning, which is generally not recorded and is relatively low in radiation dose. Second, fluorography, which essentially uses the fluoroscopic imaging chain in a pulsed radiographic mode to record and document clinically relevant temporal sequences such as blood flow through vessels (angiography), mechanical motion of joints… with the downside of higher level of radiation dose, comparable to radiography. With the improvements in the fluoroscopy system technology, the patient and staff radiation dose rate for fluoroscopy has been reduced substantially with improvement in image quality, at the same time. More complicated systems in new fluoroscopy suites include numerous methods for radiation safety to the staff, including ceiling hung clear X-ray shields for protecting the upper body of the operator, along with numerous other devices deployed for reducing the scattered radiation received by staff.

Diagnostic fluoroscopy procedures are performed daily in the radiology suites across the world. These procedures are performed safely by avoiding commonly encountered pitfalls. All the personnel in the fluoroscopy suite including the radiologist, anesthesiologist, resident, fellow, fluoroscopy technician, and nurses have a crucial role in making sure the patient's procedure is performed in a safe manner. High patient doses during a fluoroscopic study increase the chance of adverse reactions. For instance, a dose of 2 Gy leads to early transient erythema, a dose of 3 Gy leads to temporary epilation, a dose of 6 Gy leads to chronic erythema, a dose of 7 Gy leads to permanent epilation, a dose of 10 Gy leads to telangiectasia, a dose of 13 Gy leads to dry desquamation, a dose of 18 Gy leads to moist desquamation and ulceration and a dose of 24 Gy leads to secondary ulceration.

2. Qualification and responsibility of personnel

To perform a fluoroscopic guided procedure, an individual should be one of the following as per the American College of Radiologists: qualified physician to perform or supervise fluoroscopically guided procedures, qualified medical physicist, qualified non-physician radiology provider, certified radiologic technologist, or radiation therapist. Other ancillary personnel who are qualified and duly licensed may perform also fluoroscopic guided procedures under the supervision of a qualified physician. A qualified physician should have a fundamental clinical knowledge and specific skills to perform fluoroscopic procedures safely [34]. In addition to the basic understanding of anatomy, physiology and pathophysiology, the physician should have sufficient knowledge of the clinical and imaging evaluation. The physician should also evaluate the patient's clinical status to identify the risks for complications and contraindications for the procedure. Each facility should have a policy for granting physicians fluoroscopy privileges. Besides, physicians should comply with all applicable state and federal laws and regulation for fluoroscopy licensure or certification [35, 36]. A physician qualified to perform or supervise fluoroscopic guided procedures should have the following initial qualifications: Certification in Radiology, Diagnostic Radiology or Interventional Radiology/Diagnostic Radiology (IR/DR) or completion of an accredited residency that includes 6 months of training in fluoroscopic guided procedures or be privileged to perform a specific procedure after performing at least 10 of a certain procedure under the supervision of a training physician qualified for that procedure.

3. Procedural Specifications

Written or electronic request for fluoroscopic procedures should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination. Documentation that satisfies medical necessity includes sign and symptoms and/or relevant history including known diagnosis. The request for the examination must be originated by a physician or other appropriately licensed health care provider who provide the clinical information. Clinical management of radiation is essential for every procedure [37-39].

All equipment must have spacers to maintain the minimum source-to-skin distance (SSD) and should have spacers to achieve the recommended SSD [40-41]. All interventional fluoroscopy equipment should be equipped with displays of air kerma rate, kerma area product and cumulative air kerma.

4. Patient exposure controls to reduce patient dose

Multiple patient exposure controls can be used to reduce patient exposure as per the ACR recommendations. These behaviors include the following [42]: "

1. Use of fluoroscopy sparingly and only when real-time imaging guidance is needed.
2. Use of a lower acquisition (imaging-recording) frame rate.
3. Use of a low fluoroscopic pulse rate. Items #1 and #2 adhere to the guideline: "Pause and Pulse."
4. When fluoroscope provides multiple dose rate modes for fluoroscopy and/or acquisition, select the lowest dose rate that provides adequate image quality.
5. Use of short duration of recorded exposure runs for image acquisition, which reduces the total number of images acquired and therefore the associated patient dose. Record spot images only when higher quality images are essential for review and documentation. When lower quality images are adequate for documentation, fluoroscopic images should be recorded instead.
6. Use of an electronic magnification mode for fluoroscopy or image recording only when the improved image quality is necessary.

7. Collimate to the smallest area needed for the imaging task, to restrict the volume of tissue receiving a direct radiation dose.

8. To the extent that is practical, maximize the distance between the entrance plane of the patient and the focal spot of the X-ray tube.

9. Place the image receptor as close as reasonably possible to the patient.

10. Remove anti-scatter grid when imaging small bodies or body parts.

11. Use other available dose-reducing features."

5. Staff and Operator Exposures

Everyone with routine exposure to radiation from fluoroscopic procedures must be provided with at least one personal radiation monitor. If a single monitor is provided, it is normally worn outside the apron at the collar level. However, some facilities or areas where they do complex interventional procedures, another monitor is also provided and worn underneath the apron [43]. All monitors should be consistently worn in the same location. In addition, there should be periodic testing of the apron for adequacy of protection provided. Auxiliary shielding that is ceiling mounted and machine mounted should be used whenever practical. The principal behaviors to reduce staff and operator exposure as per the ACR include [42]:"

1. Wearing personal protective equipment and using auxiliary shields.

2. Reducing patient exposure since staff exposure due to scatter is directly related to patient exposure.

3. Positioning the X-ray tube under the patient minimizes staff exposure due to scatter. For angled views, staff should be positioned on the side of the patient opposite to the X-

ray tube. As a goal staff should maintain at least one meter distance from the point at which the X-ray beam enters the patient.

4. Directing staff to step back farther from the patient, move behind a shield, or leave the room during acquisition imaging (eg, DSA, Cine modes)".

E. Fluoroscopic guided lumbar puncture (LP)

Lumbar puncture was first introduced to diagnostic medicine in 1891 by a German physician Dr. Heinrich Quincke [44]. The technique is still very similar since its introduction in 1891 except for imaging guidance in difficult lumbar puncture cases. Lumbar puncture is an invasive procedure requiring skill and experience with the aim to remove cerebrospinal fluid (CSF) from the thecal sac in a safe approach. The aiming location is caudal to the L2 level to avoid the spinal cord and conus medullaris. In certain patient populations such as obese patients, patients with congenital abnormalities, patients with extensive spinal post-surgical changes, or extensive degenerative disease of the lumbar spine, the success rate of the bedside lumbar puncture significantly decreases. Hence, fluoroscopic guidance plays a major role in this patient population to increase the success rate of the lumbar puncture. The requests for fluoroscopic guided lumbar punctures have increased in the past 2 decades making the radiology team the dominant provider of lumbar puncture in Medicare patients [45].

1. Indications for Fluoroscopic guided Lumbar Puncture

Lumbar puncture is performed to obtain cerebrospinal fluid for laboratory analysis such as cytology, to evaluate for subarachnoid hemorrhage or for markers for demyelinating disease, to obtain an opening pressure, to obtain access for intrathecal chemotherapy infusion of other medications such as Spinraza or to inject contrast material for diagnostic myelograms. The principal indication for fluoroscopic guidance is failed bedside attempt or strong belief that a bedside attempt will be unsuccessful. In other circumstances, ordering providers may lack adequate training in bedside lumbar puncture technique or may not be credentialed to do an LP, hence opting to send the patient for imaging guided LP. However, given the radiation exposure with fluoroscopic guidance and the increased expenses and logistics with using the fluoroscopy suite, bedside lumbar puncture remains the first line of approach.

2. Contraindications and complications for Fluoroscopic guided Lumbar Puncture

Patients with coagulopathy are at higher risk for bleeding due to the procedure and this can progress to neurologic damage if the coagulopathy is left uncorrected before the procedure. For instance, the risk of spinal hematoma is higher in a patient with coagulopathy [46]. Although subarachnoid and subdural spinal hematomas can lead to spinal cord compression and myelopathy, subarachnoid is more dangerous since it is in direct contact with the nerve roots and in some cases, imaging cannot differentiate between the 2 hematoma locations [47]. The guidelines by the society of interventional radiology (SIR) should be always followed with recommendations to correct INR to a value less than 2 and platelets to more than 20 $x10^9/L$ [48]. Anticoagulation and antiplatelet medications should be discontinued before LP as per the SIR guidelines [48]. In patients on Heparin Drip, the risk of bleeding is negligible if the total dose is less than 10,000 U [49]. If there is a concern regarding heparin status, activated PTT value should be obtained [50]. Besides, the prolonged use of heparin increases the risk for heparin-induced thrombocytopenia (HIT), and the platelet count should be assessed in such settings [51].

The incidence of spinal hematomas post LP is extremely low in patient with corrected coagulopathy but have been reported [52]. However, the incidence is increased if anticoagulation therapy is started immediately after LP. Therefore, anticoagulation therapy should be delay to one hour post LP [53]. The incidence of a traumatic tap is reduced with fluoroscopic guided lumbar puncture in comparison with bedside LP [54]. Spinal hematoma with cord compression is an emergency due to risk of irreversible spinal cord ischemic injury and the outcome worsens with delay in diagnosis and delay in emergent treatment [55]. Another rare complication of LP is intracranial subdural hemorrhage seen in patients with uncorrected coagulopathies and cranial vault abnormalities such as cerebral atrophy, shunts and meningiomas [56]. Intracranial subdural hematoma can be a late complication of CSF leak and intracranial hypotension and should be suspected in patients with unremitting headache post LP [57, 58].

Elevated intracranial pressure and clinical findings that suggest an obstruction to CSF flow is a contraindication to lumbar puncture due to the risk of downward herniation secondary to removing CSF from the lumbar thecal sac with lumbar puncture. Therefore, if there is a possibility of intracranial mass or obstructive hydrocephalus, preprocedural head imaging is mandatory. Small lesions such as an obstructive colloid cyst or a Chiari I malformation can also pose a risk for herniation as a result of LP [59, 60]. In addition, the removal of CSF below an obstructing spinal cord lesion can create a pressure gradient shifting the position of the spinal cord, leading to spinal cord compression, ischemia or both, a phenomenon termed ‘spinal coning’ [61, 62]. Although, performing an LP in such a clinical situation is rare, however, the incidence of spinal coning in this setting is significant and therefore close monitoring for signs of neurologic deterioration is recommended post LP [63].

Another relative contraindication for LP is a patient with superficial skin infection or deep fascial infection or epidural abscess because of the risk of the spread of the infection to the subarachnoid space [64]. Pregnancy is another relative contraindication because of the risk of radiation effects to the fetus and therefore, it is the radiologist's responsibility to discuss the risks and benefits with the patient and to do his utmost best to minimize the radiation dose during the fluoroscopic guided lumbar puncture. The patient's cooperation is an essential part of the procedure and in some cases, sedation may be necessary to optimize procedure success.

The typical post-LP headache is reported to occur in up to one third of patients [65]. There are several ways that are believed to be effective in preventing and treating post-LP headache. It is mostly attributed to technique including needle gauge, bevel orientation and number of LP attempts [65]. Caffeinated beverages are recommended and help. Post procedure bedrest remains the standard of care for at least 1 hour. Hydration is still recommended; however, the evidence-based reports did not show any difference in the incidence of headache post LP between the patients who got hydration and the patients who did not [66, 67]. Persistent post LP headache is attributed to CSF leak and is treated with a blood patch.

3. Myelography, Intrathecal chemotherapy, intrathecal Spinraza injection and opening pressure measurement

Diagnostic myelography is a procedure where the lumbar CSF space is accessed through a lumbar puncture and iodinated contrast is injected intrathecally followed by CT scan of the area of interest in the spine which is called CT myelogram. The procedure approach and technique are the same as a fluoroscopic guided lumbar puncture, however instead of removing CSF fluid, an iodinated contrast is injected, and fluoroscopic imaging is obtained to confirm the adequate dispersion of the contrast in the CSF space at the area of interest. The result is a CT image with better contrast in the thecal sac and around the nerve roots. The major indications for myelography are spinal cord compression in patients with contraindications to MRI, CSF leak and spinal arachnoid cyst. Common contraindications to MRI include pacemaker or cochlear implants that are not MRI compatible. Additional risk for myelograms besides the risks of the lumbar puncture is reaction to the injected contrast material [68]. Commonly the contrast administered can cause headache that resolves more rapidly than the post-LP headache. The headache can be minimalized by slowly injecting the contrast media and by elevation of the head of the patient after the procedure. In addition, bed rest and hydration help in preventing the myelography headache [69, 70]. Another rare complication of myelography contrast agents is seizure [71, 72].

Intrathecal chemotherapy or Spinraza in another procedure done under fluoroscopic guidance. The steps are similar to fluoroscopic guided lumbar puncture with an additional step of injecting chemotherapy or Spinraza in the thecal sac. The contraindications and risk are like the fluoroscopic guided lumbar puncture too. However, there is an additional risk or error of accidental administration of the medication or chemotherapy in the epidural or subdural space which is thought to occur in up to 10% of the cases [73]. Spinraza (nusinersen) is a medication used in treating patients with spinal muscular atrophy, a rare neuromuscular disorder. Biogen recommends four single-injection doses, the first three at 14-day intervals and the fourth dose 30 days after the third, followed by a maintenance dose every 4 months thereafter [74]. The frequency of fluoroscopic guided lumbar puncture and Spinraza injection in these pediatric patients in addition to their higher radiation sensitivity puts a bigger responsibility on the performing physician to keep the radiation dose as low as possible.

4. The Mechanics of Fluoroscopic Guidance for Lumbar Puncture

Several different approaches are common for fluoroscopic guided LP and are a matter of preference for the institutions and physicians [75]. In each of the approaches, proper patient positioning is key in optimizing the likelihood of success. The invasive portion of the procedure should not be attempted until the patient is stably and comfortably positioned and the target is clearly identified with fluoroscopy. The time invested in optimal patient positioning simplifies the invasive portion of the procedure and decreases the radiation dose and time. There are 2 common approaches, the prone approach, and the prone oblique approach.

For the prone midline approach, the patient should be centered on the fluoroscopy table with pillows under the patient at L2-L3 and L3-L4 levels to reverse the lumbar lordosis and mimic the decubitus position. The needle target is between the spinous processes. Prone positioning gives better control of needle and with optimal centering decreases parallax. In some cases, there is degenerative disease with hypertrophy of the spinous processes, narrowing the target space for this approach.

For the prone oblique approach, the patient is positioned slightly oblique to the right or left side depending on the position which provides wider target. This off midline approach avoids the spinous processes which are hypertrophied in cases with degenerative disease and the strong midline ligaments and midline bridging osteophytes. Data suggests that there is no significant difference in the incidence of post-LP headache between the oblique approach and the median or midline approach [76]. Patients generally find positioning for the oblique approach to be more comfortable, and the oblique paramedian position is advocated for older patients with osteoarthritis or a hip injury [76].

The choice of the level for lumbar puncture depends on the degenerative disease. However, optimal levels are L2-L3 and L3-L4 levels since the conus terminates typically at L1. Prior studies should always be reviewed to check the conus level. The ideal level has a vertebral body at the "backstop" rather than a disc to prevent deep positioning of the needle [77]. The needle size is generally 20-gauge or 22-gauge. A standard needle length is 3.5 inches (9 cm), while obese patients may require a longer needle measuring 5.5 inches (14 cm). Smaller caliber needles have been shown to result is lower incidence of post-LP headache, however, needles of gauge higher than 22 are easily bent during LP and not typically used [78]. The stylet should always be fully in place when advancing or removing the needle to prevent cutting a nerve root or creating a suction to the nerve root when the needle is removed.

Post procedure, the patient is advised to remain horizontal for the remainder of the day after the LP to give the puncture site a chance to heal. The patient should not engage in strenuous activity for at least 24 hours post LP and should not soak the puncture site in water for at least 24 hours post LP. If the patient is being discharged, it is advisable to have a driver with him/her to drive him or her home. Hydration post LP is also advised because dehydration exacerbates post-LP headache.

5. Radiation Exposure with Fluoroscopic Guided Lumbar Puncture

Efforts should be made to minimize the fluoroscopy radiation dose to the patient and health care personnel. Studies in the literature report a wide range of radiation dose values and fluoroscopy times for the fluoroscopic guided lumbar puncture [79]. The published benchmark fluoroscopic times in minutes were the following: 0.48 (95% CI, 0.40–0.56) for normal, 0.61 for overweight (95% CI, 0.52–0.71), 0.63 (95% CI, 0.58–0.73) for obese, and 0.86 (95% CI, 0.74–1.01) in extremely obese body mass index categories [79]. Some of the fluoroscopic guided lumbar puncture doses are comparable to those from a lumbar CT which are on the high end and reported more in obese patients [80].

F. Systematic Intervention for fluoroscopy radiation time reduction with checklist

1. Systematic Intervention for fluoroscopy radiation time reduction

In addition to the above dose reduction technique, a systematic intervention was implemented by Dr. Sebaaly in July 2019 in the radiology department at the University of Iowa Hospitals and Clinics aiming to reduce fluoroscopic radiation time of fluoroscopic guided lumbar puncture. Fluoroscopic radiation time is a measure of the radiation dose to the patient and relatively to the medical team in the procedure room that gets about 0.1% of the patient's dose at 1 meter distance from the patient. A 3 points checklist was implemented and revised before each fluoroscopic guided lumbar puncture. The idea behind it was providing three direct clear recommendations to reduce the radiation dose for fluoroscopic guided lumbar puncture. The three points are:

1- **Use one pulse per second as a fluoroscopy rate and take one fluoroscopic screen capture/image at a time.** Dr. Sebaaly realized that although recommendations are to try to decrease the fluoroscopy rate during a procedure as low as possible, the fluoroscopy rate was always kept at 15 pulse per second (highest pulse fluoroscopy rate and is comparable to continuous fluoroscopy).

Since general, non-specific and indirect recommendations are not effective in the majority of times and after studying the different pulse rates for fluoroscopic guided lumbar puncture, it was realized that we can go down with the rate from 15 pulses per second to 1 pulse per second and still have the same success rates with lower radiation dose [81].

2- **Move the marker while marking the location without continuous fluoroscopy and take one fluoroscopy image to check if you got to the target spot.** Dr. Sebaaly realized that moving the marker under direct fluoroscopy while marking the satisfactory entry site increases the radiation dose.

3- **Puncture all the way until you hit bone along the orientation of the tube and then confirm needle position with one fluoroscopic image.** Dr. Sebaaly realized that when the physician doing the fluoroscopic guided lumbar puncture advances the needle incrementally by 0.5 cm taking fluoroscopic images with every advancement, resulted in substantial radiation dose increase. The approach was based on the fact that the needles used are of small gauge (20 or 22) and there are no structures that can be severely injured between the skin entry side and the spinal canal. Besides, LP is a procedure that can be performed bedside without fluoroscopy and the need for fluoroscopy in certain cases is to guide the operator to hit the target and not to visualize moving structures such as contrast in swallow studies. So, the third checklist point of advancing the needle until you hit bone along the axis of the tube will lead to entry into the thecal sac from the first advancement or hitting the border of the target area and then entering the thecal sac with minimal adjustment.

2. Checklist

A checklist is a simple mechanism to help remember simple tasks and make sure you do not miss any of them. During the medical and surgical internship, every physician uses checklists to help him provide a timely high quality patient care. For example, the checklist to check the dose of Lasix, check urine output or check the result of the MRI or CT scan or urine analysis on patient X. These checklists work because they are simple, efficient, and readily adopted. It is tough for a physician to remember all the items for every procedure. Hence a good checklist should be precise, efficient, and easy to use. Whereas a bad checklist is vague, imprecise, hard to use, impractical and long. Thus, it was believed that the 3-point precise and clear checklist that is described above should be reviewed before every fluoroscopic lumbar puncture to reduce the fluoroscopy time of the procedure which in turn decreases procedure time and improves workflow efficiency [82, 83]. It reminds users of the most critical and important steps.

3. Knowledge Gap

The radiation dose delivered during a fluoroscopy procedure is highly dependent on the operator [5]. Despite the several campaigns and movements such as ALARA, Image Gently and Image Wisely to reduce patients' radiation exposure during radiological studies, the lack of direct, clear, simple and efficient recommendations and checklists for fluoroscopic guided procedures in general and fluoroscopic guided lumbar puncture in specific is likely contributing to increased radiation dose exposure to the patient and at the same time to the healthcare team performing the procedure in the fluoroscopy suite. The aim of our study is to check if our developed 3-point systematic approach with checklist for the fluoroscopic guided lumbar puncture will reduce the fluoroscopic time for the procedure with similar or improved complications, traumatic tap and failure rates compared to the standard technique. This will improve patient care and will help the health care professionals in extrapolating similar approaches to other fluoroscopic guided procedures.

CHAPTER II

RESEARCH QUESTION AND OBJECTIVES

A. Research question

How does our developed 3-point systematic approach with checklist for fluoroscopic guided lumbar puncture compare to the standard technique in terms of fluoroscopy time/radiation dose, complication rates, traumatic tap rates and success rates of the procedure?

B. Primary Objectives

1- Compare the fluoroscopy time which is proportional to the radiation dose between the cases where we used the 3-point systematic approach with checklist and the cases where we only used the standard technique.

2- Compare the fluoroscopic guided lumbar puncture success rates, defined as CSF flow return [84], between the cases where we used the 3-point systematic approach with checklist and the cases where we only used the standard technique.

C. Secondary Objectives

1- Compare the fluoroscopic guided lumbar puncture immediate complication rates between the cases where we used the 3-point systematic approach with checklist and the cases where we only used the standard technique.

2- Compare the fluoroscopic guided lumbar puncture traumatic tap rates, defined as the contamination of CSF obtained with peripheral blood [84], between the cases where we used the 3-point systematic approach with checklist and the cases where we only used the standard technique.

D. Hypothesis

We hypothesize that fluoroscopic guided lumbar punctures performed with our developed 3-point systematic approach with checklist will have a shorter fluoroscopic time compared to fluoroscopic guided lumbar punctures performed using the standard technique.

CHAPTER III

METHODS

A. Study design and data sources

Our study is a retrospective review conducted at the University of Iowa Hospitals and Clinics (UIHC). We included all the patients who underwent fluoroscopic guided lumbar puncture at UIHC between the years 2019 and 2021. We obtained Institutional Review Board (IRB) approval from the University of Iowa Hospital Clinics IRB. The fluoroscopic guided lumbar puncture examinations, using our developed 3-point systematic approach with checklist or using the standard technique, had already been performed at UIHC at the time of our research study. A formal radiological report for the procedure had already been provided to the patient and the referring medical team. Ethical approval was granted for the retrospective review of the patients' data included in this study. We identified using an Epic EHR software tool called slicer dicer all the cases of fluoroscopic guided lumbar puncture between 2019 and 2021. Then, we reviewed the charts of the eligible patients. We collected data on relevant patient demographics, date of procedure, type of procedure, fluoroscopy time, immediate complications, traumatic tap rate, physician performing the procedure and procedure technical success rate up to December 2021.

B. Eligibility Criteria

<u>Inclusion criteria:</u>

- Cases with documented Fluoroscopy time
- Procedure done at UIHC main hospital

- Cases with documentation of the name of the physician performing the procedure
- Patients of all ages with the ability to lie on their stomach without movement on the fluoroscopy table for the time of the procedure

Exclusion criteria:

- Cases where the patient requested to abort the procedure
- Cases with uncooperative patients that prompted the performing physician to abort the procedure
- Cases where the patient cannot lie on his/her stomach
- Cases where the patient did not stop anticoagulation or antiplatelets as per the SIR guidelines and the procedure was done as an emergency procedure.
- Cases with prior lumbar spinal fusion surgery

C. Outcome Measures

1. Primary Outcomes

- Difference in the fluoroscopic time (time the X-ray beam is on), as reported on the dose report that is automatically generated by the fluoroscopy machine at the end of every procedure in seconds, between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used.
- Difference in the technical success rates, defined as CSF flow return [84], of the procedure between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used.

2. Secondary Outcomes

- Difference in the immediate complications rates (within one week of procedure), including all severities (post-LP headache, infection, bleeding, cerebral herniation, minor neurologic symptoms: radicular pain or numbness and back pain [85]) of the procedure between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used.

- Difference in the traumatic tap rates of the procedure, defined as the contamination of CSF obtained with peripheral blood [84], between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used.

D. Data Collection

1. Sources and methods of selection

Patients who underwent fluoroscopic guided lumbar puncture in UIHC between 2019 and 2021 were identified and their medical record numbers (MRN) were extracted by the image management team of the radiology department at UIHC using slicer dicer. One of the radiology fellows and Dr. Mikhael Sebaaly reviewed the images of the Fluoroscopic guided lumbar puncture procedures on the picture archive and communication system (PACS). The electronic charts were then reviewed by Dr. Sebaaly and the radiology fellow, to extract the required information onto an IRB preapproved SPSS comprehensive data collection sheet. The access to the data collection sheets was restricted to study members only. All data sheets were password encrypted and stored on password protected computers. Participants that did not meet the eligibility criteria were excluded from the study sample.

2. Study Variables

We collected and analyzed information relating to patient demographics (age at the time of the procedure, weight, height and gender, anticoagulation use, antiplatelets use, prior procedures, comorbidities). Furthermore, we collected and analyzed data relating to the date of the exam, retrieved CSF color (clear, straw-colored, bloody) in cases with CSF return, exam type (Fluoroscopic guided lumbar puncture and myelography, fluoroscopic guided lumbar puncture, Fluoroscopic guided lumbar puncture and spinraza injection, fluoroscopic guided lumbar puncture with intrathecal chemotherapy injection, fluoroscopic guided lumbar puncture with intrathecal radionucleotide injection), fluoroscopic time of the procedure, success rate (yes/no) and if no, we collected data for cause of failure, complications and if yes, what complications. We also collected and analyzed the data related to the performing physician and whether the 3-point systematic approach with checklist or only the standard technique was used.

3. Definition of Variables

Age of the patient at the time of the procedure was used and was calculated based on the date of the fluoroscopic guided procedure and not the age at the time of data collection. Data on the date of the exam was obtained from the patient's study history in the Epic EHR software. CSF return success, the color of the retrieved CSF (clear, straw-colored, bloody) in cases with CSF return and indication of the procedure (Fluoroscopic guided lumbar puncture and myelography, fluoroscopic guided lumbar puncture, Fluoroscopic guided lumbar puncture and spinraza injection, fluoroscopic guided lumbar puncture with intrathecal chemotherapy injection, fluoroscopic guided lumbar puncture with intrathecal radionucleotide injection) were obtained from the original staff approved final radiology report. The fluoroscopic time of the procedure was obtained from the radiation time section in Epic EHR software.

In addition, we gathered data about the procedure success which we defined as ability to reach the thecal sac, from the radiology report and what was the cause of failure/ why was the procedure stopped in cases where the healthcare team was unsuccessful in performing the procedure. Data on intra procedure complications were collected from the radiology report. Besides, data on acute post procedure complications were collected from admission history, physician notes and emergency department and clinic visits. Furthermore, we collected data on the name of the operator doing the procedure from the radiology report, the seniority of the performing radiologist, and whether the 3-point systematic approach with checklist or only the standard technique was used from the patient Epic EHR software.

4. Follow up Data

Data on Follow up to check for late complications within one week of the procedure were collected using the electronic health records and epic software from admission history, physician notes, emergency department and clinic visits in inpatients or outpatients with clinic visit within one week after the procedure. Since the patient is instructed to call the radiology department for any concerns post procedure, we checked if there is any note indicating that the patient called with new symptoms in the cases of outpatients with no hospital visit during the one week after the procedure. If there was no note about a patient phone call, we considered the case as no complications. The time to event variables were calculated from the time of the procedure.

E. Data Cleaning

During data collection and SPSS spreadsheet data entry, Dr. Sebaaly and the radiology fellow had shared live access to the data that was projected on a big screen to identify any data entry mistakes. Besides, Dr. Sebaaly extracted the data from the patient EHR while the fellow entered the data into the SPSS data spreadsheet and at the same time Dr. Sebaaly checked the entered data on the big screen to identify any data entry mistakes which were corrected on the spot.

F. Data Management

Three age categories were used: patients less than 35 years old (children and young adults), patients between 35 and 55 years old (middle-aged adults) and patients above 55 years old (older adults) since the technical difficulty of the procedure increases with degenerative disease which increases with age. By the age of 35, approximately 30% of people will show evidence of disc degeneration at one or more levels and by the age of 60, more than 90% of people will show evidence of some disc degeneration. Facet degeneration is seen in 9% of patients at 30 years of age, with a sharp increase after age 40 reaching 50% of patients at 50 years of age [86]. We had a small number of pediatric patients in their late teens undergoing fluoroscopic guided lumbar puncture, and since they rarely have degenerative changes, we decided to include them in the young adults group. BMI of the patient was calculated from the height and weight of the patient at the time of the procedure. The BMI formula used is weight in kilograms divided by height in meters squared and hence it was reported in kg/m^2 [87]. BMI values were lumped into 4 categories: patients with BMI less than 25 (normal), patients with BMI between 25 and 29.99 (overweight), patients with BMI between 30 and 34.99 (obesity class I) and patients with BMI of 35 and more (obesity class II and III) [88-89]. The date of the exam was computed into 2 categories: first half of the academic year (July 1 – December 31) and second half of the academic year (January 1 – June 30) to check if the learning curve of trainees is a confounder.

G. Data auditing

To minimize any potential mistakes, after finishing the data collection, multiple data audits were introduced by randomly checking multiple entries (approximately 5 entries reviewed for every 100 entries) to ensure the integrity of the data. In addition, in case of any suspected mistakes, the charts were reviewed to make sure the data was entered correctly.

H. Missing Data

Most of our variables had no missing data except for two variables with less than 10% of missing data. In 6.5 % of the cases, there was at least one of the height or weight data missing and hence we had 24 cases out of the 271 cases with missing BMI data. We plan to impute the BMI in these 24 cases from the measurement of weight and height that is closest to the procedure time if available.

I. Statistical Analysis

We started by stratifying the data set into two groups based on the technique used for the procedure: the first group where the 3-point systematic approach with checklist was used and the second group where only the standard technique was used. After testing for normality, we reported the descriptive statistics for both groups including baseline characteristics (demographic and background factors), staff performing the procedure, type of the procedure done and procedure date (first or second half of the academic year). We used the mean and standard deviation to report continuous variables (median and Inter-Quartile range if data is not normally distributed) and frequencies/percentages to report categorical variables. Fluoroscopy time, technical success rate, complication rate and CSF color/traumatic tap were compared between both groups using chi-squared test for categorical variables and independent t-test for continuous variables. Group stratification and subgroup analysis was performed for type of the procedure (lumbar puncture with or without myelogram), age categories, BMI categories, date of the study (first vs second half of the academic year), gender and staff performing the procedure to adjust for potential confounding variables. Independent sample t test and ANOVA was used to compare the fluoroscopy time between the subgroups in the sample population, in the group where the 3-point systematic approach with checklist was used and, in the group, where only the standard technique was used. Several patient factors can act as confounders for the success rate and the fluoroscopy time of the lumbar puncture including female gender, obesity, prior spinal surgery, and increasing age [89-90]. Univariate and multivariate linear regressions was done for the fluoroscopy time. Variables of interest were BMI in kg/m^2, age in years, gender (female or male), date of procedure (categorized as first half and second half of the academic year which is between July 1 and June 30 of the second year) and whether myelogram is performed or not after the lumbar puncture. The beta values of these variables were reported for each variable across the 2 technique groups to examine trends, we did not include p-values when comparing trends across the 2 groups because this will make our analysis prone to false positives due to multiplicity of testing. Similarly in our multivariate analysis we adjusted for the variables BMI in kg/m^2, age in years, gender (female or male), date of procedure (categorized as first half and second half of the academic year which is between July 1 and June 30 of the second year) and whether myelogram is performed or not after the lumbar puncture. Univariate and multivariate logistic regressions was done for the traumatic tap rate. Variables of interest were BMI in kg/m^2, age in years, gender (female or male), staff performing physician, date of procedure (categorized as first half and second half of the academic year which is between July 1 and June 30 of the second year), whether myelogram is performed or not after the lumbar puncture and fluoroscopy time in seconds. Similarly in our multivariate analysis we adjusted for the variables BMI in kg/m^2, age in years, gender (female or male), staff performing the procedure, date of procedure (categorized as first half and second half of the academic year which is between July 1 and June 30 of the second year), whether myelogram is performed or not after the lumbar puncture and fluoroscopy time in seconds. We used IBM SPSS version 28.0 to conduct all statistical analysis. Significance level was set at the 5% level.

CHAPTER IV

RESULTS

A. General description of the data set

Our data set contains 371 patients who underwent fluoroscopic guided lumbar puncture between the years 2019 and 2021 in the University of Iowa Hospitals and Clinics with 145 patients (39.1%) who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used and 226 patients (60.9%) who underwent fluoroscopic guided lumbar puncture where the standard technique was used. The mean age of the patients in the entire data set is 51.09 $\pm$ 20.29 years. The mean BMI of the patients in the entire data set is 31.49 $\pm$ 8.79 kg/m^2. 220 patients (59.3%) are females. 158 patients (42.6%) have hypertension, 112 patients (30.2%) have diabetes and 143 patients (38.5%) have cancer. None of the patients undergoing fluoroscopic lumbar puncture had prior posterior spinal surgery and instrumentation with bony fusion of the posterior elements, as per our exclusion criteria.

B. Comparison of baseline characteristics between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

The baseline characteristics at the sample population level and across the two groups can be seen in table 1. The mean age of the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 46.34 $\pm$ 23.85 years which is significantly lower than the mean age of the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, 54.14 $\pm$ 16.99 years (P-value: <0.001). The mean BMI of the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 30.98 $\pm$ 8.30 kg/m^2 which is not statistically significantly different compared to the mean BMI of the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, 31.84 $\pm$ 9.11 years (P-value: 0.374). 68 patients (46.9%) in the 3-point systematic approach group are males and 77 patients (53.1%) are females versus 83 patients (36.7 %) in the standard technique group are males and 143 patients (63.3%) are females with no statistically significant difference (P: 0.052). 61 patients (42.1%) in the 3-point systematic approach group have hypertension versus 97 patients (42.9 %) in the standard technique group with no statistically significant difference (P: 0.871). 43 patients (29.7%) in the 3-point systematic approach group have diabetes mellites type 2 versus 69 patients (30.5 %) in the standard technique group with no statistically significant difference (P: 0.858). 54 patients (37.2%) in the 3-point systematic approach group have history of cancer versus 89 patients (39.4 %) in the standard technique group with no statistically significant difference (P: 0.680).

C. Comparison of the categorized baseline characteristics (age and BMI) between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

The categorized baseline characteristics at the sample population level and across the two groups can be seen in table 2. In the entire data set, 94 patients (25.3%) are less than 35-year-old, 95 patients (25.6%) are 35 to 55 years old, and 182 patients (49.1%) are above 55 years old. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, 54 patients (37.2%) are less than 35-year-old, 30 patients (20.7%) are 35 to 55 years old, and 61 patients (42.1%) are more than 55 years old compared to 40 patients (17.7%) are less than 35-year-old, 65 patients (28.8%) are 35 to 55 years old, and 121 patients (53.5%) are more than 55 years old in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique, with statistically significant difference (P: <0.001).

In the entire data set with BMI data, 80 patients (23.1%) have BMI less than 25 kg/m^2, 93 patients (26.8%) have BMI of 25 to 29.99 kg/m^2, 78 patients (22.5%) have BMI of 30 to 34.99 kg/m^2 and 96 patients (27.7%) have BMI equal or greater than 35 kg/m^2. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, 34 patients (24.1%) have BMI less than 25 kg/m^2, 42 patients (29.8%) have BMI of 25 to 29.99 kg/m^2, 26 patients (18.4%) have BMI of 30 to 34.99 kg/m^2 and 39 patients (27.7%) have BMI equal or greater than 35 kg/m^2 compared to 46 patients (22.3%) have BMI less than 25 kg/m^2, 51 patients (24.8%) have BMI of 25 to 29.99 kg/m^2, 52 patients (25.2%) have BMI of 30 to 34.99 kg/m^2 and 57 patients (27.7%) have BMI equal or greater than 35 kg/m^2 in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique, with no statistically significant difference (P: 0.452).

D. Comparison of the procedural factors between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

The procedural factors, which include the categorized date exam, whether myelogram was performed or not performed as well as the performing physician, at the sample population level and across the two groups can be seen in table 3. In the entire data set, 202 fluoroscopic guided lumbar punctures (54.4%) were performed during the first half of the academic year between July 1 and December 31, and 269 fluoroscopic guided lumbar punctures (45.6%) were performed during the second half of the academic year between January 1 and June 30. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, 86 fluoroscopic guided lumbar punctures (59.3%) were performed during the first half of the academic year, and 59 fluoroscopic guided lumbar punctures (40.7%) were performed during the second half of the academic year compared to 116 fluoroscopic guided lumbar punctures (51.3%) were performed during the first half of the academic year, and 110 fluoroscopic guided lumbar punctures (48.7%) were performed during the second half of the academic year in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique, with no statistically significant difference (P: 0.132).

In the entire data set, 305 fluoroscopic guided lumbar punctures (82.2%) were performed without myelogram and 66 fluoroscopic guided lumbar punctures (17.8%) were performed with myelogram. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, 133 fluoroscopic guided lumbar punctures (91.7%) were performed without myelogram and 12 fluoroscopic guided lumbar punctures (8.3%) were performed with myelogram compared to 172 fluoroscopic guided lumbar punctures (76.1%) were performed without myelogram and 54 fluoroscopic guided lumbar punctures (23.9%) were performed with myelogram in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique, with statistically significant difference (P: <0.001).

In the entire data set, 67 fluoroscopic guided lumbar punctures (18.1%) were staffed by physician A, 33 fluoroscopic guided lumbar punctures (8.9%) were staffed by physician B, 35 fluoroscopic guided lumbar punctures (9.4%) were staffed by physician C, 66 fluoroscopic guided lumbar punctures (17.8%) were staffed by physician D, 61 fluoroscopic guided lumbar punctures (16.4%) were staffed by physician E, 73 fluoroscopic guided lumbar punctures (19.7%) were staffed by physician F, and 36 fluoroscopic guided lumbar punctures (9.7%) were staffed by physician G. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, 22 fluoroscopic guided lumbar punctures (15.2%) were staffed by physician A, 6 fluoroscopic guided lumbar punctures (4.1%) were staffed by physician B, 14 fluoroscopic guided lumbar punctures (9.7%) were staffed by physician C, 20 fluoroscopic guided lumbar punctures (13.8%) were staffed by physician D, 30 fluoroscopic guided lumbar punctures (20.7%) were staffed by physician E, 24 fluoroscopic guided lumbar punctures (16.6%) were staffed by physician F, and 29 fluoroscopic guided lumbar punctures (20.0%) were staffed by physician G compared to 45 fluoroscopic guided lumbar punctures (19.9%) were staffed by physician A, 27 fluoroscopic guided lumbar punctures (11.9%) were staffed by physician B, 21 fluoroscopic guided lumbar punctures (9.3%) were staffed by physician C, 46 fluoroscopic guided lumbar punctures (20.4%) were staffed by physician D, 31 fluoroscopic guided lumbar punctures (13.7%) were staffed by physician E, 49 fluoroscopic guided lumbar punctures (21.7%) were staffed by physician F, and 7 fluoroscopic guided lumbar punctures (3.1%) were staffed by physician G in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique, with statistically significant difference (P: <0.001).

E. Comparison of the outcomes between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

The outcomes at the sample population level, in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used and in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used can be seen in table 4. The mean procedure fluoroscopy time of the fluoroscopic guided lumbar puncture in the entire data set is 16.40 $\pm$ 29.86 sec. The mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.03 $\pm$ 3.57 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 25.62 $\pm$ 35.21 sec (P-value: <0.001).

In the entire data set, 360 fluoroscopic guided lumbar punctures (97.0%) were successful and 11 fluoroscopic guided lumbar punctures (3.0%) were unsuccessful. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, there was a higher success rate with 144 (99.3%) successful procedures compared to 216 (95.6%) successful procedures in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, statistically significant (P: 0.033).

In the entire data set, 345 patients that underwent fluoroscopic guided lumbar punctures (93.0%) did not report complications in the 7 days after the procedure, 15 patients (4.0%) reported back pain in the 7 days after the procedure and 11 patients (3.0%) reported headache in the 7 days after the procedure. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, there was a lower complication rate in the 7 days after the procedure, with 138 (95.2%) patients did not report complications, 5 patients (3.4%) reported back pain and 2 patients (1.4%) reported headache compared to 207 (91.6%) patients did not report complications, 10 patients (4.4%) reported back pain and 9 patients (4.0%) reported headache in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, but this result did not reach statistical significance (P: 0.346).

In the entire data set, out of the 360 successful fluoroscopic guided lumbar punctures, 325 (90.3%) were non-traumatic and 35 (9.7%) fluoroscopic guided lumbar punctures were traumatic. In the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used, there was a lower traumatic lumbar puncture rate with 12 (8.3%) traumatic lumbar punctures compared to 23 (10.6%) traumatic lumbar punctures in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, but this result did not reach statistical significance (P: 0.468).

F. Group stratification and subgroup analysis with comparison of procedure fluoroscopic time between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

1. Group stratification for fluoroscopic guided lumbar puncture with myelogram and fluoroscopic guided lumbar puncture without myelogram

The group stratified primary outcome (procedure fluoroscopy time) by fluoroscopic guided lumbar puncture with myelogram and fluoroscopic guided lumbar puncture without myelogram, in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach and in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used can be seen in table 5. In the subgroup where fluoroscopic guided lumbar puncture without myelogram was performed; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.77 ± 3.36 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 17.45 ± 22.50 sec (P-value: <0.001). In the subgroup where fluoroscopic guided lumbar puncture with myelogram was performed; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 4.92 ± 4.66 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 51.61 ± 52.19 sec (P-value: <0.001). There is a statistically significant increase in the fluoroscopy time in the group where myelogram was performed with the lumbar puncture in the entire sample population (P-value: <0.001), in the group that underwent fluoroscopic guided lumbar puncture where the standard technique (P-value: <0.001) was used and in the group that underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used (P-value: 0.041).

2. Group stratification for age categories

The group stratified primary outcome (procedure fluoroscopy time) by the three age categories: less than 35 years old, 35 to 55 years old and more than 55 years old, in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-

point systematic approach with checklist was used and in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used can be seen in table 6. In the subgroup where the patients are less than 35 years old; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.24 $\pm$ 5.30 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 16.63 $\pm$ 19.14 sec (P-value: <0.001). In the subgroup where the patients are 35 to 55 years old; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.07 $\pm$ 1.88 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 19.46 $\pm$ 29.24 sec (P-value: <0.001). In the subgroup where the patients are above 55 years old; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.82 $\pm$ 2.013 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 31.89 $\pm$ 40.77 sec (P-value: <0.001). There is a statistically significant increase in the fluoroscopy time with increase in age category in the entire sample population (P-value: 0.001) and in the group that underwent fluoroscopic guided lumbar puncture where the standard technique (P-value: 0.014) was used. There is no statistically significant difference in fluoroscopy time between different age categories in the group that underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used (P-value: 0.820).

3. Group stratification for BMI categories

The group stratified primary outcome (procedure fluoroscopy time) by the four BMI categories: patients with BMI less than 25 kg/m^2 (normal), patients with BMI between 25 and 29.99 kg/m^2 (overweight), patients with BMI between 30 and 34.99 kg/m^2 (obesity class I) and patients with BMI of 35 kg/m^2 and more (obesity class II and III), in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used and in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used can be seen in table 7. In the subgroup where the patients BMI values are less than 25 kg/m^2; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.85 ± 2.29 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 24.39 ± 32.60 sec (P-value: <0.001). In the subgroup where the patients BMI values are between 25 and 29.99 kg/m^2; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.79 ± 2.64 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 21.12 ± 19.80 sec (P-value: <0.001). In the subgroup where the patients BMI values are between 30 and 34.99 kg/m^2; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 3.54 $\pm$ 6.99 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 29.21 $\pm$ 47.75 sec (P-value: <0.001). In the subgroup where the patients BMI values are 35 kg/m^2 and more; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.54 $\pm$ 1.47 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 31.04 $\pm$ 39.39 sec (P-value: <0.001). There is no statistically significant difference in the fluoroscopy time between the different BMI groups in the entire sample population (P-value: 0.331), in the group that underwent fluoroscopic guided lumbar puncture where the standard technique was used (P-value: 0.337) and in the group that underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used (P-value: 0.200).

4. Group stratification for procedure date (first of second half of the academic year) categories

The group stratified primary outcome (procedure fluoroscopy time) by the two date categories: performed during the first half of the academic year between July 1 and December 31 and performed during the second half of the academic year between January 1 and June 30, in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used and in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used can be seen in table 8. In the subgroup where the procedure was performed during the first half of the academic year; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.88 $\pm$ 3.94 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 33.98 $\pm$ 44.56 sec (P-value: <0.001). In the subgroup where the procedure was performed during the second half of the academic year; the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.24 $\pm$ 2.97 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 16.79 $\pm$ 17.63 sec (P-value: <0.001). There is a statistically significant decrease in the fluoroscopy time in the second half of the year in the entire sample population (P-value: 0.003) and in the group that underwent fluoroscopic guided lumbar puncture where the standard technique was used (P-value: <0.001). There is no statistically significant difference in the fluoroscopy time between the first and second half of the academic year in the group that underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used (P-value: 0.560).

5. Group stratification for gender categories

The group stratified primary outcome (procedure fluoroscopy time) by the two gender categories: females and males, in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used and in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used can be seen in table 9. In the female subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.21 ± 4.36 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, 26.00 ± 37.18 sec (P-value: <0.001). In the male subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.82 ± 2.41 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, 24.95 ± 31.74 sec (P-value: <0.001).

6. Group stratification for different performing faculty categories

The group stratified primary outcome (procedure fluoroscopy time) by the seven different preforming physician categories, in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used and in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used can be seen in table 10. In the physician A performing physician subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.55 ± 2.77 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, 31.22 ± 39.99 sec (P-value: <0.001). In the physician B performing physician subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.00 $\pm$ 0.00 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 24.74 $\pm$ 33.05 sec (P-value: <0.001). In the physician C performing physician subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 3.29 $\pm$ 4.34 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 20.48 $\pm$ 21.17 sec (P-value: 0.002). In the physician D performing physician subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.50 $\pm$ 1.15 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 23.20 $\pm$ 20.85 sec (P-value: <0.001). In the physician E performing physician subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 1.13 $\pm$ 0.434 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 16.16 $\pm$ 13.06 sec (P-value: <0.001). In the physician F performing physician subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.13 $\pm$ 2.37 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used 32.02 $\pm$ 53.45 sec (P-value: <0.001). In the physician G performing physician subgroup, the mean procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the 3-point systematic approach with checklist was used is 2.45 $\pm$ 6.55 sec which is significantly lower than the procedure fluoroscopy time in the group of patients who underwent fluoroscopic guided lumbar puncture where the standard technique was used, 21.29 $\pm$ 19.07 sec (P-value: 0.04).

G. Predictors for fluoroscopic guided lumbar puncture procedure fluoroscopy time in the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used

The univariate linear regression for procedure fluoroscopy (Table 11) reveals several trends in the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. Fluoroscopic guided lumbar puncture with myelogram increases the fluoroscopy time by 3.150 sec vs fluoroscopic guided lumbar puncture without myelogram (P:0.003) in the cases where the 3-point systematic approach with checklist was used and by 34.158 sec (P:<0.001) in the group where only the standard technique was used. Fluoroscopic guided lumbar punctures performed during the second half of the year increases the fluoroscopy time by 0.354 sec vs fluoroscopic guided lumbar puncture performed the first half of the year, but the difference is not statistically significant (P:0.560) in the cases where the 3-point systematic approach with checklist was used. However, fluoroscopic guided lumbar punctures performed during the second half of the year decreases the fluoroscopy time by 17.19 sec vs fluoroscopic guided lumbar puncture performed the first half of the year

(P:<0.001) with statistically significant difference in the cases where only the standard technique was used. Being a female increases the fluoroscopy time by 0.384 sec compared to males in the cases where the 3-point systematic approach with checklist was used, not statistically significant (P:0.520) and by 1.05 sec in the cases where only the standard technique was used, also not statistically significant (P:0.830). As age increases by 1 year, the fluoroscopy time decreases by 0.009 sec in the cases where the 3-point systematic approach with checklist was used, not statistically significant (P:0.470) and increases by 0.496 sec in the cases where only the standard technique was used, statistically significant (P:<0.001). As BMI increases by 1 kg/m^2, the fluoroscopy time decreases by 0.014 sec in the cases where the 3-point systematic approach with checklist was used, not statistically significant (P:0.524) and decreases by 0.093 sec in the cases where only the standard technique was used, which is also not statistically significant (P:0.405).

For our multivariate linear regression (Table 12) we adjusted for all the variables included in the univariate analysis (BMI in kg/m^2, age in years, gender (female or male), date of procedure (categorized as first half and second half of the academic year which is between July 1 and June 30 of the second year) and whether myelogram is performed or not after the lumbar puncture. As in our univariate analysis, the statistically significant trends were similar in the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. Fluoroscopic guided lumbar puncture with myelogram revealed larger increase in the fluoroscopy time in both groups, by 3.58 sec vs fluoroscopic guided lumbar puncture without myelogram (P:0.001) in the cases where the 3-point systematic approach with checklist was used and by 28.81 sec (P:<0.001) in the group where only the standard technique was used. Fluoroscopic guided lumbar punctures performed during the second half of the year increases the fluoroscopy time by 0.61 sec vs fluoroscopic guided lumbar puncture performed the first half of the year, but the difference is still not statistically significant (P:0.304) in the cases where the 3-point systematic approach with checklist was used. However, fluoroscopic guided lumbar punctures performed during the second half of the year decreases the fluoroscopy time by 13.38 sec vs fluoroscopic guided lumbar puncture performed the first half of the year (P:0.002) in the cases where only the standard technique was used, smaller effect compared to the univariate analysis but still statistically significant. Being a female increases the fluoroscopy time by 0.424 sec compared to males in the cases where the 3-point systematic approach with checklist was used but remains not statistically significant (P:0.484) and decreases fluoroscopy time by 1.46 sec in the cases where only the standard technique was used, opposite change compared to the univariate analysis, but remains not statistically significant (P:0.736). As age increases by 1 year, the fluoroscopy time decreases by 0.016 sec in the cases where the 3-point systematic approach with checklist was used but remains not statistically significant (P:0.208) and increases by 0.369 sec, smaller magnitude compared to the univariate analysis, in the cases where only the standard technique was used and remains statistically significant (P: 0.006). As BMI increases by 1 kg/m^2, the fluoroscopy time decreases by 0.014 sec in the cases where the 3-point systematic approach with checklist was used but remains not statistically significant (P:0.512) and decreases by 0.005 sec in the cases where only the standard technique was used but remains not statistically significant (P:0.961).

H. Predictors for the odd of traumatic tap in the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used

The univariate logistic regression for the odds of traumatic tap (Table 13) reveals several trends in the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. Fluoroscopic guided lumbar punctures performed during the second half of the year increases the odds of traumatic tap by 0.431 vs fluoroscopic guided lumbar puncture performed the first half of the year, but the difference is not statistically significant (P:0.476) in the cases where the 3-point systematic approach with checklist was used and decreases the odds of traumatic tap by 0.494 vs fluoroscopic guided lumbar puncture performed the first half of the year (P:0.274) in the cases where only the standard technique was used, also did not reach statistical significance. There was no statistically significant difference in the odds of traumatic tap between the different staff performing the procedure where the 3-point systematic approach with checklist was used or where only the standard technique was used. Fluoroscopic guided lumbar puncture with myelogram decreases the odd of traumatic tap by 18.90 vs fluoroscopic guided lumbar puncture without myelogram (P:0.999) in the cases where the 3-point systematic approach with checklist was used, not reaching statistical significance, and decreases the odd of traumatic tap by 2.12 (P: 0.041) in the group where only the standard technique was used, statistically significant. Being a female decreases the odds of traumatic tap by 0.152 compared to males in the cases where the 3-point systematic approach with checklist was used, not statistically significant (P:0.801) and by 0.791 in the cases where only the standard technique was used, also not statistically significant (P:0.106). As age increases by 1 year, the odds of traumatic tap increases by 0.003 in the cases where the 3-point systematic approach with checklist was used, not statistically significant (P:0.797) and odds of traumatic tap increases by 0.006 in the cases where only the standard technique was used, not statistically significant (P:0.661). As BMI increases by 1 kg/m^2, the odds of traumatic tap increases by 0.014 in the cases where the 3-point systematic approach with checklist was used, not statistically significant (P:0.431) and decreases by 0.012 in the cases where only the standard technique was used, also not statistically significant (P:0.381). As fluoroscopy time increases by 1 sec, the odds of traumatic tap increases by 0.118 in the cases where the 3-point systematic approach with checklist was used, not statistically significant (P:0.056) and decreases by 0.015 in the cases where only the standard technique was used, also not statistically significant (P:0.213).

For our multivariate logistic regression (Table 14) we adjusted for all the variables included in the univariate analysis (BMI in kg/m^2, age in years, gender (female or male), staff performing physician, date of procedure (categorized as first half and second half of the academic year which is between July 1 and June 30 of the second year), whether myelogram is performed or not after the lumbar puncture and fluoroscopy time in seconds). Fluoroscopic guided lumbar punctures performed during the second half of the year increases the odd of traumatic tap by 0.380 vs fluoroscopic guided lumbar puncture performed the first half of the year, but the difference remains not statistically significant (P:0.597) in the cases where the 3-point systematic approach with checklist was used and decreases the odds of traumatic tap by 0.722 vs fluoroscopic guided lumbar puncture performed the first half of the year (P:0.145) in the cases where only the standard technique was used, remains not statistically significant. There remains no statistically significant difference in the odds of traumatic tap between the different staff physicians performing the procedure where the 3-point systematic approach with checklist was used or where only the standard technique was used. Fluoroscopic guided lumbar puncture with myelogram decreases the odd of traumatic tap by 18.28 vs fluoroscopic guided lumbar puncture without myelogram (P:0.999) in the cases where the 3-point systematic approach with checklist was used, remains not statistically significant, and decreases the odd of traumatic tap by 2.01 (P:0.072) in the group where only the standard technique was used, lost statistical significance. Being a female decreases the odds of traumatic tap by 0.687 compared to males in the cases where the 3-point systematic approach with checklist was used but remains not statistically significant (P:0.366) and by 0.730 in the cases where only the standard technique was used but remains not statistically significant (P:0.128). As age increases by 1 year, the odds of traumatic tap increases by 0.005 in the cases where the 3-point systematic approach with checklist was used but remains not statistically significant (P:0.837) and odds of traumatic tap increases by 0.017 in the cases where only the standard technique was used, remains not statistically significant (P:0.240). As BMI increases by 1 kg/m^2, the odds of traumatic tap increases by 0.024 in the cases where the 3-point systematic approach with checklist was used but remains not statistically significant (P:0.311) and decreases by 0.004 in the cases where only the standard technique was used but remains not statistically significant (P:0.763). As fluoroscopy time increases by 1 sec, the odds of traumatic tap increases by 0.365 in the cases where the 3-point systematic approach with checklist was used but remains not statistically significant (P:0.072) and decreases by 0.008 in the cases where only the standard technique was used but remains not statistically significant (P:0.490).

CHAPTER V

DISCUSSION

A. Summary of our findings and comparison to the standards

In summary, our study showed statistically significant reduction in radiation dose and fluoroscopy time in the group where the 3-point systematic approach with checklist was used (2.03 sec) compared to the group where only the standard technique was used (25.62 sec). This statistically significant dose reduction remained statistically significant when adjusting for several potential confounders: type of the procedure (lumbar puncture with or without myelogram), age, BMI, date of the study (first vs second half of the academic year), gender and staff performing the procedure (tables 5, 6, 7, 8, 9 and 10). Furthermore, our study showed statistically significantly higher success rate of the fluoroscopic guided lumbar puncture in the group where the 3-point systematic approach with checklist was used (99.3%) compared to the group where only the standard technique was used (95.6%). There is no statistically significant difference in the complication rate and traumatic tap rate between the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. In our linear regression, doing a myelogram, increased patient age and doing the procedure in the first half of the year are associated with statistically significant increase in fluoroscopy time (Tables 11 and 12).

The average fluoroscopy time in our sample population is (16.40 seconds=0.27 min), (2.03 sec=0.03 min) in the group where the 3-point systematic approach with checklist was used and (25.62 sec=0.43 min) in the group where only the standard technique was used. This is smaller than the result of a previous study by Crosthwait from the United Kingdom (UK) where they reviewed the fluoroscopy time of 300 fluoroscopic guided lumbar punctures, 150 LP were carried out by either a consultant radiologist or radiology registrar and 150 LP were carried out by the advanced practitioner following the completion of their training, the average fluoroscopy time for fluoroscopic guided lumbar punctures performed by advanced practitioners was 0.74 min and the average fluoroscopy time for fluoroscopic guided lumbar punctures performed by the radiologists was 0.94 min [92]. In another study by Faulkner et al from the University of Tennessee Medical Center, where simulation-based educational curriculum for fluoroscopically guided lumbar puncture was used, 114 lumbar punctures (LPs) performed by six trained residents (prospective cohort) were compared to data from 514 LPs performed by 17 residents who did not receive simulation-based training (retrospective cohort), the fluoroscopy time for fluoroscopic guided lumbar punctures was on average 1.09 min before the simulation and 0.87 min after the simulation [93]. In addition, another study performed by Bakrukov el al from State University of New York Upstate Medical University, Syracuse, USA, demonstrated fluoroscopic guided lumbar puncture fluoroscopy time of 0.97 min in the lateral decubitus position (181 LP) and 1.07 min in the prone position (46 LP) [94]. Comparison of the baseline characteristics and fluoroscopy time between our study and Bakrukov el al study is summarized in table 15 [94]. In our institution, the fluoroscopy time is smaller than the fluoroscopy time reported by the above studies, with the fluoroscopy time where the standard technique was used estimated at 0.43 min, the fluoroscopy time where the 3-point technique was used estimated at 0.03 min rendering the fluoroscopy time in our entire sample population estimated at 0.27 min. This supports two points. The first is that the fluoroscopic guided lumbar puncture technique used at the University of Iowa Hospitals and Clinics meets the standards and the fluoroscopy time and radiation dose for the procedure is better that the reported benchmarks and data in the literature. Second, it makes further dose reduction challenging because the fluoroscopy time for the standard technique is already better than the doses reported in the literature. Hence, for an intervention to show statistically significant results in cases where the baseline is already better that the reported benchmarks, it must be effective and impactful.

B. Association between baseline characteristics and fluoroscopy time in the sample population, cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

1. Association between age and fluoroscopy time

There is a statistically significant difference in the age of the patients (P< 0.001) between the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. Hicks et al study demonstrated increased prevalence of lumbar spine degenerative disease in patients who are 65 years old and older [95]. Nayate el al study demonstrated that the increase in spine degenerative disease resulted in increase in the fluoroscopy time of fluoroscopic guided lumbar puncture from 0.72 min in the patients with ages between 18 and 64 years old to 1.14 min in patients with ages greater than or equal to 65 years old [96]. In our study, we have similar trends at the sample population level and in the group where the standard technique was used showing increase in the fluoroscopy procedure time with increase in the patient age. However, there is no statistically significant difference in the fluoroscopy time between the different age categories in the group where the 3-point systematic approach with checklist was used. A likely explanation is in the technique itself where fluoroscopy is used for checking the needle position after it touches bone with pulse rate of 1 fps rather than incremental advancement of the needle with higher pulse rate which is used in the standard technique. With degenerative disease in the spine, the target becomes smaller and the incremental approach in the standard technique leads to more fluoroscopy time due to increase in the number of needed fluoroscopic images.

2. Association between BMI and fluoroscopy time

There is no statistically significant difference in BMI distribution (P: 0.374) between the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. Boddu el al study demonstrated that fluoroscopy time increases with BMI and benchmark fluoroscopic times in minutes were the following: 0.48 (95% CI, 0.40–0.56) for normal, 0.61 for overweight (95% CI, 0.52–0.71), 0.63 (95% CI, 0.58–0.73) for obese, and 0.86 (95% CI, 0.74–1.01) in extremely obese body mass index categories [79]. Frett et al study showed that patient BMI of more than 25 kg/m^2 is the most common associated factor (81.8% of the time) with difficult lumbar puncture [97]. Cushmann et al study demonstrated that increasing BMI leads to elevated radiation dose during fluoroscopically guided intra-articular hip injections [98]. Hudgins et al study showed that the fluoroscopic guided lumbar puncture is more difficult when the needle length increases and when landmarks are more difficult to visualize with increasing subcutaneous fat [99]. Our study results demonstrate similar trends of increase in the fluoroscopy time with increase in patient BMI, but the difference is not statistically significant between the different BMI categories in the subgroup analysis or in the linear regression analysis neither in the sample population, nor in the group where the 3-point systematic approach with checklist was used nor in the group where only the standard technique was used. The likely explanation for the lack of statistical significance in our study is the small change in fluoroscopy time with change in BMI due to the good experience of the performing physicians in our study with different patients BMIs. Hence there might be a need for a bigger sample size to detect this small difference but there is always the question about how clinically significant this difference is.

3. Association between gender and fluoroscopy time

There is borderline statistically significant difference in gender distribution (P: 0.052) between the group where the 3-point systematic approach with checklist was used and the group where only the standard technique was used. Boddu et al study showed that fluoroscopic time was higher in female patients (1.07 minutes; 95% CI, 0.95–1.20) than in male patients (0.91 minutes; 95% CI, 0.79–1.03) in patient undergoing fluoroscopic guided lumbar punctures [79]. Similarly in our study, the fluoroscopy time was higher in females in our sample population, the group where the 3-point systematic approach with checklist was used and, in the group where only the standard technique was used, however, none of the differences were statistically significant. Hence there might be a need for a bigger sample size to detect this small difference but how clinically significant this difference. A likely explanation for the higher fluoroscopy time in females compared to males is the fat distribution in the trunk which is higher in post-menopausal women (average fat in trunk: 9.6 kg) compared to men (average fat in trunk: 8.8 kg) as per a study by Ley et al [114].

C. Effect of procedural factors on fluoroscopy time in the sample population, cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

1. Effect of doing myelogram with the fluoroscopic guided lumbar puncture on the fluoroscopy time

In our study, there is a statistically significant increase in the fluoroscopy time when a myelogram was performed with the fluoroscopic guided lumbar puncture compared to when a fluoroscopic guided lumbar puncture was performed without a myelogram in the sample population (by 32.51 sec), in the group where the 3-point systematic approach with checklist was used (by 3.15 sec) and, in the group where only the standard technique was used (by 34.16 sec). Faulkner el al study results showed that the average fluoroscopy time was higher in patient that underwent fluoroscopic guided lumbar puncture with myelogram compared to the diagnostic fluoroscopic guided lumbar puncture without myelogram [93]. One explanation is the fact that with myelogram, the performing health care professional must take additional fluoroscopic images after the tip of the needle is positioned in the thecal sac while injecting contrast material in the thecal sac to document the flow of contrast to the desired level of the spine (cervical, thoracic, or lumbar), which represents and additional dose requiring step [115]. Another contributing factor is the patient population that undergo myelograms. The major indication for myelogram is a patient with clinical symptoms of thecal sac or spinal cord compression due to degenerative disease or compressing mass. These patients are on the older side and more likely to have facet joint hypertrophy making the procedure more challenging and contributing to the increase fluoroscopy time.

2. Effect of doing the fluoroscopic guided lumbar puncture in the first half of the academic year vs second half of the academic year on the fluoroscopy time

In our study, there was a statically significant decrease in the fluoroscopy time between the first half and second half of the academic year in the sample population (P:

0.003) and in the group where only the standard technique was used ($P < 0.001$). However, there was no statistically significant difference in the fluoroscopy time between the first and second half of the academic year in the group where the 3-point systematic approach with checklist was used (P: 0.560). Nayate el al study demonstrated that there was a decrease of 0.47 minute (35%) in fluoroscopy time in patients ≥65 years old from the first to the fourth quarters of the year; however, this trend was not statistically significant ($P = 0.4$) [96]. With experience and more training, the skills of the of the operator improve and the fluoroscopy time in fluoroscopic guided lumbar punctures decrease to a certain extent. In our study, this is seen with the statistically significant decrease in fluoroscopy time in the second half of the academic year compared to the first half of the academic year in the sample population and the group where only the standard technique was used. However, in the group where the 3-point systematic approach with checklist was used, there was no statistically significant change in fluoroscopy time. The explanation lies in the 3 points of the technique which aim to limit the use of fluoroscopy to just checking the position of the marker or the needle and adjusting based on the image rather than adjusting under continuous fluoroscopy which is subject to operator experience and quick hand eye coordination while the fluoroscopy tube is on. These skills are affected by experience and improve with the increase in the number of procedures performed by the operator. The three points of this technique minimalize the effect of these skills on increasing the fluoroscopy time.

D. Comparison of fluoroscopy time (primary outcome) between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

In our study, there was a statistically significant decrease in fluoroscopic guided lumbar puncture fluoroscopy time in the group where the 3-point systematic approach with checklist was used (2.03 $\pm$ 3.57 sec) compared to the cases where only the standard technique was used (25.62 $\pm$ 35.21 sec) ($P < 0.001$). Sabat el study showed that using low dose pulsed fluoroscopy of 3 fps significantly reduces radiation exposure by about 600% compared with standard dose continuous fluoroscopy in fluoroscopic guided lumbar puncture [100]. Likewise, in our study decreasing the pulse rate to 1 fps contributed to the decrease in the fluoroscopy time by approximately 1150% compared to standard technique where 15 fps was used. This limited the use of unnecessary radiation and helped in taking only one image to check the position of the needle or marker. There is no need for more than 1 image to check the position of a needle or marker that is not moving. Kramer et al did a systematic review of electronic checklist use in healthcare and found some benefit from checklist use and that there is a clear indication that e-checklists can be effective regarding the measured outcomes (either clinical outcomes or adherence outcomes) [101]. Hence, in our study creating a three-point checklist for our systematic approach and reviewing it prior to each procedure was a key factor in adherence to the changes in the fluoroscopic guided lumbar puncture technique that lead to reduction in fluoroscopy time. Shultz described in his chapter "Needle Manipulation Techniques" the different approaches for needle advancements during procedures and indicated that the use of "tissue feel" for needle placement is an important adjunct to fluoroscopy, but modern physicians performing the procedure must combine learned tactile skills with expertise in fluoroscopy to become successful interventional pain specialists [102]. Likewise, in 3-point systematic approach with checklist, the approach of advancing a needle along the axis of the tube and using tissue feel until the needle hits the vertebrae contributed to the decrease in the radiation dose by decreasing the number of fluoroscopic images obtained compared to approaching the needle in an incremental fashion and obtained multiple fluoroscopic images to check needle position and orientation.

1. Comparison of fluoroscopy time between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used with subgroup analysis for performing a myelogram acting as a possible confounder

Geise et al reported that the radiation dose increases with the addition of myelogram compared to fluoroscopic guided lumbar puncture [102]. Our subgroup analysis confirmed the statistically significant increase in fluoroscopy time/radiation dose with the addition of myelogram to the fluoroscopic guided lumbar puncture by 170% to 300% compared to the fluoroscopic guided lumbar puncture without myelogram, among the 2 groups where the 3-point systematic approach with checklist was used and where only the standard technique was used. However, there remained a statistically significant decrease in the fluoroscopy time by 890% in the subgroup where fluoroscopic guided lumbar puncture without myelogram was performed and by 950% in the subgroup where fluoroscopic guided lumbar puncture with myelogram was performed between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used. This confirms the validity of our statistically significant results accounting for myelogram as a confounder.

2. Comparison of fluoroscopy time between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used with subgroup analysis for age acting as a possible confounder

Nayate et al reported that the fluoroscopy time increases with the patient age in fluoroscopic guided lumbar puncture [96]. Our subgroup analysis confirmed the statistically significant increase in fluoroscopy time with increasing age of the patient by approximately 160% in patients older than 55 years old compared to patients younger than 35 years old. However, there remained a statistically significant decrease in the fluoroscopy time by 640% in the subgroup with patients less than 35 years old, by 840% in the subgroup with patients between 35 and 55 years old and by 1852% in the subgroup with patients older than 55 years old between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used. This confirms the validity of our results accounting for age as a confounder. In addition, this subgroup analysis demonstrates the insignificant change in fluoroscopy time with age in the group where the 3-point systematic approach with checklist was used compared to the significant increase in the fluoroscopy time with increasing age in the group where only the standard technique was used. With increase in patient age, the target becomes smaller and hence more fluoroscopy images on average are needed to hit the target. This amplified the difference in fluoroscopy time between the 2 study groups.

3. Comparison of fluoroscopy time between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used with subgroup analysis for BMI acting as a possible confounder

Hudgins et al and Boddu et al reported that the fluoroscopy time increases with the patient BMI in fluoroscopic guided lumbar puncture [79, 99]. Our subgroup analysis did not show any statistically significant increase in fluoroscopy time with increasing

BMI of the patient between patients with BMI less than 25 kg/m^2 (normal), patients with BMI between 25 and 29.99 kg/m^2 (overweight), patients with BMI between 30 and 34.99 kg/m^2 (obesity class I) and patients with BMI of 35 kg/m^2 and more (obesity class II and III). In addition, there remained a statistically significant decrease in the fluoroscopy time by 1218% in the subgroup of patients with BMI less than 25 kg/m^2 (normal), by 1079% in the subgroup of patients with BMI between 25 and 29.99 kg/m^2 (overweight), by 725% in the subgroup of patients with BMI between 30 and 34.99 kg/m^2 (obesity class I) and by 1915% in patients with BMI of 35 kg/m^2 and more (obesity class II and III) between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used. This confirms the validity of our results accounting for BMI as a possible confounder. Possible factors that can explain the statistically insignificant difference in fluoroscopy time between cases with different patient BMI categories is the approximately equal distribution of our patient population between the different BMI categories which contributes to expertise of the performing physician in performing fluoroscopic guided lumbar puncture in patients with wide spectrum of BMI.

4. Comparison of fluoroscopy time between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used with subgroup analysis for date of exam acting as a possible confounder

Nayate et al reported that the fluoroscopy time decreases during the year in fluoroscopic guided lumbar puncture performed by the neuroradiology fellows [96]. Our subgroup analysis showed a statistically significant decrease in fluoroscopy time in the second half of the academic year compared to the first half of the academic year in the group where only the standard technique was used but failed to show statistically significant difference in the group where the 3-point systematic approach with checklist was used. There remained a statistically significant decrease in the fluoroscopy time by 1707% in the subgroup of patients where the fluoroscopic guided lumbar puncture was performed during the first half of the academic year and by 650% in patients where the fluoroscopic guided lumbar puncture was performed during the second half of the academic year between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used. This confirms the validity of our results accounting for date of examination as a possible confounder. However, the above results show that the effect of procedure performing physician experience is larger in the cases where the standard technique is used but not statistically significant in the cases where the 3-point systematic approach with checklist was used. The fact that the 3-point systematic approach with checklist technique is less dependent on the performing physician training level highlights its importance and advantage over the standard technique in reducing the fluoroscopy time in fluoroscopic guided lumbar punctures. The explanation for this effect is the direct clear 3 points that are reviewed in the checklist before the procedure which simplify the dose reduction steps for the procedure that the physician performing the procedure should follow.

5. Comparison of fluoroscopy time between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used with subgroup analysis for gender acting as a possible confounder

Boddu et al reported that the fluoroscopy time increases in females compared to males in fluoroscopic guided lumbar puncture [79]. Our subgroup analysis showed no statistically significant difference in fluoroscopy time in the female and male subgroups between the group where only the standard technique was used and the group where the

3-point systematic approach with checklist was used. There remained a statistically significant decrease in the fluoroscopy time by 1076% in the female subgroup of patients and by 1270% in the male subgroup between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used. This confirms the validity of our results accounting for gender as a possible confounder. On the contrary to Boddu et al study results, our study did not show any statistically significant difference in the fluoroscopy time between males and females.

6. Comparison of fluoroscopy time between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used with subgroup analysis for performing physician acting as a possible confounder

Several studies demonstrated the change in fluoroscopy time of fluoroscopic guided lumbar puncture with different performing health care professionals, i.e. operator dependance [92, 93, 96]. Our subgroup analysis showed a persistent statistically significant decrease in the fluoroscopy time among the 7 different neuroradiologist, by 1124% in the physician A subgroup of patients, by 2374% in the physician B subgroup of patients, by 522% in the physician C subgroup of patients, by 1447% in the physician D subgroup of patients, by 1330% in the physician E subgroup of patients, by 6366% in the physician F subgroup of patients and by 769% in the physician G subgroup of patients between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used. This confirms the statistical significance of our results accounting for different performing physician as a possible confounder. However, the range of the effect varied between 522% and 6366% decrease in the fluoroscopy time among the different performing physician subgroups between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used. This proves the operator dependence effect on the fluoroscopy time. Accounting for the operator dependence, the residual effect is further evidence that our three-point systematic approach with checklist is effective in reducing the fluoroscopy time of the fluoroscopic guided lumbar puncture regardless of the performing physician. This is likely explained by the clear, direct, and concise 3 step systematic approach that is easy to follow.

E. Comparison of fluoroscopic guided lumbar puncture success rate between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

In our study, there was a statistically significant higher fluoroscopic guided lumbar puncture success rate in the group where the 3-point systematic approach with checklist was used (99.3%) compared to the cases where only the standard technique was used (95.6%) (P: 0.033). Bakrukov et al study showed fluoroscopic guided lumbar puncture success rates of 98.3% and 89.1% in the lateral decubitus and prone groups respectively [94]. Nigrovic el al study showed an average lumbar puncture success rate of 87% [104]. Yu et al study showed a success rate of 96.8% in fluoroscopic guided lumbar punctures [105]. The success rates of both groups in our study are equal or larger than the reported success rates of fluoroscopic guided lumbar puncture in the literature. This indicates that we already have high success rates for fluoroscopic guided lumbar punctures in our institution which makes further improvement in success rates challenging. The higher fluoroscopic guided lumbar puncture success rate in the group where the 3-point systematic approach with checklist was used compared to the cases where only the standard technique was used can be explained by the shorter fluoroscopy time which translates in a shorter procedure time and this translates in a more compliant patient, increasing the success rate of the procedure.

F. Comparison of fluoroscopic guided lumbar puncture complication rate between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

In our study, there was no statistically significant difference in the fluoroscopic guided lumbar puncture complication rate in the group where the 3-point systematic approach with checklist was used (4.8%) compared to the cases where only the standard technique was used (8.4%) (P: 0.346). Rodriguez et al study showed fluoroscopic guided lumbar puncture complication rates as follow: 0.8% of patients reported having a severe headache, 2.2% reported having any headache, and 2.6% reported having any complaint [105]. Evans described several lumbar puncture complications including headache occurring in up to 40 % of patients after lumbar puncture; however, cranial neuropathies, prolonged backache, nerve root injury, and meningitis, are rare, occurring after 0.3 % of lumbar punctures [106]. The complication rates of both groups in our study are comparable to the complication rates of fluoroscopic guided lumbar puncture in the literature. The similar fluoroscopic guided lumbar puncture complication rate without statistically significant difference in the group where the 3-point systematic approach with checklist was used compared to the cases where only the standard technique was used rules out the possibility of increased complication rates with the 3-point systematic approach with checklist technique at the expense of decreasing fluoroscopy time compared to the standard technique.

G. Comparison of fluoroscopic guided lumbar puncture traumatic tap rate between the cases where the 3-point systematic approach with checklist was used and the cases where only the standard technique was used

In our study, there was no statistically significant difference in the fluoroscopic guided lumbar puncture traumatic tap rate in the group where the 3-point systematic approach with checklist was used (8.3%) compared to the cases where only the standard technique was used (10.6%) (P: 0.468). Yu el al study reported a rate of traumatic LP of 13.3% [105]. Ogilvy et al study showed fluoroscopic guided lumbar puncture traumatic tap rates of 3.5% [108]. The traumatic tap rates of both groups in our study are comparable to those of fluoroscopic guided lumbar puncture reported in the literature. The similar fluoroscopic guided lumbar puncture traumatic tap rate without statistically significant difference in the group where the 3-point systematic approach with checklist was used compared to the cases where only the standard technique was used rules out the possibility of increased traumatic tap rates with the 3-point systematic approach with checklist technique at the expense of decreasing fluoroscopy time compared to the standard technique.

H. What factor contribute to increase in fluoroscopy time in fluoroscopic guided lumbar puncture

In our study, in the group where the 3-point systematic approach with checklist was used, the only statistically significant variable that predicts fluoroscopy time was if a myelogram was performed or not. Performing a myelogram after the fluoroscopic guided lumbar puncture increased the fluoroscopy time by 3.150 sec when compared to doing a fluoroscopic guided lumbar puncture without a myelogram in the univariate regression and increased to 3.557 sec with the multivariate regression. Age, BMI, gender, and date of exam in the first or second half of the academic year did not have a statistically significant effect on the fluoroscopy time in the univariate or multivariate analysis. However, with different performing neuroradiologists, the average fluoroscopy time ranged from 1 sec to 3.3 sec, which highlights the element of operator dependence. Multiple studies in the literature highlighted the factor of operator dependence on different procedures [109-113]. Therefore, the challenge is always to minimalize the effect of the operator dependence factor which was one of the strengths of the 3-point systematic approach with checklist which decreased the operator dependence range in fluoroscopy time of fluoroscopic guided lumbar punctures to 2.3 sec. In 82.7% of the fluoroscopic guided lumbar punctures without myelogram performed using the 3-point systematic approach with checklist, the fluoroscopy time of the procedure was less than or equal to 1 second.

On the other hand, in the group where only the standard technique was used, age of the patient, date of the exam (performed during the first half of the second half of the academic year) and type of exam (whether a myelogram was performed or not) had a statistically significant effect on fluoroscopic time of the procedure in the univariate linear regression which persisted in the multivariate linear regression. The increase in patient's age is associated with increase in the fluoroscopy time, doing the procedure in the second half of the academic year is associated with decrease in the fluoroscopy time compared to the first half of the year and performing a myelogram during the fluoroscopic guided lumbar puncture is associated with increase in the fluoroscopy time. Besides, with different performing neuroradiologists, the average fluoroscopy time ranged from 16.16 sec to 32.02 sec, which also highlights the element of operator dependence. However, the range of fluoroscopy time of about 15.86 sec highlights the greater effect of operator skills on the fluoroscopy time in fluoroscopic guided lumbar puncture with the standard technique compared to 2.3 sec in the 3-point systematic approach with checklist. These findings are important and can be used in the future when consenting patients for a fluoroscopic guided lumbar to inform them about the expected approximate fluoroscopy time and radiation dose that they will be exposed to during the procedure.

I. What factor contribute to increase in rates of traumatic tap in fluoroscopic guided lumbar puncture

In our study, in both groups where the 3-point systematic approach with checklist was used and where only the standard technique was used, no statistically significant variables were found to predict the likelihood of traumatic tap. One of the explanations for the lack of a statistically significant risk factor is the low rate of traumatic taps with fluoroscopic guided lumbar punctures which is similar to the benchmarks [105, 108]. A larger sample size may show an association between traumatic taps and patient or procedure factors, however, given the low rate of traumatic taps, there is always a question if it will be clinically significant and impactful of patient care.

J. Limitations and strengths

Our study is not without limitations, first the relatively small sample size may have affected the power to detect significant differences for some variables in our analysis. Besides, the retrospective design of our study can be considered to have more potential sources of bias and confounding variables compared to a prospective study design; however, our data was collected from the hospital electronic records by reviewing the patients' charts, decreasing the chance of bias. In addition, missing data in the BMI variable slightly limited its use in our study. Moreover, our study was conducted in one institution, the University of Iowa Health Care which may affect the generalizability of our results. However, UIHC is a quaternary care center and is a referral center for the entire state of Iowa and patients from border cities in neighboring states. Hence, the distribution of patients receiving treatment at UIHC is like the population distribution in Iowa, including the challenging cases that are referred to our institution.

On the other hand, our study has many strengths, this is to our knowledge the first study to highlight 3 simple steps combining them with checklist to reduce the radiation dose of fluoroscopic guided lumbar puncture. Moreover, a major advantage of our study is that unlike older studies that experienced variability due to the use of different metrics to measure the radiation dose such as dose length product, skin dose, or dose area product, which are not always documented in all institutions, we used the fluoroscopy time which is always documented in all interventional procedures. Besides, our study occurred over a short period of time in a single center using 2 similar machines which limits the fluoroscopy machine as a possible confounder or source of bias.

CHAPTER VI

CONCLUSION AND FUTURE IMPLICATIONS

In conclusion, in this study we investigated the effect of the 3-point systematic approach with checklist on fluoroscopy time/radiation dose, success rates, complication rates and traumatic tap rates of fluoroscopic guided lumbar puncture in Iowa. We found that the 3-point systematic approach with checklist was associated with 1162% decrease in fluoroscopy time/radiation dose and statistically significantly increase in success rate reaching more than 99% of fluoroscopic guided lumbar punctures compared to the standard technique. No difference in traumatic tap rates and complication rates was noted between the two groups. We believe that our study will provide a cornerstone for future research on effective interventions and approach for dose reduction in fluoroscopy guided procedures. We already started expanding our approach to other fluoroscopic guided procedures such as fluoroscopic guided musculoskeletal procedures such as joint aspiration, joint injections, arthrograms… We are planning on doing prospective studies to check the effect of our systematic approach with checklist on radiation dose of multiple fluoroscopic guided procedures.

APPENDIX

Figure 1: Quasi-threshold dose relationship between the radiation dose and cell survival

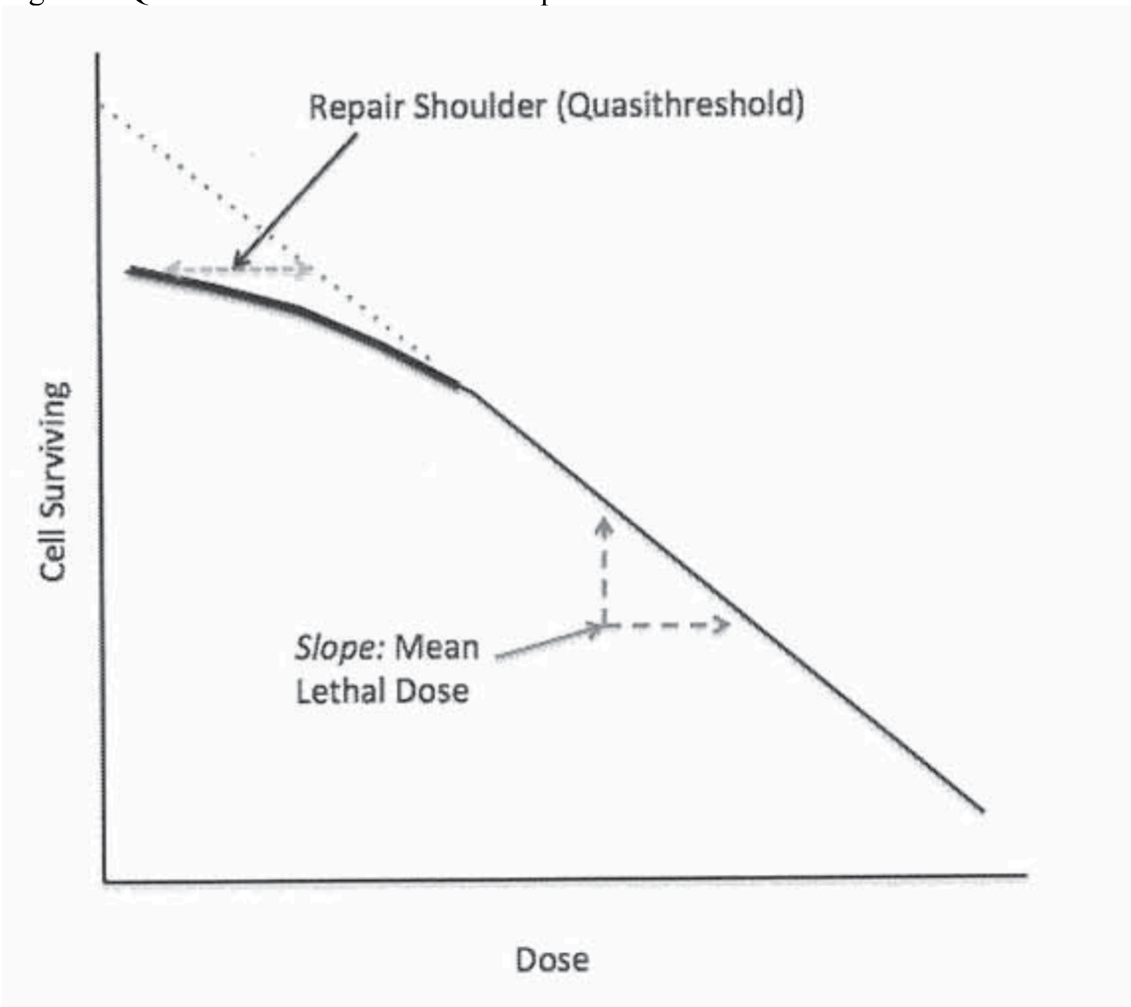

Table 1: Baseline Characteristics Between the Cases Where the 3-Point Systematic Approach with Checklist Was Used and the Cases Where Only the Standard Technique Was Used

Variable	Population (N=371)	3-Point Systematic Approach (N=145)	Standard Technique (N=226)	P-value
Age in years	51.09 ± 20.29	46.34 ± 23.85	54.14 ± 16.99	< 0.001
BMI	31.49± 8.79	30.98 ± 8.30	31.84 ± 9.11	0.374
Hypertension				0.871
Yes	158 (42.6%)	61 (42.1%)	97 (42.9%)	
No	213 (57.4%)	84 (57.9%)	129 (57.1%)	
Diabetes				0.858
Yes	112 (30.2%)	43 (29.7%)	69 (30.5%)	
No	259 (69.8%)	102 (70.3%)	157 (69.5%)	
Gender				0.052
Female	220 (59.3%)	77 (53.1%)	143 (63.3%)	
Male	151 (40.7%)	68 (46.9%)	83 (36.7%)	
Cancer				0.680
Yes	143 (38.5%)	54 (37.2%)	89 (39.4%)	
No	228 (61.5%)	91 (62.8%)	137 (60.6%)	

Table 2: Categorized Baseline Characteristics Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard Technique Was Used

Variable	Population (N=371)	3-Point Systematic Approach (N=145)	Standard Technique (N=226)	P-value
Age Categorized Less than 35 yo 35 to 55 yo Above 55 yo	 94 (25.3%) 95 (25.6%) 182 (49.1%)	 54 (37.2%) 30 (20.7%) 61 (42.1%)	 40 (17.7%) 65 (28.8%) 121 (53.5%)	<0.001
BMI Categorized <25 kg/m^2 25-29.99 kg/m^2 30-34.99 kg/m^2 ≥ 35 kg/m^2	(N=347) 80 (23.1%) 93 (26.8%) 78 (22.5%) 96 (27.7%)	(N=141) 34 (24.1%) 42 (29.8%) 26 (18.4%) 39 (27.7%)	(N=206) 46 (22.3%) 51 (24.8%) 52 (25.2%) 57 (27.7%)	0.452

Table 3: Procedural Factors Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard Technique Was Used

Variable	Population (N=371)	3-Point Systematic Approach (N=145)	Standard Technique (N=226)	P-value
Staffing Physician				<0.001
A	67 (18.1%)	22 (15.2%)	45 (19.9%)	
B	33 (8.9%)	6 (4.1%)	27 (11.9%)	
C	35 (9.4%)	14 (9.7%)	21 (9.3%)	
D	66 (17.8%)	20 (13.8%)	46 (20.4%)	
E	61 (16.4%)	30 (20.7%)	31 (13.7%)	
F	73 (19.7%)	24 (16.6%)	49 (21.7%)	
G	36 (9.7%)	29 (20.0%)	7 (3.1%)	
Categorized Procedure Date				0.132
First half of AY	202 (54.4%)	86 (59.3%)	116 (51.3%)	
Second half of AY	269 (45.6%)	59 (40.7%)	110 (48.7%)	
Lumbar Puncture				<0.001
Without Myelogram	66 (17.8%)	133 (91.7%)	172 (76.1%)	
With Myelogram	305 (82.2%)	12 (8.3%)	54 (23.9%)	

Table 4: Outcomes Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard Technique Was Used

Variable	Population (N=371)	3-Point Systematic Approach (N=145)	Standard Technique (N=226)	P-value
Procedure Fluoroscopy Time (in seconds)	16.40 ± 29.86	2.03 ± 3.57	25.62 ± 35.21	<0.001
Successful Yes No	 360 (97.0%) 11 (3.0%)	 144 (99.3%) 1 (0.7%)	 216 (95.6%) 10 (4.4%)	0.033
Complications No Back pain Headache	 345 (93.0%) 15 (4.0%) 11 (3.0%)	 138 (95.2%) 5 (3.4%) 2 (1.4%)	 207 (91.6%) 10 (4.4%) 9 (4.0%)	0.346
Traumatic tap Yes No	(N=360) 35 (9.7%) 325 (90.3%)	(N=144) 12 (8.3%) 132 (91.7%)	(N=216) 23 (10.6%) 193 (89.4%)	0.468

Table 5: Fluoroscopic Guided Lumbar Puncture with Myelogram and Fluoroscopic Guided Lumbar Puncture Without Myelogram Group Stratified Outcomes Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard

Fluoroscopic Guided Lumbar Puncture Without Myelogram				
Variable	Population (N=305)	3-Point Systematic Approach (N=133)	Standard Technique (N=172)	P-value
Procedure Fluoroscopy Time (in seconds)	10.61 ± 18.72	1.77 ± 3.36	17.45 ± 22.50	<0.001
Fluoroscopic Guided Lumbar Puncture with Myelogram				
Variable	Population (N=66)	3-Point Systematic Approach (N=12)	Standard Technique (N=54)	P-value
Procedure Fluoroscopy Time (in seconds)	43.12 ± 50.54	4.92 ± 4.66	51.61 ± 52.19	<0.001
P-value	<0.001	0.041	<0.001	

Table 6: Age Categories Stratified Outcomes Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard Technique Was Used

< 35 Years Old				
Variable	Population (N=94)	3-Point Systematic Approach (N=54)	Standard Technique (N=40)	P-value
Procedure Fluoroscopy Time (in seconds)	8.36 ± 14.85	2.24 ± 5.30	16.63 ± 19.14	<0.001
35 To 55 Years Old				
Variable	Population (N=95)	3-Point Systematic Approach (N=30)	Standard Technique (N=65)	P-value
Procedure Fluoroscopy Time (in seconds)	13.97 ± 25.48	2.07 ± 1.87	19.46 ± 29.24	<0.001
> 55 Years Old				
Variable	Population (N=182)	3-Point Systematic Approach (N=61)	Standard Technique (N=121)	P-value
Procedure Fluoroscopy Time (in seconds)	21.81 ± 36.14	1.82 ± 2.01	31.89 ± 40.77	<0.001
P-value	0.001	0.820	0.014	

Table 7: BMI Categories Stratified Outcomes Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard Technique Was Used

< 25 kg/m^2				
Variable	Population (N=80)	3-Point Systematic Approach (N=34)	Standard Technique (N=46)	P-value
Procedure Fluoroscopy Time (in seconds)	14.81 ± 27.08	1.85 ± 2.29	24.39 ± 32.60	<0.001
Between 25 And 29.99 kg/m^2				
Variable	Population (N=93)	3-Point Systematic Approach (N=42)	Standard Technique (N=51)	P-value
Procedure Fluoroscopy Time (in seconds)	12.39 ± 17.60	1.79 ± 2.64	21.12 ± 19.80	<0.001
Between 30 And 34.99 kg/m^2				
Variable	Population (N=78)	3-Point Systematic Approach (N=26)	Standard Technique (N=52)	P-value
Procedure Fluoroscopy Time (in seconds)	20.65 ± 40.92	3.54 ± 6.99	29.21 ± 47.75	<0.001
≥ 35 kg/m^2				
Variable	Population (N=96)	3-Point Systematic Approach (N=39)	Standard Technique (N=57)	P-value
Procedure Fluoroscopy Time (in seconds)	19.05 ± 33.58	1.54 ± 1.47	31.04 ± 39.39	<0.001
P-value	0.331	0.200	0.337	

Table 8: Fluoroscopic Guided Lumbar Puncture Performed During First Half of The Academic Year Vs Second Half of The Academic Year Group Stratified Outcomes Between The Cases Where The 3-Point Systematic Approach With Checklist Was Used and The Cases Where Only

Fluoroscopic Guided Lumbar Puncture Performed During First Half of Academic Year				
Variable	Population (N=202)	3-Point Systematic Approach (N=86)	Standard Technique (N=116)	P-value
Procedure Fluoroscopy Time (in seconds)	20.32 ± 37.36	1.88 ± 3.94	33.98 ± 44.56	<0.001
Fluoroscopic Guided Lumbar Puncture Performed During Second Half of Academic Year				
Variable	Population (N=169)	3-Point Systematic Approach (N=59)	Standard Technique (N=110)	P-value
Procedure Fluoroscopy Time (in seconds)	11.71 ± 15.91	2.24 ± 2.97	16.79 ± 17.63	<0.001
P-value	0.003	0.560	<0.001	

Table 9: Gender Group Stratified Outcomes Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard Technique Was Used

Females				
Variable	Population (N=220)	3-Point Systematic Approach (N=77)	Standard Technique (N=143)	P-value
Procedure Fluoroscopy Time (in seconds)	17.67 ± 32.13	2.21 ± 4.36	26.00 ± 37.18	<0.001
Males				
Variable	Population (N=151)	3-Point Systematic Approach (N=68)	Standard Technique (N=83)	P-value
Procedure Fluoroscopy Time (in seconds)	14.54 ± 26.20	1.82 ± 2.41	24.95 ± 31.74	<0.001
P-value	0.321	0.520	0.830	

Table 10: Performing Staff Physician Categories Stratified Outcomes Between the Cases Where The 3-Point Systematic Approach with Checklist Was Used and The Cases Where Only the Standard Technique Was Used

Physician A				
Variable	Population (N=67)	3-Point Systematic Approach (N=22)	Standard Technique (N=45)	P-value
Procedure Fluoroscopy Time (in seconds)	21.81 ± 35.40	2.55 ± 2.77	31.22 ± 39.99	<0.001
Physician B				
Variable	Population (N=33)	3-Point Systematic Approach (N=6)	Standard Technique (N=27)	P-value
Procedure Fluoroscopy Time (in seconds)	20.42 ± 31.21	1.00 ± 0.00	24.74 ± 33.05	<0.001
Physician C				
Variable	Population (N=35)	3-Point Systematic Approach (N=14)	Standard Technique (N=21)	P-value
Procedure Fluoroscopy Time (in seconds)	13.60 ± 18.54	3.29 ± 4.34	20.48 ± 21.17	0.002
Physician D				
Variable	Population (N=66)	3-Point Systematic Approach (N=20)	Standard Technique (N=46)	P-value
Procedure Fluoroscopy Time (in seconds)	16.62 ± 20.06	1.50 ± 1.15	23.20 ± 20.85	<0.001
Physician E				
Variable	Population (N=61)	3-Point Systematic Approach (N=30)	Standard Technique (N=31)	P-value
Procedure Fluoroscopy Time (in seconds)	8.77 ± 11.95	1.13 ± 0.434	16.16 ± 13.06	<0.001

Physician F				
Variable	Population (N=73)	3-Point Systematic Approach (N=24)	Standard Technique (N=49)	P-value
Procedure Fluoroscopy Time (in seconds)	22.19 $\pm$ 45.89	2.13 $\pm$ 2.37	32.02 $\pm$ 53.45	<0.001
Physician G				
Variable	Population (N=36)	3-Point Systematic Approach (N=29)	Standard Technique (N=7)	P-value
Procedure Fluoroscopy Time (in seconds)	6.11 $\pm$ 12.40	2.45 $\pm$ 6.55	21.29 $\pm$ 19.07	0.04

Table 11: Univariate Linear Regression for Procedure Fluoroscopy Time

Variable	3-Point Systematic Approach			Standard Technique		
	ß	95% CI	P-value	ß	[95% CI]	P-value
With vs Without Myelogram	3.150	1.079 – 5.220	0.003	34.158	24.287 – 44.028	<0.001
First vs Second Half of the Year	0.354	-0.842 – 1.549	0.560	-17.192	-26.165 – -8.219	<0.001
Gender	0.384	-0.793 – 1.561	0.520	1.048	-8.546 – 10.642	0.830
Age	-0.009	-0.034 – 0.016	0.470	0.496	0.231 – 0.761	<0.001
BMI	-0.014	-0.056 – 0.029	0.524	-0.093	-0.314 – 0.127	0.405

Table 12: Multivariate Linear Regression for Procedure Fluoroscopy Time

Variable	3-Point Systematic Approach			Standard Technique		
	ß	95% CI	P-value	ß	[95% CI]	P-value
With vs Without Myelogram	3.577	1.444 – 5.709	0.001	28.807	18.808 – 38.806	<0.001
First vs Second Half of the Year	0.611	-0.560 – 1.783	0.304	-13.376	-21.721 – -5.031	0.002
Gender	0.424	-0.771 – 1.620	0.484	-1.456	-9.954 – 7.042	0.736
Age	-0.016	-0.042 – 0.009	0.208	0.369	0.108 – 0.631	0.006
BMI	-0.014	-0.056 – 0.028	0.512	-0.005	-0.213 – 0.203	0.961

Table 13: Univariate Logistic Regression for the Odds of Traumatic Tap

Variable	3-Point Systematic Approach			Standard Technique		
	ß	95% CI	P-value	ß	[95% CI]	P-value
With vs Without Myelogram	-18.900	0.000 –	0.999	-2.120	0.016 – 0.913	0.041
First vs Second Half of the Year	0.431	0.471 – 5.028	0.476	-0.494	0.252 – 1.477	0.274
Gender	-0.152	0.263 – 2.802	0.801	-0.719	0.204 – 1.164	0.106
Age	0.003	0.979 – 1.028	0.797	0.006	0.980 – 1.032	0.661
BMI	0.014	0.980 – 1.049	0.431	-0.012	0.963 – 1.014	0.381
Staff						
A	1					
B	1.435	0.222 – 79.319	0.338	0.062	0.232 – 4.882	0.937
C	-18.158	0.000 –	0.999	0.668	0.463 – 8.212	0.363
D	2.197	0.975 – 83.064	0.053	-0.248	0.195 – 3.122	0.725
E	0.405	0.127 – 17.667	0.747	-1.347	0.029 – 2.345	0.230
F	-18.158	0.000 –	0.998	0.182	0.338 – 4.261	0.778
G	0.442	0.132 – 18.340	0.726	-19.149	0.000 –	0.999
Fluoroscopy Time	0.118	0.997 – 1.271	0.056	-0.015	0.963 – 1.008	0.213

Table 14: Multivariate Logistic Regression for the Odds of Traumatic Tap

Variable	3-Point Systematic Approach			Standard Technique		
	ß	95% CI	P-value	ß	[95% CI]	P-value
With vs Without Myelogram	-18.275	0.000 –	0.999	-2.011	0.015 – 1.200	0.072
First vs Second Half of the Year	0.380	0.357 – 5.977	0.597	-0.722	0.184 – 1.283	0.145
Gender	-0.687	0.114 – 2.229	0.366	-0.730	0.188 – 1.234	0.128
Age	0.005	0.962 – 1.050	0.837	0.017	0.989 – 1.046	0.240
BMI	0.024	0.978 – 1.074	0.311	-0.004	0.970 – 1.022	0.763
Staff						
A	1					
B	2.439	0.319 – 411.27	0.182	-0.291	0.150 – 3.739	0.723
C	-18.079	0.000 –	0.998	0.316	0.301 – 6.243	0.683
D	2.627	0.849 – 225.32	0.065	-0.284	0.176 – 3.215	0.701
E	0.799	0.106 – 46.756	0.607	-1.386	0.025 – 2.481	0.236
F	-17.792	0.000 –	0.998	0.174	0.312 – 4.533	0.799
G	0.493	0.034 – 77.839	0.803	-19.062	0.000 –	0.999
Fluoroscopy Time	0.365	0.969 – 2.142	0.072	-0.008	0.968 – 1.016	0.490

Table 15: Comparison of Baseline Characteristics Between the Cases Where the 3-Point Systematic Approach with Checklist Was Used and the Cases Where Only the Standard Technique Was Used And the Cases From Bakrukov el al study.

	Our Study			Bakrukov el al	
Variable	Population (N=371)	3-Point Systematic Approach (N=145)	Standard Technique (N=226)	Lateral decubitus position LP	Prone LP
Age in years	51.09 ± 20.29	46.34 ± 23.85	54.14 ± 16.99	48.3	48.1
BMI	31.49± 8.79	30.98 ± 8.30	31.84 ± 9.11	33.79 ± 0.79	31.95 ± 1.25
Gender Female Male	 220 (59.3%) 151 (40.7%)	 77 (53.1%) 68 (46.9%)	 143 (63.3%) 83 (36.7%)	 112 (61.9%) 69 (38.1%)	 29 (61.7%) 18 (38.3%)
Procedure Fluoroscopy Time (in seconds)	16.40 ± 29.86	2.03 ± 3.57	25.62 ± 35.21	58.2 ± 6	64.2 ± 9.6
Successful Yes No	 360 (97.0%) 11 (3.0%)	 144 (99.3%) 1 (0.7%)	 216 (95.6%) 10 (4.4%)	 175 (96.7%) 6 (3.3%)	 42 (89.10%) 5 (10.9%)

Missing Data Table

Variable	Population (N=371)	3-Point Systematic Approach (N=145)	Standard Technique (N=226)
BMI (in kg/m^2) Missing	24 (6.5%)	4 (2.8%)	20 (8.8%)
Age	0 (0%)	0 (0%)	0 (0%)
Diabetes	0 (0%)	0 (0%)	0 (0%)
Cancer	0 (0%)	0 (0%)	0 (0%)
Hypertension	0 (0%)	0 (0%)	0 (0%)
Date of Exam	0 (0%)	0 (0%)	0 (0%)
Gender	0 (0%)	0 (0%)	0 (0%)
Exam Type	0 (0%)	0 (0%)	0 (0%)
CSF Color	0 (0%)	0 (0%)	0 (0%)
Staff Performing the Procedure	0 (0%)	0 (0%)	0 (0%)
Fluoroscopy Time	0 (0%)	0 (0%)	0 (0%)
Success Rate	0 (0%)	0 (0%)	0 (0%)
Complications	0 (0%)	0 (0%)	0 (0%)
Technique Used	0 (0%)	0 (0%)	0 (0%)

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