Examining the Association of Body Mass Index With the Depth of Epidural Space, Radiation Dose Exposure and Fluoroscopic Screening Time During Transforaminal Nerve Block Injection: A Retrospective Cohort Study

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Citation
Galbraith A. Examining the Association of Body Mass Index With the Depth of Epidural Space, Radiation Dose Exposure and Fluoroscopic Screening Time During Transforaminal Nerve Block Injection: A Retrospective Cohort Study [Masters dissertation]. Dublin: Royal College of Surgeons in Ireland; 2018.
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13th June 2017

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MASTER OF SURGERY PROGRAMME 2017
MCh BY MODULE

DISSERTATION TITLE:

Examining the association of Body Mass Index with the Depth of Epidural Space, Radiation Dose Exposure and Fluoroscopic Screening Time During Transforaminal Nerve Block Injection: a retrospective cohort study.

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Student Number

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## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACP</td>
<td>American College of Physicians</td>
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<tr>
<td>AHCPR</td>
<td>Agency for Healthcare Policy and Research</td>
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<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<td>AP</td>
<td>Anterior-posterior</td>
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<td>APS</td>
<td>American Pain Society</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>CD</td>
<td>Compact Disc</td>
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<tr>
<td>CDC</td>
<td>Centres for Disease Control and Prevention</td>
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<tr>
<td>CI</td>
<td>Confidence Interval</td>
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<td>CMS</td>
<td>Centres for Medicare and Medicaid Services</td>
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<tr>
<td>CT</td>
<td>Computed Tomography</td>
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<tr>
<td>DDD</td>
<td>Degenerative Disc Disease</td>
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<tr>
<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>IQR</td>
<td>Interquartile Range</td>
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<tr>
<td>LBP</td>
<td>Low Back Pain</td>
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<tr>
<td>LDH</td>
<td>Lumbar Disc Herniation</td>
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<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>p-value</td>
<td>Probability Value</td>
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<tr>
<td>RC</td>
<td>Regression Coefficient</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>RMDQ</td>
<td>Roland-Morris Disability Questionnaire</td>
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<tr>
<td>RNA</td>
<td>Ribonucleic Acid</td>
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<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<tr>
<td>SS</td>
<td>Spinal Stenosis</td>
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<tr>
<td>TFESI</td>
<td>Transforaminal Epidural Spinal Injection</td>
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<td>TFNB</td>
<td>Transforaminal Nerve Block</td>
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<tr>
<td>TPI</td>
<td>Trigger Point Injection</td>
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<tr>
<td>US</td>
<td>United States</td>
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<tr>
<td>USPSTF</td>
<td>United States Preventative Services Task Force</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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Tables

Table 1: Definitions of variables of interest

Table 2: Descriptive statistics for study participants’ (n=317)

Table 3: Correlation between study participants’ BMI (kg/m$^2$) and SE depth (mm), Radiation Dose Exposure (cGy/cm$^2$) and Screening time(s) (n=317).

Table 4: Multivariable linear regression model of the unadjusted and adjusted coefficients (95% C.I.'s, p-value) for the Primary outcome ‘Depth of tissue from skin to the epidural space (mm)’ by exposure to BMI (kg/m$^2$) accounting for patient level confounding variables (n=317).

Table 5: Multivariable linear regression model of the unadjusted and adjusted coefficients (95% CI, p-value) for the secondary outcome ‘Radiation Dose Exposure (cGy/cm$^2$)’ by exposure to BMI (kg/m$^2$) and patient level confounding variables (n=317).

Table 6: Linear regression model with unadjusted and adjusted coefficients (95% C.I.'s, p-value) for the secondary outcome ‘Fluoroscopic Screening Time (seconds)’ by exposure to BMI (kg/m$^2$) and adjustment for patient level confounding variables (n=317).
Abstract

Introduction
The Transforaminal Nerve Block (TFNB) represents a widely accepted treatment modality, often utilised in the setting of lumbosacral radicular pain. Optimal outcomes of this minimally invasive technique are multifactorial, and rely largely upon accurate instillation of the injectate to the appropriate site. Fluoroscopic imaging guidance is essential to aid in the accurate placement of the injectate resulting in ionised radiation exposure to both patients and physicians. With the increased incidence of radiologically assisted procedures it is likely that a patients’ cumulative lifetime ionised radiation exposure profile will increase and with that, the potential for development of associated adverse effects.

The primary objective of this study is to examine the association between Body Mass Index (BMI) and depth of epidural space (distance of tissue from skin to epidural space). Secondary objectives aim to examine the association between BMI and the following outcomes i) radiation dose exposure; and, ii) fluoroscopic screening time.

Methodology

Study design and study population: Retrospective cohort study of adult (aged ≥16 years) patients who underwent unilateral single level TFNB in a single hospital centre were identified over 28 months from January 2015 to April 2017. Study procedure: All injections were performed by a single experienced spinal orthopaedic surgeon. Demographic data, BMI (kg/m^2), fluoroscopic screening time (seconds) and unit area radiation dose exposure (centi-Gray per square centimetre squared(cGy-cm^2)) were recorded.

Exposure of interest: BMI, Primary outcome: Depth of epidural space, Secondary outcomes: 1) Patient radiation dose exposure, 2) Fluoroscopic screening time. Statistical analysis: Descriptive statistics for study participants’ demographics are presented. Spearman’s rank (r) coefficient was utilised to determine correlations between BMI, and primary and secondary outcomes variables. Linear regression
analysis was performed examining the association between BMI, and primary and secondary outcomes. Unadjusted and adjusted regression coefficients (RC) with 95% confidence intervals (CIs) and p-values are presented.

Results
A total of 362 patients met inclusion criteria, 45 patients had missing data and were excluded from statistical analysis. Final statistical analysis included 317 patients. Mean age 62.58 years (IQR 53-74, Range 16-92). Male: Female ratio was 37.85% (n=120): 62.15% (n=197). The mean BMI was 26.85 kg/m$^2$ (IQR 24.38 – 28.90 kg/m$^2$, Range 18.45 – 49.35 kg/m$^2$). The majority of injections were carried out at the L4/5 and L5/S1 (lumbosacral junction), 93.06% (n=295). In linear regression analysis, the unadjusted model demonstrated that increasing BMI was associated with an increased depth of tissue from skin to the epidural space (unadjusted coefficient 2.49 (95% CI (2.24, 2.74), p<0.001). Following adjustment for age, gender and spinal comorbidities this association remained (adjusted coefficient 2.41 (95% CI (2.14, 2.68), p<0.001). For secondary outcomes, in the unadjusted regression model increasing BMI was associated with an increased radiation dose exposure (unadjusted coefficient 1.49 (95% CI (0.92, 2.05), p<0.001). Following adjustment for relevant confounders this association persisted (adjusted coefficient 1.45 (95% CI (0.84, 2.06), p<0.001) In the unadjusted model increasing BMI was also associated with an increase in fluoroscopic screening times (unadjusted coefficient 0.12 (95% CI (0.04, 0.21), p<0.001). This association persisted following adjustment for confounders (adjusted coefficient 0.11, (95% CI (0.02, 0.20), p=0.02).

Conclusion
This current research demonstrates that there is an association between increasing BMI and increased depth of the epidural space. Furthermore, our study has indicated that increasing BMI is associated with increased radiation dose exposure and fluoroscopy screening time during transforaminal nerve block injections. The potential effects of an individual’s lifetime cumulative exposure to ionised radiation from medical procedures, remains unclear. It is generally accepted that there is no amount
of radiation that is completely without risk and ultimately care should be taken to maximise safety for patients and physicians alike.
Acknowledgements

I wish to express gratitude to my supervisors, Dr Emma Wallace and Mr Aiden Devitt. Their guidance and support was exemplary throughout.

Sincere thanks also to all the helpful staff in the Bon Secours Hospital Group, Renmore, Galway for facilitating the data collection for this project.

Many thanks to the programme co-ordinator Professor O’Byrne and all the support staff in RCSI who facilitate and assist with the smooth running of the MCh Taught Masters in Surgery.
Chapter 1

1.1. Introduction

Transforaminal Nerve Block (TFNB) represents a widely accepted and effective treatment modality, often utilised in the setting of lumbosacral radicular pain.\(^1\)\(^,\)\(^2\) There are multiple factors associated with optimal outcomes of this minimally invasive technique, that relies upon accurate delivery of the injectate to the appropriate site.\(^3\)\(^-\)\(^5\) Fluoroscopic imaging guidance is essential to aid in the accurate placement of the injectate and has become standard practice when performing such procedures which results in patient exposure to ionised radiation.\(^6\) It is widely understood that exposure to ionised radiation has potential for the development of associated detrimental effects.\(^7\)\(^-\)\(^9\) Detrimental effects from ionised radiation exposure can be categorised into ‘deterministic’ or ‘stochastic’ effects. Deterministic effects occur due to extensive cell death and/or cell malfunctioning.\(^10\) The skin is more commonly affected and can manifest as erythema, desquamation, dermal atrophy, dermal necrosis or ulceration, which may culminate in the need for plastic surgery.\(^11\)\(^-\)\(^13\) Other effects include cataract formation if the primary radiation beam passes through the orbit.\(^12\) Stochastic effects are a result of the genetic modification of cell DNA, which can predispose to solid tumour formation, leukaemia and heritable disease.\(^10\) Despite potential for development of these effects, there is an absence of consensus in both the scientific and medical communities regarding the clinical significance of the adverse risk profile posed with exposure to ionised radiation.\(^12\)

With the advent of minimally invasive procedures there has been a significant increase in the utilisation of radiological image guidance.\(^2\) The literature has demonstrated that obese patients (Body Mass Index (BMI) > 30 kg/m\(^2\)) are more likely to be exposed to larger doses of radiation.\(^14\)\(^-\)\(^16\) The explanation for this increased exposure risk is multifactorial, and may be due to the depth of tissue through which the radiation has to travel in order to reach the detector.\(^16\) Furthermore, this increased exposure may be due to technical reasons including the depth of tissue (from skin to epidural space) that the needle must traverse to reach the desired location. As TFBN’s represent a conservative therapeutic option for pain management, this patient cohort will often
undergo repeat procedures, with each injection adding to their cumulative radiation profile and their potential for developing an adverse outcome.(17)

The primary aim of this thesis is to determine if there is an association between BMI and the depth of tissue from skin to the epidural space, and if so, if this has an impact upon fluoroscopic screening time and patient radiation exposure.

1.2. Thesis Outline

This thesis is presented across six chapters. Chapter one will include an introduction to the research area of interest. Chapter two will present a comprehensive literature review pertaining to the topic of interest, and will summarise the overall aim and objectives. Chapter three will include a detailed methodology overview and consideration of ethical considerations and ethical approval. Chapter four will present the results and statistical analysis. Chapter five will focus on discussion of study results, critical analysis of these findings and a description of potential study limitations of the research and any clinical implications of the results. Finally, Chapter six will provide an overall summary of the research conclusions.
Chapter 2

2.1 Literature Review

2.1.1. Epidemiology of Low Back Pain

Low back pain (LBP) accounts for a significant proportion of decreased mobility and work hours lost due to sick leave.\(^{(18-20)}\) The lifetime incidence of LBP has been reported to be as high as 80% among the general population.\(^{(21)}\) A systematic review was conducted examining the prevalence of low back pain in the elderly (\(\geq 65\) years of age living in the community, nursing home residents and those in medical facilities). This review included 12 studies, seven of which utilised self-report data i.e. postal questionnaires or telephone interviews. In community-dwellers the reported prevalence of LBP ranged from 12.8% - 49%, and was up to 51% in those in the medical facilities.\(^{(22)}\) However this review was published in 1998 and as such does not include recent prevalence estimates of LBP. In a Swedish study (\(n=2,305\) aged 35-45 years) using self-report questionnaire data back pain prevalence was 66.3%, of which 56% was reported as LBP.\(^{(23)}\) Furthermore 19% of individuals with a history of back pain reporting taking at least one day in official sick leave resulting from LBP.

Sciatica, which is otherwise known as lumbar radicular pain often presents in the context of low back pain. The prevalence of lower limb radicular pain is reported at 4.8% between 1980 to 2006, with an annual incidence of approximately 0.5% in adults.\(^{(24, 25)}\) Research indicates that individuals with radicular symptoms have a greater intensity of pain than those with isolated LBP and an increased tendency to develop chronic pain.\(^{(26)}\) The aetiology of lumbosacral radicular pain is varied however greater than 90% is attributed to lumbar disc herniation (LDH). Potential risk factors have not been definitively identified, however; smoking, obesity and heavy physical labour have been highlighted as possible contributors.\(^{(27)}\)
2.1.2. Economic Burden of Low Back Pain

The economic burden of chronic pain is estimated at $560 - $635 billion in the United States (US) per annum, of this back and neck pain is responsible for approximately 15% with estimates ranging from $86 - $96 billion in health care expenditure. In an analysis undertaken in 2010 the growth and financial cost of interventional injection procedures for LBP and associated neuropathic pain was reviewed. Manchikanti and colleagues’ reviewed the Centre for Medicare and Medicaid Services (CMS) data over a nine year period evaluating all types of epidural injection (caudal, interlaminar and transforaminal). The CMS currently serves as the largest healthcare payer in the US. They reported an annual growth rate of 13.5% and overall increase of 121% in the number of injections performed from 1997 to 2006 in the US. This also attributed to an annual increase of 21.8% in Medicare expenditure to $743 million in 2006. Another analysis of US Medicare Physician reimbursement information included a 5% national sample of the CMS reimbursement examined from 1994 – 2001. The study authors reported an overall increase of 271% in the usage of minimally invasive spinal injections, from 633 per 100,000 in 1994, to 2319 per 100,000 in 2001. In addition, they found a seven-fold increase in inflation-adjusted expenditure for lumbosacral injections from $24 million in 1994 to $175 million in 2001.

2.1.3. Categorisation, Investigation and Diagnosis of Low Back Pain

Much of LBP is self-limiting and does not require radiological investigation or medical intervention. In a systematic review examining nonspecific back pain and radiological investigations up to 85% of back pain was reported as nonspecific, with no attributable spinal aetiology following radiological investigation. It is therefore, recommended that careful consideration is necessary when evaluating these patients and identifying those who may benefit from radiological investigations. Routine imaging including computed tomography (CT) and magnetic resonance imaging (MRI) is not recommended and has not shown correlation with improved patient outcomes, appropriate patient selection is essential. The American College of Physicians (ACP) and the American Pain Society (APS) have constructed guidelines for the management of low back pain, which recommends low back pain should be categorised into one of
three options based upon clinical assessment; 1) nonspecific low back pain; 2) back pain with radiculopathy; and; 3) back pain with another potentially associated spinal cause.(34) While the aetiology of lumbosacral radicular pain is varied, the literature indicates that 2-3% of this is attributable to intervertebral disc prolapse, and nerve root irritation or impingement, 95% of which occurs at the level of the lumbosacral junction at the L4-L5 or L5-S1 intervertebral discs.(35-37) Subsequently, patients with low back pain and radicular symptoms should undergo a MRI of the lumbar spine with a view to further intervention, under the premise that they are otherwise suitable candidates for surgery or epidural spinal injection.

2.1.4. Low Back Pain and Radiculopathy: Conservative Management

LBP with associated lumbosacral radicular pain is a commonly occurring clinical problem and remains a clinically difficult pathology to manage, with no widely accepted successful treatment algorithm.(34, 38) There are multiple available options for the assessment and treatment of lumbosacral pain. The ACP and APS of Low Back Pain published guidelines in 2007 to provide a framework for all healthcare professionals involved in the management of low back and lumbosacral radicular pain.(34) A multidisciplinary panel reviewed Medline, EMBASE and the Cochrane Database of Systematic reviews to formulate the recommendations. The natural history of lumbar disc herniation (LDH) with associated radicular pain is improvement within four weeks with conservative management.(39, 40) Conservative management of LDH typically includes advice to stay active, analgesics, antidepressants or muscle relaxants, however, a comprehensive systematic review in 2011 found limited evidence to support the effectiveness of conservative non-drug and drug therapy in the treatment of LDH.(41) The same systematic review found no randomised controlled trials (RCTs) pertaining to the use of antidepressants in the management of patients with symptomatic LDH and so the potential role for antidepressants remains unknown.(36, 41) Since this, there have been animal studies which may indicate a role for the use of antidepressants in LDH.(42, 43) The ACP/APS guidelines recommend in the setting of LDH that if pain persists beyond four weeks with optimal conservative
management, then minimally invasive epidural steroid injections should be considered prior to more invasive alternatives such as discectomy surgery.(34)

2.1.5. Low Back Pain and Radiculopathy; Epidural Steroid Injections

Epidural spinal injections via transforaminial, caudal or interlaminar routes represent some of the most frequently utilised interventional procedures performed in North America.(21) TFNB is an accepted and commonly utilised therapeutic modality in the setting of persistent lumbosacral radicular pain.(1)

A systematic review published in 2009 examined therapeutic lumbar transforaminal epidural steroid injections (TFESIs).(21) The authors utilised Cochrane Musculoskeletal Review criteria when assessing RCTs pertaining to interventional techniques and Agency for Healthcare Research and Quality (AHRQ) criteria for relevant observational studies.(44) A comprehensive literature search focused on RCT’s and observational studies in relation to chronic LBP and lower extremity pain, use of lumbar transforaminal epidural injection and clinical outcomes at six-month follow-up. Articles were classified using the Modified and weighted Cochrane Methodological quality assessment criteria, which attributes a methodology quality score to a maximum of 100. Only studies scoring between 50 and 100 were included. Included studies were further categorised into one of five evidence levels, in line with the US Preventive Services Task Force (USPSTF), ranging from level one evidence (RCT) to level five (case reports/expert opinion).(45) Ultimately four RCTs met the inclusion criteria for analysis, representing level I data. All four studies demonstrated that transforaminal epidural injections were effective for the short-term relief of LBP whereas only two studies had positive outcomes for long-term pain relief. One study failed to record long-term outcomes and the other reported no long-term benefit of the procedure.

Another systematic review critically appraised clinical evidence and outcomes pertaining to selective nerve root injection, a similar process of data extraction was utilised in line with AHRQ guidelines.(46) Six studies were assessed, five of which were prospective, randomised and double-blinded controlled trials, while one study was
randomised but did not blind subjects. Studies were deemed positive if the primary author determined that selective nerve root blockade was more efficacious than the control treatment. Reference treatments varied amongst the selected studies, three studies incorporated placebo controls administering 0.9 % normal isotonic saline and the fourth study administered 0.25% Bupivacaine as an alternative treatment to their control patients. Studies were stratified in accordance with the AHCPR rating scheme into five levels of evidence based on the strength of the individual studies.(47) Four of the included studies recorded positive outcomes and the remaining two were negative. Study methodological quality ranged from good to poor, with variability in the use of fluoroscopic guidance, inclusion of satisfactory placebo groups and variability in the cumulative number of injections performed on each individual patient. In summary, this systematic review and meta-analysis concluded that there is currently limited level II and level III evidence supporting the case of minimally invasive transforaminal injections as effective procedures for the management of lumbosacral radicular pain.

The efficacy of this procedure remains undetermined as the current literature has failed to identify reproducible beneficial outcomes from these interventional injections and there is a lack of level 1 evidence in the area.(21, 46) Despite this definitive lack of clarity, demand for lumbosacral injections has increased dramatically in recent years.

2.1.6. Transforaminal Nerve Block (TFNB); Procedural Technique

The paramedian approach is typically utilised when performing TFNB injections. Standard procedural steps include informed consent as well as discussion of risks, benefits and potential outcomes with the patient. TFNB procedures are usually single level unilateral (right or left sided) procedures but may be bilateral and/or multilevel depending on the pre-diagnosed underlying pathology. The side and level must be checked and confirmed during WHO surgical checklist protocol.(48) The patient is positioned prone and a pillow may be placed under their chest to prevent hyperextension of the neck. The procedure site is draped following the application of
standard antiseptic preparation solution to the skin. Anatomical landmarks including the iliac crests are utilised to estimate the underlying spinal level.

Practitioners are recommended to utilise a high-resolution C-arm to confirm anatomical location and facilitate accurate delivery of the injectate. The mobile C-arm is a medical imaging device, its name derived from the C-shaped arm used to connect the X-ray source to and X-ray detector. The C-arm represents the source of ionised radiation created during these procedures. Its design allows for the device to move about a swivel axis and simultaneously through both the horizontal and vertical planes. These devices produce immediate high-resolution X-ray images allowing the user to make instant adjustments intra-operative.

The C-arm is placed in the lateral position and will produce lateral radiographs of underlying spine when activated. When the level has been determined, the overlying skin is anaesthetised with 1% lidocaine. Then a 22- or 25-guage cannulated spinal needle is advanced toward the corresponding transverse process and then redirected 1 cm anterior and inferior and into the ‘safe triangle.’(4) As described by Lutz et al, the safe triangle consists of a roof; the pedicle, oblique base; exiting nerve root, and lateral side; the lateral border of the vertebral body. Orthogonal fluoroscopic x-ray images are obtained in both the, lateral and anterior-posterior(AP) plains to verify appropriate needle position. When reviewing the lateral fluoroscopic image, the preferred needle position is located just beneath the pedicle in the anterior aspect of the intervertebral foramen and on the AP projection, just beneath the midportion of the corresponding pedicle.

When position has been confirmed 1- 2cc of radio-opaque ‘Omnipaque’ contrast in injected and fluoroscopic epidurogram confirms appropriate needle placement. The therapeutic injectate of local anaesthetic (1% lidocaine 1–2 ml) and long acting steroid (e.g. 10mg Triamcinolone acetonide (Adcortyl)) is then instilled into the epidural space, neighbouring the desired exiting nerve root. Typical procedural time is in the order of five to ten minutes, fluoroscopic screening times is in the order of three to four seconds.
2.1.7. Fluoroscopic Image Guidance in Transforaminal Epidural Spinal Injection

Optimising clinical outcomes of this minimally invasive technique relies upon accurate delivery of the injectate to the appropriate anatomical site. Without use of fluoroscopic guidance the error rate in placing the injectate may be as high as 30%. As a result, increased emphasis has been placed upon the operator to utilise high resolution C-arm for fluoroscopic image guidance as an adjunct when performing the procedure. One RCT demonstrated significantly improved clinical outcomes in patients receiving steroid injections under fluoroscopic guidance when compared to patients undergoing standard trigger point injection without guidance.

Vad et al, 2002, recruited adult patients aged ≥ 18 years old, with the incident complaint of radicular leg pain worse than back pain, pain duration greater than six weeks and confirmatory diagnosis of LDH on MRI or positive sensory or motor signs of radiculopathy on physical examination. Patients were randomised into two treatment groups; Group one (Transforaminal epidural steroid injection (TFESI)) and Group two (Trigger Point Injection (TPI)). Group one patients underwent TFESI which included 1.5ml of betamethasone acetate and 2% lidocaine under fluoroscopic image guidance while group 2 patients underwent local anaesthetic administration to skin and 3ml of normal saline into the point of maximal tenderness of the para-spinal muscles without image guidance. Follow-up was conducted at 3 weeks, 6 weeks, 3 months, 6 months and 12 months. Outcomes measures included; completion of a subjective Roland-Morris Disability Questionnaire (RMDQ) for low back pain (assessing pain and function) and a subjective patient satisfaction scale ranging from; 0 (poor) through to 4 (excellent). The RMDQ is a 24 item questionnaire with a maximum score of one point per question, thus a patients individual score may range from zero (no disability) to 24 (severe disability). Group one patients consistently recorded higher patient satisfaction scores, Roland-Morris scores (8.8 ± 1.2 to 22.1 ± 1.6, P<0.05) and attained maximal improvement within 6 weeks of treatment. This was in contrast with lower patient satisfaction and Roland-Morris scores (9.6 ± 1.3 to 18.3 ± 2.1, P<0.05) observed in Group 2 patients and maximal improvement at 12 weeks following treatment. The use of fluoroscopic image guidance is now common practice and
viewed as essential to achieve accurate placement of the injectate. However, this technique results in exposure of both patients and healthcare professionals to ionised radiation.\(^{(51, 52)}\)

### 2.1.8. Ionised Radiation – Adverse Risks

Ionized radiation is defined as, “radiation that has enough energy to displace electrons from atoms inside of the patient, causing the atom to become charged or ionised.”\(^{(53)}\) This ionised radiation can produce free radicals, and damage molecules in human cells that regulate DNA and RNA replication.\(^{(54)}\) Currently, there remains much uncertainty when determining ‘safe’ levels of radiation exposure for patients. It is generally accepted that there is no amount of radiation that is completely without risk and the level of risk is proportional to the level of radiation exposure.\(^{(55)}\) The Food and Drug Administration (FDA) states that, “a CT examination with an effective dose of 10 millisieverts (abbreviated mSv; 1 mSv = 1 mGy in the case of x-rays.) may be associated with an increase in the possibility of fatal cancer of approximately 1 chance in 2000.”\(^{(7)}\) This represents a much smaller risk of an individual’s lifetime natural risk of developing cancer which is currently one in two and one in three for males and females respectively.\(^{(54)}\) However small the additional risk is, it is not negligible and is additive to the lifetime natural risk. Radiation exposure during spinal injections for radicular pain is typically < 1.0 mSv, in comparison a typical chest radiograph demands a typical effective dose of 0.02 mSv, lumbar spine radiograph 1.5 mSv or Computed Tomography(CT) of the brain at 2 mSv.\(^{(7)}\) The adverse risk profile for the typical level of radiation exposure sustained during diagnostic or therapeutic radiological procedures remains widely speculative and largely unknown.\(^{(7, 55)}\)

As previously outlined, experimental radiation research has provided extensive information surrounding the mechanisms through which ionised radiation exposure can result in adverse health effects. These effects are widely varied and are visible at a molecular level, chromosomes, cells through to tissues, organs and complete organisms. The most significant site of damage is to the DNA which make up the chromosomal subunits within cells. DNA damage in normally repaired, however when this is not the case, abnormal gene expression, abnormal cell function and even cell
death can be seen. The detrimental effects from ionised radiation exposure are
categorised into ‘deterministic’ or ‘stochastic’ effects. Extensive stem and progenitor
cell death within tissues can result in what are known as deterministic effects.(10)
Deterministic effects are usually apparent within hours or days following acute
radiation exposure and often manifest via skin changes including erythema,
desquamation, dermal atrophy, dermal necrosis and ulceration which may culminate
in the need for plastic surgery or haematopoietic or gastrointestinal damage.(11-13)
Other effects include cataract formation if the primary radiation beam passes through
the orbit.(12)

In contrast with deterministic effects, stochastic effects are a result of genetic
modification and transformation of cellular DNA, in turn this may alter the original
characteristics and function of the affected cell without impairing the cells ability to
replicate and proliferate. Subsequently, this provides the capacity for predisposition to
solid tumour formation, leukaemia and heritable disease.(10)

There is some research to suggest that female gender, exposure at young age and
body part exposed may be associated with an elevated risk of adverse event, however,
there is a lack of level one evidence to characterize the potential significance of these
factors.(56-58) Nonetheless, with the rapid growth in the use of ionised radiation for
both diagnostic and therapeutic interventional radiological procedures, greater
frequency of scanning, improved access to medical imaging, expanded applications of
imaging technology the risks associated with ionised radiation may become more
apparent and measurable.(59)

2.1.9. Medical Imaging and Obesity

Obesity is a current global epidemic with at least 300 million individuals worldwide
whom are clinically obese and 30% of the American adult population who are
obese.(60) Obesity is often defined as a disproportionate ratio of an individual’s weight
to their height, via a ratio known as body mass index (BMI). BMI is calculated by
dividing an individual’s weight in kilograms by the square of height in metres. A normal
BMI range as 18.5 kg/m² to 24.9 kg/m², overweight as 25.0 kg/m² to 29.9 kg/m², obese
as 30.0 kg/m^2 to 39.9 kg/m^2 and morbidly obese as ≥40 kg/m^2. Image quality obtained with fluoroscopy is associated with the depth of tissue through which ionised particles must traverse in order to reach the detector. Prior studies have shown that patients with elevated body mass index (BMI ≥ 25.0 kg/m^2) who are overweight or obese (BMI ≥ 30.0 kg/m^2) require increased radiation dosages to identify the anatomical structures and to produce useable images. It is postulated that obese patients’ increased radiation exposure is multifactorial, resulting from increased technical difficulty, difficulty in identifying surface landmarks, the need for adjustment of instrumentation and the necessity of repeat or ‘check’ imaging which are otherwise avoided in normal bodyweight individuals. Furthermore, with increasing levels of obesity, a corresponding increase in the AP diameter of the patient results in a greater amount of tissue through which the ionised radiation must traverse to reach the detector. Consequently, this requires a higher dose of ionised radiation in order to produce images of acceptable quality. Finally, an increase in radiation may also be associated with increased depth from skin to the epidural space.

2.1.10. Obesity, BMI and depth of tissue overlying Epidural Space

Multiple studies have attempted to identify a correlation between BMI and depth of tissue overlying the epidural space (i.e. the posterior subcutaneous fat and soft tissue). Inconsistencies within the literature regarding this theory continue to persist. In 2009 a prospective observational study examined the relationship between BMI and depth of epidural space. A total of 88 patients were recruited over a six-month period from June 2007 to January 2008, all patients enrolled were aged ≥ 18 years ranging from 21 to 84 years of age. The typical paramedian approach to injection as earlier described was utilised, and primary outcome measure was the depth of final needle placement from skin surface. The authors’ reported a positive association (regression coefficient [RC], 1.13; P < 0.001) between the depth of epidural space and patient BMI. However, this study was limited by its small sample size.

A comparable study published in 2011 recruited 120 adult patients between 18 and 70 years. They identified patients who were either awaiting lumbar spinal surgery or pain relief procedures via epidural block. They subdivided patients as non-obese (BMI <
30 kg/m²) and obese (BMI > 30 kg/m²). The authors reported that for all ages the depth of epidural space from skin was significantly greater in obese (BMI > 30 kg/m²) than non-obese patients (BMI < 30 kg/m²) (p-value< 0.01).(65) They also reported a positive correlation between BMI and depth of epidural space, for both males (BMI < 30, mean depth of epidural space 44.43 ± 4.67, (r=0.033), BMI> 30 depth is 51.40 ± 5.96 (r=0.713) and females (BMI < 30 mean epidural depth of 38.77 ± 5.48 mm, (r value 0.476) and BMI> 30 is 52.53 ± 4.52 (r = 0.687). However, this correlation was statistically significant with respect to females only.

In contrast, an earlier retrospective cohort study published in 2005 (n= 101, aged between 14 and 83 years) measured anterior and posterior epidural fat depth as well as posterior subcutaneous fat depth and defined the presence of obesity as BMI > 27.5 kg/m². The authors reported that BMI was correlated with posterior subcutaneous fat (r=0.71, p<0.0001), however, BMI was not correlated with either posterior (r=0.12, p=0.221) or anterior epidural fat (r=0.11, p=0.271). Furthermore, this study reported that the depth from skin to epidural space was neither correlated with height or gender.(66)

In a cross-sectional study (n=63 adult patients with low back radicular pain) analysis, sagittal MRI images were performed to record the thickness of the anterior and posterior epidural fat pad and the posterior subcutaneous fat depth.(67) In addition, age, gender, height, weight and waist circumference (WC) was recorded. This study reported a statistically significant positive correlation between subcutaneous fat depth and the patients weight (r = 0.484, p= 0.00), BMI (r=0.683, p= 0.00), and WC (r=0.507, p= 0.00). They also found that epidural fatty tissue was not correlated with BMI (p= 0.571 for anterior epidural fat and p=0.307 for posterior epidural fat).(67) The authors reported no relationship between WC and epidural fat tissue.

In summary, the conflicting literature in this area underpins the need for further research in an attempt to establish if a true association exists between BMI and the depth from skin to the epidural space, and the potential impact of these variables upon radiation dose exposure and fluoroscopy screening time during TFNB. Minimising
the use of ionising radiation and its potential for associated adverse effects is essential for the ongoing safety of patients and healthcare providers,(8) All radiation exposure poses some degree of risk to those exposed.(9) Furthermore, in the majority of cases, all types of spinal injection provide only short term management of pain. Subsequently this patient group will likely undergo recurrent repeated injections under image guidance adding to their lifetime cumulative radiation profile and risk for development of potential adverse effects associated to ionised radiation exposure.

The key focus of this research is to determine if there is an association between BMI and the depth of tissue from the skin to the epidural space. If this is the case we also aim to determine if this has an impact upon radiation exposure to the patient or procedural fluoroscopic screening time.
2.2 Research Aims and Objectives

2.2.1. Research Question

In adult patients (aged ≥16 years) is there an association between increased BMI and the depth of subcutaneous tissue from the skin to the epidural space? If so, does this impact upon radiation dose exposure and fluoroscopic screening time for patients undergoing TFNB?

2.2.2. Research Aim

The overall aim of this study is to examine the association between patient BMI and the depth of subcutaneous tissue overlying the epidural space.

2.2.3. Research Objectives

The primary objective is;

1. Through a retrospective observational study to identify if there is an association between patient BMI and the depth of tissue overlying the epidural space.

The secondary objectives are:

1. Determine any association between patient BMI and radiation dose exposure.
2. Determine any association between patient BMI and fluoroscopic screening time.
Chapter 3

3.1. Methodology

3.1.1 Study Design

This study is a retrospective cohort study conducted in adherence with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines.(68)

3.1.2. Study setting

The study took place in one Irish private hospital in which approximately 400 TFNB injections are performed on an annual basis. All patients included within the study were ≥ 16 years old at the time of their procedure. All adult patients who underwent a single level unilateral (i.e. a single exiting nerve root on either the right or left side) TFNB over a period of 28 months, from 1st January 2015 – 30th April 2017 were included. All procedures were performed by a single consultant spinal orthopaedic surgeon.

3.1.3. Study variables

Data collection was performed retrospectively. Eligible patients were identified using the Impax radiology system currently used in the institution. This system was installed prior to the commencement date of the study and a search algorithm was used within Impax to identify all patients who underwent intra-operative fluoroscopic screening during the chosen study interval. As intra-operative screening is also employed for open spinal procedures, these patients were removed from the dataset and only those who underwent TFNB injection were included. All patients identified via the Impax radiology system were cross-checked and the exact anatomical level of procedure confirmed via the secure consultant specific booking system which is created at the time of procedure booking by administrative staff. Following identification of all eligible patients, each patient was assigned a patient study identifier number and entered into a secure research database.
Demographic data; gender (Male/Female), date of birth, age (years and months), height (metres; m) and weight (kilograms; kg) was collected for each patient by the primary investigator (AG). This information is routinely collected for every patient who attends the outpatient clinic of the spinal orthopaedic consultant at this institution and is uploaded to a database available locally via a password protected intranet platform. BMI was calculated using the equation BMI (kg/m\(^2\)) = Weight (Kilograms, Kg) / Height (metres\(^2\), m\(^2\)). Using the Centre for Disease Control (CDC) and Prevention definitions, morbid obesity was defined at BMI ≥40 kg/m\(^2\), obese as BMI as ≥30 kg/m\(^2\), overweight as BMI between 25 kg/m\(^2\) inclusive and 30 kg/m\(^2\), and normal BMI as less than 25 kg/m\(^2\).(61)

The load of radiation exposure delivered to each patient during their TFNB was collected; this takes the form of dose area product (centi-gray per centimetre squared; cGy/cm\(^2\)). The fluoroscopic screening time (seconds; s) per procedure was also recorded. This value corresponds to the length of time for which the x-ray tube on the fluoroscopic C-arm is emitting ionised radiation. The C-arm is operated by a trained radiographer under instruction from the operator, in this case, the spinal orthopaedic consultant, and is therefore only activated upon request of the orthopaedic consultant. Radiation exposure (Dose Area Product), and the Fluoroscopic screening time, are recorded under the mandatory hospital protocol and are available via the radiology viewing platform of this institution, known as ‘Impax’. Data for each of these variables was extracted from Impax by the primary investigator.

In order to obtain the depth to epidural space, we utilised pre-procedural axial MRI lumbar spine images which have been performed on each patient prior to undergoing their procedure (TFNB). All measurements were recorded from T1- weighted sagittal images in the midline by a sole independent observer trained in the use of the Impax radiology system. The thickness of the posterior subcutaneous tissue (i.e. depth of tissue overlying epidural space, SE Distance) was measured in millimetres (mm) from the ligamentum flavum to the skin of the back at the level of the superior end-plate of the fifth lumbar vertebrae (L5).
The exposure variable of interest is patient BMI. The primary outcome of interest is the depth of tissue overlying the epidural space. Secondary outcomes of interest include; ionised radiation exposure (Dose area product) and, fluoroscopic screening time.

Table 1 presents a summary of the definitions used for included variables.

Potential confounding variables might include variation of the radiographer operating the C-arm, underlying spinal disease such as spinal stenosis which may impede normal injection and increase difficulty of the procedure. The presence of co-existing spinal pathology was also recorded in the database. This information was collected upon review of the MRI report which is completed by the consultant radiologist reading the MRI images. Co-existing spinal pathology included; spinal stenosis (SS), degenerative intervertebral disc disease (DDD), lumbar disc herniation (LDH), facet joint arthritis and foraminal stenosis. These factors were accounted for in the regression analysis.

### Table 2: Definitions of variables of interest

<table>
<thead>
<tr>
<th>Variable</th>
<th>Data</th>
<th>Units</th>
<th>Abbreviated Units</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI</strong></td>
<td>Body Mass Index</td>
<td>Kilograms/ (Height in metres)$^2$</td>
<td>kg/m$^2$</td>
<td>Consultant Booking Form</td>
</tr>
<tr>
<td><strong>Depth of tissue from skin to epidural space (SE distance)</strong></td>
<td>Distance from skin to epidural space</td>
<td>Millimetres</td>
<td>mm</td>
<td>Impax</td>
</tr>
<tr>
<td><strong>Radiation Dose Exposure</strong></td>
<td>Dose Area Product</td>
<td>Centi-gray per centimetre squared</td>
<td>cGy/cm$^2$</td>
<td>Impax</td>
</tr>
<tr>
<td><strong>Screening Time</strong></td>
<td>Fluoroscopic Screening Time</td>
<td>Seconds</td>
<td>s</td>
<td>Impax</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>Date of Birth</td>
<td>Years</td>
<td>Yr.</td>
<td>Impax</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Male or Female</td>
<td>Male/Female</td>
<td>M/F</td>
<td>Impax</td>
</tr>
</tbody>
</table>
3.1.4. Study Participants

All patients aged ≥ 16 years old who underwent single level unilateral TFNB carried out by the same spinal orthopaedic consultant surgeon in a single institution during the specified time interval from 1st January 2015 to 30th April 2017 were eligible for inclusion. Any individual who underwent multi-level injections or bilateral injections were excluded from the study.

3.1.5. Data Protection and ethical considerations

Ethical approval from the research ethics committee of the institution (Bon Secours Hospital Group) was obtained prior to commencement of data collection. All data was coded by assigning a study identifier to each participant. The key for de-identification of data is held by the primary investigator (AG). Data protection was in adherence to the data protection guidelines as outlined by the relevant Data Protection Acts.

Data was collated on a secure research database. Data processing was undertaken by the principle investigator. Only the principal investigator and those supervising this research had access to the data.

Analysis of the data did not deviate from the proposed objectives and plan of analysis as outlined within the research proposal. Collected data will be securely for a period of seven years following completion of to study to facilitate future verification of the results as required.

3.1.6. Statistical Analysis

Bio-statistical analysis was undertaken using Stata/IC Windows(64bit) software (StataCorp, Texas, USA). Descriptive statistics are presented for patient demographics (age, gender), BMI, presence of spinal comorbidity, side of procedure (left/right) and vertebral level of procedure. Spread of data was assessed for continuous variables using mean, standard deviation (SD) median and interquartile range (IQR). Number (n) and percentage (%) was performed for categorical variables. Spearman’s rank (r) coefficient was utilised to determine correlations for this the nonparametric data set.
Chi-square testing was utilised for categorical data examination and analysis of variance testing employed to evaluate relationships between numerical data.

Linear regression analysis was undertaken using BMI ((kg/m²): (continuous variable)) as the predictor of interest and epidural space depth (SE Distance (mm)-continuous variable) as the outcome of interest controlling for confounding variables (i.e. age, gender, underlying spinal disease such as spinal stenosis which may impede normal injection and increase difficulty of the procedure). Unadjusted coefficients with 95% confidence intervals (CIs) and p values are presented in addition to adjusted coefficients (95% CIs, p value), following adjustment for relevant confounders. In addition, two additional linear regression models were performed examining the association between BMI and secondary outcomes of radiation dose exposure and fluoroscopic screening time, adjusting for relevant confounders.
Chapter 4

4.1. Results

A total of 362 patients met the inclusion criteria. Patients often present to outpatient clinics with hard copy compact disc (CD’s) containing their MRI images. As a result, these images are often not uploaded to the institutions inhouse radiology platform and so they are irretrievable without the original CD. This resulted in some difficulties accessing images from external institutions and therefore resulted in 12.4% (n=45) of missing data with regard to depth to epidural space. The final number of patients included in statistical analysis therefore was n=317.

4.1.1. Study participants demographic characteristics

The mean age of patients was 62 years, (S.D 15.31) with a median age of 64 years, interquartile range (IQR) 53 – 74 years. The mean participant BMI was 26.85 kg/m$^2$, (S.D 4.04) with a median BMI of 26.59kg/m$^2$ (IQR 24.38 – 28.90 kg/m$^2$) and positively skewed indicating that the majority of patients within the study were either overweight (BMI ≥25, <30, n=162, 51.1%), or obese (BMI ≥30, n=58, 18.3%).

Approximately two-thirds of study participants were female, (n=197, 62.1%) and n=120 (37.9%) were male. There was no difference in the n procedure side with an almost 50:50 division between left (n=156, 49.2%) and right sided injections, (n=161, 50.8%) respectively. Of all TFNB injections performed 93%, (n=295) where undertaken at the L4/5 (n=171, 53.9%) or L5/S1 intervertebral levels, (n=124, 39.1 %) respectively.

Mean SE depth for patients was 65.38 mm, ranging from 38-110 mm (S.D 13.58, median 64.0mm, IQR 55-74mm). Mean radiation dose exposure was 28.86 cGy/cm$^2$, S.D 13.58, median 23.38 cGy/cm$^2$, IQR 16.04-36 cGy/cm$^2$. Mean screening time was 5.57 seconds, S.D 3.14, median 5 seconds, IQR 4-7 seconds ranging from 1-28 seconds.

A summary of study participants’ demographics is presented in Table 2.
Table 2: Descriptive statistics for study participants’ (n=317)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>IQR</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr.)</td>
<td>62.58</td>
<td>15.31</td>
<td>64.0</td>
<td>53 – 74</td>
<td>16 – 92</td>
</tr>
<tr>
<td>SE Depth (mm)</td>
<td>65.38</td>
<td>13.58</td>
<td>64.0</td>
<td>55 – 74</td>
<td>38 – 110</td>
</tr>
<tr>
<td>Radiation Dose (cGy/cm²)</td>
<td>28.86</td>
<td>21.47</td>
<td>23.38</td>
<td>16.04 – 36</td>
<td>2.21- 209</td>
</tr>
<tr>
<td>Screening Time (seconds)</td>
<td>5.57</td>
<td>3.14</td>
<td>5</td>
<td>4 – 7</td>
<td>1 – 28</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>&lt;20</th>
<th>≥20, &lt; 25</th>
<th>≥25, &lt; 30</th>
<th>≥30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4 (50.0)</td>
<td>33 (37.08)</td>
<td>59 (36.42)</td>
<td>24 (41.38)</td>
</tr>
<tr>
<td>Female</td>
<td>4 (50.0)</td>
<td>56 (62.92)</td>
<td>103 (63.58)</td>
<td>34 (58.64)</td>
</tr>
<tr>
<td>Total (n)</td>
<td>8</td>
<td>89</td>
<td>162</td>
<td>58</td>
</tr>
<tr>
<td>Procedure Side, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>1 (12.5)</td>
<td>50 (56.18)</td>
<td>86 (53.09)</td>
<td>24 (41.38)</td>
</tr>
<tr>
<td>Left</td>
<td>7 (87.5)</td>
<td>39 (43.82)</td>
<td>76 (46.91)</td>
<td>34 (58.62)</td>
</tr>
<tr>
<td>Total (n)</td>
<td>8</td>
<td>89</td>
<td>162</td>
<td>58</td>
</tr>
<tr>
<td>Procedure Level, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L2/3</td>
<td>0</td>
<td>1 (1.12)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>L3/4</td>
<td>0</td>
<td>8 (8.99)</td>
<td>12 (7.41)</td>
<td>1 (1.72)</td>
</tr>
<tr>
<td>L4/5</td>
<td>3 (37.50)</td>
<td>43 (48.31)</td>
<td>91 (56.17)</td>
<td>34 (58.62)</td>
</tr>
<tr>
<td>L5/S1</td>
<td>5 (62.50)</td>
<td>37 (41.57)</td>
<td>59 (36.42)</td>
<td>23 (39.66)</td>
</tr>
<tr>
<td>Total (n)</td>
<td>8</td>
<td>89</td>
<td>162</td>
<td>58</td>
</tr>
</tbody>
</table>

| Spinal Comorbidity               |        |           |           |     |
| Spinal Stenosis, n (%)           |        |           |           |     |
| Yes                             | 3 (37.50) | 26 (29.21) | 32 (19.75) | 8 (13.79) | 69 (21.77) |
| No                              | 5 (62.50) | 62 (69.66) | 129 (79.63) | 49 (84.48) | 245 (77.29) |
| Degenerative Disc Disease, n (%) |        |           |           |     |
| Yes                             | 4 (50.0) | 48 (53.93) | 110 (67.90) | 38 (65.52) | 200 (63.09) |
| No                              | 4 (50.0) | 40 (44.94) | 51 (31.48) | 20 (34.48) | 115 (36.28) |
### Variable

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>IQR</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar Disc Herniation, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6 (75.0)</td>
<td>76 (85.39)</td>
<td>129 (79.63)</td>
<td>42 (72.41)</td>
<td>253 (79.81)</td>
</tr>
<tr>
<td>No</td>
<td>2 (25.0)</td>
<td>12 (13.48)</td>
<td>32 (19.75)</td>
<td>16 (27.59)</td>
<td></td>
</tr>
<tr>
<td>Facet Joint Arthritis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (12.50)</td>
<td>42 (47.19)</td>
<td>63 (38.89)</td>
<td>16 (27.59)</td>
<td>122 (38.49)</td>
</tr>
<tr>
<td>No</td>
<td>7 (87.5)</td>
<td>46 (51.69)</td>
<td>98 (60.49)</td>
<td>42 (72.41)</td>
<td>193 (60.88)</td>
</tr>
<tr>
<td>Foraminal Stenosis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (25.00)</td>
<td>49 (55.06)</td>
<td>115 (70.99)</td>
<td>49 (84.48)</td>
<td>215 (67.82)</td>
</tr>
<tr>
<td>No</td>
<td>6 (75.00)</td>
<td>39 (43.82)</td>
<td>46 (28.40)</td>
<td>9 (15.52)</td>
<td></td>
</tr>
</tbody>
</table>

IQR = Interquartile Range, SD = Standard Deviation, BMI = Body Mass Index

### 4.1.2. Nonparametric Statistical analysis

The correlation between the predictor of interest (BMI) and outcomes of interest was assessed using the Spearman rank correlation coefficient. Statistically significant positive correlations were identified between BMI and the primary outcome of SE distance (r=0.72, p<0.001), and secondary outcomes of Radiation Dose Exposure (r=0.34, p<0.001) and procedural Fluoroscopic Screening time (r=0.22, p<0.001). A summary of the results is presented in Table 3.

**Table 3: Correlation between study participants’ BMI (kg/m²) and SE depth (mm), Radiation Dose Exposure (cGy/cm²) and Screening time (seconds) (n=317)**

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>r</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE Depth</td>
<td>0.72</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Radiation Dose</td>
<td>0.34</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Screening Time</td>
<td>0.22</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiation Dose (cGy/cm²)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>SE Depth</td>
<td>0.29</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Screening Time</td>
<td>0.69</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
4.1.3. Linear Regression Analysis

i) Primary outcome: Depth of tissue from skin to the epidural space

Unadjusted and adjusted linear regression analysis was performed with BMI as the predictor of interest and the depth of tissue from skin to the epidural space (SE distance) as the primary outcome of interest. Analysis was conducted controlling for confounding factors including age, sex and other spinal comorbidities listed in Table 4. Unadjusted and adjusted coefficients with 95% confidence intervals (CI’s) and respective p-values are presented.

In the unadjusted model increasing BMI was associated with an increased depth of tissue from skin to the epidural space (unadjusted coefficient 2.49 (95% CI (2.24, 2.74), p<0.001). Following adjustment for age, gender and spinal comorbidities this association remained (adjusted coefficient 2.41 (95% CI (2.14, 2.68), p<0.001). (See Table 4)

Table 4: Multivariable linear regression model of the unadjusted and adjusted coefficients (95% C.I.’s, p-value) for the Primary outcome ‘Depth of tissue from skin to the epidural space (mm)’ by exposure to BMI (kg/m$^2$) accounting for patient level confounding variables (n=317).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted Coefficient, (95% CI), p-value</th>
<th>Adjusted Coefficient, (95% CI) p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>2.49 (2.24, 2.74), p&lt;0.001</td>
<td>2.41 (2.14, 2.68), p&lt;0.001</td>
</tr>
<tr>
<td>Age</td>
<td>0.01 (-0.09, 0.11), p=0.87</td>
<td>-0.34 (-0.10, 0.03), p=0.33</td>
</tr>
<tr>
<td>Sex</td>
<td>1.46 (-1.62, 4.55), p=0.35</td>
<td>2.56 (0.42, 4.71), p=0.02</td>
</tr>
<tr>
<td>Spinal Stenosis</td>
<td>-3.34 (-7.03, 0.16), p=0.06</td>
<td>0.02 (-2.54, 2.58), p=0.99</td>
</tr>
<tr>
<td>Facet Joint Arthritis</td>
<td>-0.74 (-3.83, 2.35), p=0.64</td>
<td>0.43 (-1.87, 2.72), p=0.72</td>
</tr>
<tr>
<td>Foraminal Stenosis</td>
<td>7.40 (4.23, 10.52), p&lt;0.001</td>
<td>2.46 (0.17, 4.75), p=0.04</td>
</tr>
<tr>
<td>Degenerative Disc Disease</td>
<td>3.06 (-0.05, 6.17), p=0.05</td>
<td>1.68 (-0.52, 3.87), p=0.14</td>
</tr>
<tr>
<td>Lumbar Disc Herniation</td>
<td>-3.24 (-7.02, 0.53), p=0.09</td>
<td>-1.04 (-3.91, 1.82), p=0.24</td>
</tr>
</tbody>
</table>
ii) Secondary outcome: Radiation Dose Exposure

Unadjusted and adjusted linear regression analysis was performed with BMI as the predictor of interest and Radiation Dose Exposure as a secondary outcome of interest. Analysis was conducted controlling for confounding factors including age, sex and other spinal comorbidities listed in Table 5. Unadjusted and adjusted coefficients with 95% CIs and respective p-values are presented. In the unadjusted model increasing BMI was associated with an increased radiation dose exposure (unadjusted coefficient 1.49 (95% CI (0.92, 2.05), p<0.001). Following adjustment for relevant confounders the association persisted (adjusted coefficient 1.45 (95% CI (0.84, 2.06), p<0.001). (See Table 5)

Table 5: Multivariable linear regression model of the unadjusted and adjusted coefficients (95% CI, p-value) for the secondary outcome ‘Radiation Dose Exposure (cGy/cm2)’ by exposure to BMI (kg/m^2) and patient level confounding variables (n=317)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted Coefficient, (95% CI), p-value</th>
<th>Adjusted Coefficient, (95% CI), p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m^2)</td>
<td>1.49 (0.92, 2.05), p&lt;0.001</td>
<td>1.45 (0.84, 2.06), p&lt;0.001</td>
</tr>
<tr>
<td>Age</td>
<td>0.05 (-0.11, 0.20), p=0.55</td>
<td>0.03 (-0.13, 0.18), p=0.74</td>
</tr>
<tr>
<td>Sex</td>
<td>2.24 (-2.63, 7.12), p=0.37</td>
<td>2.89 (-2.05, 7.82), p=0.25</td>
</tr>
<tr>
<td>Spinal Stenosis</td>
<td>-4.74 (-10.46, 0.99), p=0.11</td>
<td>-2.85 (-8.72, 3.02), p=0.34</td>
</tr>
<tr>
<td>Facet Joint Arthritis</td>
<td>2.22 (-2.67, 7.10), p=0.37</td>
<td>3.78 (-1.50, 9.05), p=0.16</td>
</tr>
<tr>
<td>Foraminal Stenosis</td>
<td>4.58 (-0.51, 9.67), p=0.08</td>
<td>1.17 (-4.09, 6.44), p=0.66</td>
</tr>
<tr>
<td>Degenerative Disc Disease</td>
<td>-0.33 (-5.27, 4.62), p=0.90</td>
<td>-1.53 (-6.58, 3.52), p=0.55</td>
</tr>
<tr>
<td>Lumbar Disc Herniation</td>
<td>-2.80 (-8.78, 3.18), p=0.36</td>
<td>0.29 (-6.29, 6.86), p=0.93</td>
</tr>
</tbody>
</table>
iii) Secondary outcome: Fluoroscopic Screening Time

Unadjusted and adjusted linear regression analysis was performed with BMI as the predictor of interest and Fluoroscopic Screening Time as the outcome of interest. Analysis was conducted controlling for confounding factors as listed in Table 6. Unadjusted and adjusted coefficients with 95% CIs and respective p-values are presented. In the unadjusted model increasing BMI was associated with an increase in fluoroscopic screening times (unadjusted coefficient 0.12 (95% CI (0.04, 0.21), p<0.001). This association persisted following adjustment for confounders (adjusted coefficient 0.11, (95% CI 0.02, 0.20), p=0.02). Female gender was also associated with increased screening time. (See Table 6)

Table 6: Linear regression model with unadjusted and adjusted coefficients (95% C.I.'s, p-value) for the secondary outcome ‘Fluoroscopic Screening Time (seconds)’ by exposure to BMI(kg/m²) and adjustment for patient level confounding variables (n=317).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted Coefficient (95% CI) p-value</th>
<th>Adjusted Coefficient (95% CI), p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>0.12 (0.04, 0.21), p&lt;0.001</td>
<td>0.11 (0.02, 0.20), p=0.02</td>
</tr>
<tr>
<td>Age</td>
<td>-0.01 (-0.03, -0.01), p=0.49</td>
<td>-0.02 (-0.04, 0.00), p=0.11</td>
</tr>
<tr>
<td>Sex</td>
<td>0.93 (0.23, 1.64), p=0.01</td>
<td>1.18 (0.44, 1.91), p&lt;0.001</td>
</tr>
<tr>
<td>Spinal Stenosis</td>
<td>-0.83 (-1.66, 0.01), p=0.05</td>
<td>-0.79 (-1.65, 0.08), p=0.08</td>
</tr>
<tr>
<td>Facet Joint Arthritis</td>
<td>-0.55 (-1.26, 0.17), p=0.13</td>
<td>-0.59 (-1.37, 0.20), p=0.14</td>
</tr>
<tr>
<td>Foraminal Stenosis</td>
<td>0.36 (-0.39, 1.11), p=0.34</td>
<td>-0.06 (-0.83, 0.72), p=0.88</td>
</tr>
<tr>
<td>Degenerative Disc Disease</td>
<td>0.20 (-0.53, 0.92), p=0.56</td>
<td>0.36 (-0.39, 1.10), p=0.35</td>
</tr>
<tr>
<td>Lumbar Disc Herniation</td>
<td>-0.09 (-1.26, 0.17), p=0.13</td>
<td>-0.59 (-1.56, 0.38), p=0.24</td>
</tr>
</tbody>
</table>
Chapter 5

5.1. Discussion

5.1.1. Introduction

As outlined, low back pain (LBP) with radiculopathy is a common diagnosis and remains a difficult pathology to treat consistently and effectively. (21-23, 34, 38) With the advent of minimally invasive interventional radiological procedures offering acceptable therapeutic outcomes and a reduced risk profile over more invasive procedures, there has been a significant increase in demand to utilise this resource as a tool in the management of low back and radicular pain. (3, 4) With the spread in the use of radiologically assisted diagnostic and therapeutic techniques across many specialities, it should also be considered that patients may be more likely to encounter ionised radiation than they would have been in the past. Subsequently, this has sparked an era of increased awareness of radiation safety, the concept of a lifetime cumulative radiation exposure record and identifying potential risk factors of those who may be at risk of exposure to higher levels of ionised radiation and therefore at risk of developing adverse harmful effects of ionised radiation exposure to humans. (17) Obesity has been identified one of these risk factors and the literature has shown that obese patients are more likely to sustain exposure to higher levels of ionised radiation during diagnostic and medical radiological procedures. (14, 16) As the population of individuals who are obese continues to rise we cannot be sure of the potential long-term implications of ionised radiation exposure. BMI is the most widely used method to measure the degree of obesity however it does not reliably indicate the distribution of fat within an individual. (67)

Transforaminal Nerve Block (TFNB) represents one of the radiologically assisted techniques which has grown in popularity among both spine and pain specialists in the management of radicular pain. Furthermore, this conservative treatment modality, is often temporary in nature and may require the need for repeated injections on an ongoing basis and therefore contribute to an individual’s lifetime cumulative ionised radiation exposure.
The primary objective of this research was to identify if patient Body Mass Index (BMI) is associated with the depth of tissue overlying the epidural space (SE distance). Much of the research pertaining to epidural space depth and BMI has recorded intra-procedural needle depth which is liable to significant error. (64, 69, 70) This study identified epidural space depth from corresponding patient MRI images obtained prior to the procedure with a view to improving the accuracy and consistency of recording the SE distance in this study. Secondary outcomes were also generated in order to identify further associations between patient BMI, and other variables of interest including radiation dose exposure, and procedural fluoroscopic screening time during TFNB.

5.1.2. Results Summary

A total of 317 patients were included within the study, of these 62.15% (n=197) were female and 37.85% (n=120) males. There was largely equal division in the numbers of right and left sided procedures conducted, 50.79% (n=161) and 49.21% (n=156) respectively. As expected, most procedures were carried out at the L4/5 and L5/S1 (lumbosacral junction), 93.06% (n=295). The majority of patients were either overweight (BMI ≥25, <30, n=162, 51.1%), or obese (BMI ≥30, n=58, 18.3%).
5.1.3. Primary Outcome; BMI and Distance from Skin to Epidural Space

This observational study has demonstrated an association between patient BMI and the depth of tissue overlying the epidural space (SE distance). For every unit increase in BMI the depth of the space increased by almost 2.5 millimetres.

The association demonstrated in this study between BMI and the depth of tissue overlying the epidural space is in keeping with existing research which has reported comparable results within a similar patient cohort. Ravi et al, 2011, conducted a prospective cohort study in patients undergoing epidural block prior to surgery or as a form of pain relief.(65) Measuring the distance the needle travelled to reach the epidural space and correlating this with patient BMI, they reported that for all ages the depth of epidural space from skin was significantly greater in obese (BMI > 30 kg/m$^2$) than non-obese patients (BMI < 30 kg/m$^2$) ($p< 0.01$). Unlike our research in which SE distance was recorded from MRI images, Ravi et al, measured the distance which the needle was inserted intra-procedurally. Therefore, the distance recorded was clinically determined by the operator as to when they felt they had reached the epidural space. This is likely to contribute considerable inter-observer variability and error into their study.

Similarly, Brummet et al, 2009 in a small prospective observational study including 88 patients found a positive association (regression coefficient, 1.13; $p< 0.001$) between the depth of epidural space and patient BMI.(64) Our research had the benefit of a considerably larger sample size (n=317). A large scale observational study (n=2000) recorded the epidural space depth in obstetric patients at the time of epidural catheter placement during labour.(69) When adjusted for maternal age, gestational age and vertebral interspace of catheter placement, there was a positive correlation between BMI and increase in depth ($p< 0.001$, $r= 0.3646$).

This association between SE distance and BMI bears potentially significant patient impact. Previous research has shown that with increased depth of tissue, that an increased intensity of ionised radiation is required to penetrate this tissue in order to
reach the x-ray detector and create usable images. (15, 16) Subsequently this results in patient exposure to a larger dose of high intensity ionised radiation and potential for development of adverse events, whether short-term deterministic or long-term stochastic. (10, 55)
5.1.4. Secondary Outcome: BMI and Radiation Dose Exposure during TFNB

The results of this study demonstrate that for patients who underwent TFNB with fluoroscopic image guidance, the radiation dose exposure during the procedure was significantly increased with increasing BMI, $r=0.34$, p-value $<0.001$. In a linear regression model with adjustment for relevant confounders including age, sex, spinal stenosis, facet joint arthritis, degenerative disc disease and lumbar disc herniation, we found that increasing BMI was significantly associated with increased radiation dose exposure, (adjusted coefficient =1.45, (95% CI 0.84, 2.06), p<0.001.)

There is a body of existing research which echoes this finding. Cushman et al, demonstrated that increasing BMI resulted in increased radiation exposure during sacroiliac injections ($r=0.55$, p-value $<0.001$), this equated to an increased dose of 0.22 mSv for obese patients compared with patients who have a normal BMI.(63) They also reported reporting a mean radiation dose was 216.4 cGy/cm$^2$, considerably greater that that observed in this study. Of the 317 patients included in this study, the mean radiation dose exposure in terms of dose area product was 28.89 cGy/cm$^2$ (S.D 21.47, Range 2.21- 209 cGy/cm$^2$). This figure is substantially lower than that recorded in similar research.(63, 71) Hanu-Cernat who recorded radiation exposure in patients undergoing fluoroscopically guided spinal injections reported a mean exposure of 1.18 Gy/cm$^2$, the equivalent of 118 cGy/cm$^2$.(71) Conversely, Hwang et al, 2015, who examined lumbosacral TFNB procedures only, reported dose area products of 0.3–5.3 cGy/cm$^2$ which is considerably lower that observed in this present research.(70) These studies have all found a significant positive correlation between BMI and radiation dose exposure. There is significant variation in reported radiation dose exposure levels, with researchers presenting findings in varying units and orders of magnitude. It is possible that this variability is due to the use of different equipment in different centres, varying software used to collect and record such information and the level of training of radiographers and physicians alike.

The Cardiovascular and Interventional Radiology Society of Europe, have established guidelines regarding the safe use of ionised radiation within the healthcare sector.
They stipulate that a radiation safety threshold of 500 Gy/cm$^2$ for fluoroscopically assisted procedures where possible should not be exceeded.\textsuperscript{(72)} To bring this into clinical context based on the mean dose area product observed in this study an individual would have to undergo approximately 1,500 fluoroscopically assisted TFNB procedures in order to reach this threshold. Other studies have shown that the radiation exposure to patients and physicians during spinal procedures is minimal.\textsuperscript{(63, 73, 74)} However, it is also important to consider that healthcare professionals carrying out these procedures will likely perform a large volume of cases throughout their career and therefore the cumulative effect of repeated radiation exposure to these individuals may bare significance in the longer term. It remains vital that the appropriate safety precautions are taken and that personal protective equipment is made available where possible for both patients and physicians.
5.1.5. Secondary Outcome: BMI and Fluoroscopic Screening Time

Fluoroscopic screening time indicates the time for which the x-ray tube is emitting ionised radiation. If multiple images are obtained during a procedure the screening time represents a cumulative time measurement. Although BMI has been shown to have significant impact upon radiation dose exposure, the large series of images which are often generated in fluoroscopic procedures is likely to have a significant impact upon the fluoroscopic screening time; subsequently fluoroscopic screening time is likely to be a determining factor in radiation dose exposure. We found a significant association between increasing BMI and longer fluoroscopic screening time (adjusted coefficient 0.11, (95% CI 0.02, 0.20), p=0.02). Smuck et al, in a study of 202 patients undergoing zygaphyseal joint injection, medial branch nerve block, and/or transforaminal epidural injection concluded, that fluoroscopy time in patients with a BMI ≥ 25 kg/m$^2$ was increased by 30% and the procedure time was increased by 35%.(62)

It is likely that this association is multifactorial in origin. Several studies have indicated that operator experience has a significant impact on fluoroscopy screening times. Zhou et al, in an American study assessing screening time found up to four-fold in screening times in University affiliated hospitals catering for trainees versus private institutions where procedures were undertaken by single operators without trainees.(75) However, variations in screening time have also been observed amongst the same group of experienced operators and indeed Cushman found no difference in screening times between trainees and experienced operators.(63, 71) Our study included only injections performed by a single experienced orthopaedic spinal consultant. This removes operator variability as a potential confounder with respect to our results and indicates that BMI is a significant variable contributing to fluoroscopic screening time, however, it will likely impact upon the generalisability of our findings.

The mean screening time for TFNB injections in this study was 5.57 seconds (S.D 3.14). This is noticeably less than that, which has been reported in previous studies. In a large retrospective review with 2443 TFNB injections the mean fluoroscopy time was 30.5 seconds (SD 17.5), in contrast, the mean fluoroscopy time in a study conducted by
Tiegs-Heiden et al., reported an appreciably longer fluoroscopic screening time of 138 seconds (n=1844, SD 72).\(^{(63, 76)}\) The significant variation among these research groups is likely to be multifactorial in origin. With spinal orthopaedic surgeons, anaesthetists, pain medicine specialists and radiologists all performing this type of procedure, the variation in their training background is likely to carrying significant impact. Furthermore, variable equipment between healthcare facilities and practice protocols would need to be taken into consideration.

Importantly, the results of this study indicate that both fluoroscopic screening time and radiation dose exposure are associated with BMI. However, other factors such as patient positioning, and technical issues such as departmental c-arm protocol settings and beam angulation may also have a role to play in screening time duration and could be examined in future research.
5.1.6. Limitations of Study

The principle limitation of this study is its retrospective nature. Retrospective studies by their nature, may exhibit various types of human error such as documentation flaws, transcription inaccuracies and data exclusion. With the widespread availability of private radiology organisations performing radiological investigations, image quality is varied. As previously discussed, patients may present to outpatient clinics with MRI images on CD, having had their MRI scan performed in an unrelated institution. As a result, these images are often not uploaded to the institutions inhouse radiology platform. This resulted in some difficulties accessing images from external institutions and the generation of missing data with regard to depth to epidural space (n=45, 12.4%).

The study design removed operator variability as all procedures have been performed by the same surgeon. However, this may reduce generalisability of the study findings as radiologically assisted spinal pain procedures are also often performed by radiologists, anaesthetists and pain specialists alike. We must also consider that although each procedure was performed by the same surgeon, multiple different radiographers perform fluoroscopic screening under direction of the surgeon which may result in a significant variability with respect to the ionised radiation exposure dose incurred and the fluoroscopic screening time.

There is future scope for a prospective study which should aim to capture all potentially confounding factors influencing upon patient BMI and adipose tissue distribution such as thyroid disorders, Cushing’s disease and steroid users. Prospective study design should also reduce the level of missing data. Other methods to determine level of obesity and fat distribution such as waist circumference or waist to hip ratio; which have not been considered in this study but could be considered in further research. It would be beneficial to follow a cohort of patients over a period of time to record the incidence of repeat procedures and cumulative radiation dose exposure from TFNB. A multi-centre trial with a number of different experienced operators would improve generalisability of results.
Chapter 6

6.1. Conclusion

This current research supports the hypothesis of the primary outcome that there is a significant association between increasing BMI and increased depth of tissue from the epidural space to the overlying skin. Furthermore, our study has indicated significant associations with respect to the secondary outcomes between increasing BMI, and increased radiation dose exposure and fluoroscopy screening time during transforaminal nerve block injections.

Based on the European guidelines outlining safe thresholds for ionised radiation exposure it is unlikely the level of ionised radiation exposure solely from radiologically assisted spinal pain injections would pose significant risk to either patient or healthcare professional. As the levels of radiation encountered during these procedures fall well within the recommended limits the likelihood of developing adverse side effects from radiation exposure following TFNB would remain small. However, the effects of an individual’s lifetime cumulative exposure to ionised radiation from all medical procedures, remains somewhat unclear. In light of this we recommend that the concept of “as low as reasonably achievable” should be implemented while performing fluoroscopy-guided procedures on all individuals with extra consideration given to overweight and obese patients.

Ongoing clinical governance requires that those involved in radiologically assisted procedures maintain and uphold the highest standard of care achievable ensuring patient and professional safety throughout. This encompasses the need to inform patients if they carry potentially modifiable risk factors that pertain to increased ionised radiation exposure. Ultimately care should be taken to maximise safety for patients and physicians alike.
Bibliography


