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## Title

Should radiation exposure be an issue of concern in children with multiple trauma?

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## Mini-Abstract

Polytrauma patients <16-years old, treated over 10-years were identified. The level of radiation and risk of carcinogenesis was established. Younger patients are exposed to high levels of radiation, increasing risk of carcinogenesis. The injury severity score, age, injury pattern and length of hospital stay are predictive of both risks.

## Structured Abstract

### Objective

Threefold: firstly, establish the level of radiation exposure experienced by the paediatric trauma patients; secondly, model the level of risk of developing fatal carcinogenesis; thirdly, test whether pattern of injury was predictive of the level of exposure.

### Summary Background Data

There are certain conditions that cause children to be exposed to increased radiation, i.e. scoliosis, where level of radiation exposure are known. The extent that children are exposed to radiation in the context of multiple trauma remains unclear.

### Methods

Patients below the age of 16 year old and with an Injury Severity Score (ISS)  $\geq 10$ , treated by a Major Trauma Centre for the period January, 2008 to December 2018 were identified. The following data extracted for the year

following the patient's injury: number, doses, and type of radiological examination.

The sex and age of the patient was taken into account in the calculation of the risk of developing a carcinogenesis.

## Results

The median radiation dose of the 425 patients identified in the 12 months following injury, through both CT and radiographs, was 24.3 mSv. Modelling the predictive value of pattern of injury and other relevant clinical values, ISS was proportionately predictive of cumulative dose received.

## Conclusion

A proportion of younger polytrauma patients were exposed to high levels of radiation that in turn mean an increased risk of carcinogenesis. However, the injury severity score, age, injury pattern and length of hospital stay are predictive of both risks, enabling monitoring and patient advisement of the risks.

## Introduction

The greatest cause of morbidity and mortality in children between 1 to 14 years of age is trauma, with the majority of these patients treated at specialised trauma centres. Radiological investigations, plain radiographs and Computed Tomography (CT) are increasingly used in the assessment of paediatric trauma patients, with paediatric patients often receiving cumulative radiation doses higher than adults. One of the guiding principles used to determine whether a trauma CT is required, is the mechanism of injury. In children mechanism is not as predictive of injury compared to adults. A review of the United States national database found the use of a CT chest, as a screening tool for aortic injury, had a greater chance of future cancer than diagnosing an aortic injury due to radiation exposure (1).

Radiographs utilize high-frequency electromagnetic waves, possessing enough energy to displace electrons, called “ionizing” radiation. It is the displaced electron that causes damage to chromosomes or induces cell death (known as stochastic effects). If the body is unable to address the mutations, this has the potential to cause cancer. Regrettably, the stochastic effects do not occur at a known threshold dose (single or cumulative), although it is known that the greater the exposure, the higher the chance of carcinogenesis. Radiation exposure related to acquisition of radiographs can be described in a number of different units. Throughout this work, effective dose, expressed in millisieverts (mSv) will be used. This dose enables a universal comparison to be made between different types of investigations. It is widely used to predict cancer risk following radiation exposure. In the United States it has been reported that on average a child is exposed to 3 mSv due to background radiation and an additional 3 mSv due to medical imaging per annum (2).

Research into detrimental effects of radiation exposure largely emanates from conflicts, such as Hiroshima and environment disasters such as Chernobyl, Long Island and Fukushima (3). It is well known that children have a higher sensitivity to radiation exposure, partly due to their longer life expectancy and

due to the fact that they also have a greater number of dividing cells compared to adults (4). Furthermore, children are exposed to greater radiation during fixed dosed CT because of their comparatively smaller cross section area versus adults. The principle problem is that the majority of the work on levels of exposure and risk of carcinogenesis, is extrapolated from high levels of radiation exposure, rather than low levels of medical radiation exposure, leading to uncertainty in the risk estimates.

The paediatric radiology community have proactively sought to reduce radiation exposure through education and the production of radiation reducing protocols, acting as a catalyst for safer radiology in the adult community. Interestingly, there are certain conditions that cause children to be exposed to increased radiation through the elective management of their condition, such as in Cystic Fibrosis, Scoliosis and osteogenesis imperfecta (5). Over the last ten years however there has been a global reduction in the levels of radiation experienced by paediatric patients in these elective patients, through a concerted effort from both clinicians and medical physics. The extent that children are exposed to radiation in the context of multiple trauma remains obscure.

### Study Objectives

The objectives of this study were threefold: firstly, establish the level of radiation exposure experienced by the paediatric trauma patients, in a Level I trauma centre over a 10-year period; secondly, using known radiation exposure to model the level of risk of developing fatal carcinogenesis; thirdly, to test whether there was a pattern of injury that was associated with higher levels of radiation exposure and consequential carcinogenesis risk in this cohort of patients.

### **Patients and Methods**

#### ***Data Acquisition***

A data request was made to The Trauma Audit & Research Network (TARN) for patients below the age of 16 year old and with an Injury Severity Score (ISS)  $\geq 10$  (a level of substantial injury) (6, 7), treated by the Leeds Major Trauma Centre (MTC) England, for the period January, 2008 to December 2018. The Leeds MTC, picture, archiving and communication system (PACS) was interrogated for the patients supplied by TARN, where the following data extracted for the year following the patient's injury: number, doses, and type of radiological examination. **Radiological Investigations guidance was published in 2013 by the Royal College of Radiologist, "Paediatric trauma protocols" (8). This was the first imaging based trauma protocol directed specifically at children. Prior to this date adult guidance was used (9) and the general principle of 'as low as reasonably achievable'(8) adopted.**

The records of fluoroscopic radiological investigations used in fracture fixation and other procedures were unreliably recorded in our centre and frequently absent, thus were excluded. This exclusion resulted to an underestimation of the radiation exposure which is impossible to quantify. Patients' that had died within 30 days of index traumatic event were excluded, as were those with isolated injuries with an ISS  $\geq 10$ . All doses of radiation exposure were converted into effective dose (mSv) by an established factor to take into account the differing sensitivity/risk and type of tissue. Shrimpton et al. coefficients were adopted for the CT doses, where the dose length product (DLP) was known (10). For X-Ray examinations and CT investigations where the DLP was not present, accepted values for the identical body tissue were deployed (11). As all the doses of radiation were converted to mSv, which represent the effective dose received by the patient already taking into account the tissue sensitivity, which enables inter-patient comparison and the calculation of carcinogenesis risk (12).

Where there were absent figures, two strategies were adopted. Firstly, to use doses from studies that assessed children and effective dose (mSv) of various radiological and CT investigations (13) ("Literature dose"). Secondly, published radiological doses were used as a broad estimate of doses that

would have been used locally, a recognised technique (14) (“Local dose”). To test the validity of both, the Literature and Local technique of estimated doses, for the examinations in which an actual dose was present (n=3,049), a comparison was made with the predicted dose. The root mean square between the actual dose and the Literature dose (1.168,  $p < 0.01$ ) was a more reliable predictor than the Local dose (1.285,  $p < 0.01$ ).

### ***Modelling of Carcinogenesis risk and Predictive Injury pattern***

The sex and age of the patient was taken into account in the calculation of the risk of developing a carcinogenesis (15). This represents an additional risk as a result of the exposure to radiation for medical investigations, and is separated to patients related risk factors such as, previous cancer diagnosis, smoking and genotype. No patients were followed up as part of this study. The radiation risk models used from medical X-Ray examination, that have been developed by the ICRP (International Commission on Radiological Protection), have been evaluated as a function of the age and gender of the patient (16). Wall et al. (17) further developed these models into lifetime risks of cancer by age and sex for all cancers. This model was applied to the exposure experienced by the patient group.

The ISS is a medical score to assess trauma severity, correlating to mortality and morbidity of the injuries (18). The ISS is based on six body regions (head/neck, face, thorax, abdomen, spine, pelvis limb, other) within the score. The most severely injured three regions, are then given a score between 1 and 6 (1=minor, 2=moderate, 3=serious, 4=severe, 5=critical, 6=maximal (currently untreatable)), these values, up to a maximum value of 5 are each squared and added together to make a score between 1 and 75. The ISS is the sum of squares of the highest Abbreviated Injury Scale (AIS), in each of the three mostly severely injured body regions. The AIS scoring system was issued by the Advancement of Automotive Medicine (19), and injuries scored within the regions of the ISS according to severity.



## **STATISTICAL ANALYSIS**

A generalised additive model (standard non-linear regression model) was developed to use both ISS and AIS regions as predictive variables for the level of radiation exposure and thus the risk of carcinogenesis. To examine the relationship between ISS and radiation dose, dose was regressed upon ISS. To enable a nonlinear relationship, a generalised additive term was added, where splines were used to fit the curve. As well as the ISS, the model was extended to permit the use of AIS for each region as a covariate. The distribution of the radiation dose showed a strong skew to the right. After a log transformation, the log dose conformed more closely to a Gaussian (normal) distribution (10). After fitting a model for log dose, the model residuals were checked graphically, with a histogram, to ascertain if they were consistent with a Gaussian distribution. If this was not the case, then a different transformation would have been considered. To gain an alternative insight into the data, exposure to radiation was modelled using a regression tree.

The results of the scans were then analysed to ascertain where they revealed a life threatening condition, which were defined as follows: Haemorrhage requiring surgery or embolisation; Aortic Dissection; Cardiac Tamponade or Cardiac Contusion; Unstable Cervical Spinal Fracture; Tension pneumothorax or haemothorax; Substantial limb or organ injury or ischemia/Any pathology that impacts upon airway; Epidural or Extradural Haematoma or intracranial haemorrhage; Significant Bowel injury; Substantial Pelvic Injury (AIS >4). This was defined as an injury that if undiscovered could have led to death within 24 hours and the scan changed the management of the patient.

## **Ethics**

The Research and Development Department of our institution concluded that this work could be undertaken as a service evaluation, and thus formal ethical approval was not required.

## Results

During the study period 425 (343 male/82 female) patients met the inclusion criteria. The median ISS of the patient group was 21 (10-75, Interquartile Range ("IQR") 10). The patient group had a median age 8.39 years (0-16, IQR 10) and had received a total of 6,893 radiological investigations. The median per patient of both radiographs and CT examinations was 10.25 (1-63, IQR 10), CT median 4.6 (1-32, IQR 5) and radiograph median 7.3 (1-47, IQR 7.25). Each examination was then assigned the effective dose of ionizing radiation (mSv). The median radiation dose received in the 12 months following injury, through both CT and radiographs, was 24.3 (0.001-145.1, IQR 38.8) mSv. The median exposure due to radiographs was 0.54 (0.001-10.5 IQR 7.2) mSv and 23.768 (1.5-46.8, IQR 10.6) mSv for CT investigations.

The graph in **Figure 2** displays the effect of age on the log dose since the model is additive and based on a log scale (namely the effects are added) and multiplicative on the dose scale. It was observed that the distribution of radiation dose had a very strong skew to the right. Following a log transformation the distribution conformed much more closely, although not perfectly, to a Gaussian (normal) distribution (20). There was a progressive increase in radiation received with age up to 5 years of age and then it was constant over higher ages. The number of examinations in the children below the age of 5 is higher, the under 5 year old received a median 5 (1-23, IQR 5) radiographs/CT's, compared to the older group who received a median 3 (1-9, IQR 3) radiographs/CT. Interestingly, the mean dose in this lower age group was lower (36.3 mSv, 0.009-200.6, IQR 82.7) compared to the 5-16 age group (56.7 mSv, 0.73-198.9, IWR 71.1). There is a proportionate increase in the level of radiation exposure with the patient's ISS score, **Figure 1**, until a

score of below 35. Above an ISS score of 35, there is a dramatic increase in the level of exposure, between 164.3 mSv and 375.9 mSv.

Modelling the predictive value of pattern of injury and other relevant clinical values, ISS was proportionally predictive of cumulative dose received ( $p < 0.001$ ). The decision tree plot shows the modelling results, **Figure 3**, they can be understood, by working down from the top of the figure. The algorithm behind the classification tree improves the predictive estimation at each branch of the tree. At the first branch the estimate is improved by calculating the average dose for children over the age of 3.3 years and for the younger ones. This process continues using the best split based on age and injured region of the body until the box plots are displayed at the foot of the figure. The central horizontal line gives the median log dose for that node. In summary, in children below the age of 3.3 years, pelvic and limb injury was predictive of increased radiation exposure ( $p < 0.05$ ), and had a linear relationship with the AIS. The median length of stay for the patient group was 14 days (1-157, IQR 22), there was a significant relationship between length of stay in the patient group and the level of radiation exposure ( $p < 0.001$ ).

Using the ICRP models, within our patient sample the median risk of developing fatal carcinogenesis was 1:2,469 (1:338-2,150,537, IQR 6012) with the highest risk being 1:338. Of interest, the review of initial scans ( $n=377$ ) results against the criteria defining life-threatening injury demonstrated 78% of the scans showing life threatening conditions.

## **Discussion**

To our knowledge this is first study to evaluate radiation exposure in paediatric trauma patients treated by a level I trauma centre over a ten-year period. The median exposure in the patient group for the year following their injury was 24.3 mSv, with 197 patients above 50 mSv, and 8 patients above 100 mSv. There is evidence that acute exposure at a dose above 5 mSv increases the risk of carcinogenesis, which dramatically increases when in excess of 50 mSv (10). There are only generalised guiding principles for

clinicians in using radiological investigations; to only use when clinically justified (21) and at the lowest level practical (22). Often in a trauma setting they are used in an abundance of caution, not wanting to miss injury in light of the mechanism of injury. In paediatric patients the mechanism may not be critical in the choice of investigation, and in certain injuries, for example thoracic trauma, is not sensitive (23). This group of younger trauma patients is more challenging than adults in using alternative methods to diagnose blunt trauma. Focused abdominal sonography for trauma (FAST) for adults is highly sensitive, specific and negatively predictive for the identification of intraperitoneal free fluid. The accuracy of FAST however differs in paediatrics, having much lower sensitivity even in well-trained hands (24). The problem is compounded by the fact that paediatric patients may be treated at centres, which are not as familiar with these differences or paediatric scoring systems, used to determine whether a trauma CT is appropriate, as developed by the Paediatric Emergency Care Applied Research Network.

Using the radiation exposure within the patient cohort, there was a median risk was 1:2,469 of children with polytrauma (ISS  $\geq 10$ ) of developing a fatal cancer as a result of exposure medical radiation secondary to their injury. This has to be balanced against the risk of not scanning leading to a potential life threatening injury remaining undiagnosed. When the CT scan results were reviewed, 78% of the scans show life threatening conditions as previously defined. This suggests that in the main patient selected to receive the scans this was appropriate. There is no consensus on the level of risk that patients should be warned of, through consent to a medical investigation. One of the critical factors in a clinician deciding whether a risk should be told to a patient is the seriousness of the consequence. Namely, the greater the potential effect of the risk, the more onuses there are on the clinician to warn the patient. Given the potentially fatal consequences, it is the authors' view that this level of risk is sufficient and patients' should be informed of the risk.

It is important that as radiological investigations become ever more available and utilised, with CT scanners now part of emergency rooms resuscitation

areas, that the cumulative doses are monitored. Radiation exposure is mainly a necessary by-product of valued and necessary diagnostic imaging that leads to improved patient care. The consequences of the use of this type of imaging have a long latency period, and there are opportunities to reduce the effect when treating children with significant injuries.

Ultrasound may also be used in the areas where previously a plain radiograph was the main stay of investigation; a systematic review reported ultrasound as sensitive and more cost effective in the diagnosis of forearm fractures in children (25). Noteworthy, when MRI capacity was increased in centres, CT investigation in younger patients fell as it provided alternatives to evaluate paediatric trauma patients (26). Education of clinicians has been effective at reducing the rate of CT scanning in paediatric patients, along with development of protocols to guide when this type of investigation is appropriate (27).

When there is not an alternative to the radiological investigation, steps should be taken to adopt a protocol that reduces the level of radiation exposure. Paediatric protocols have been developed globally to reduce overall exposure, for example, ALARA (as low as reasonably achievable) in Canada(28). Other protocols have been developed for particular diseases; hip dysplasia and scoliosis (2). There has been great success of the “Image Gently” campaign internationally, through the Alliance for Radiation Safety in Paediatric Imaging, which has been credited with achieving progress in radiation protection for children (29).

There is a difficulty in retrospectively analysing clinical decisions, particularly in borderline cases, when the clinician is using many factors in that evaluation, that is not recorded or capable of being reviewed. Thus, any type of such of analysis needs to be treated with caution. However, in a retrospective adult study at a Level 1 trauma centre, of the clinical decisions making process to expose adults to radiation versus no change in clinical management, showed 34% of injuries were missed and this would have changed their management had they been known at the time (30). Which

would support the proposition that if in doubt imaging should be undertaken. Clinical scoring systems could be used to address this trade off between clinical evaluations with and without exposure to radiation. However, we know that when clinical scoring is used for children's minor head injuries this lead to a dramatic increase in scans, in a UK cohort from 2% to 20% and in Australia from 19% to 46% (31). There is clearly a need for a well-designed prospective study to be undertaken.

Our findings support the practice of recording the cumulative dose of patients in their first year following the index trauma, to facilitate patient's being given the appropriate warning of the risks of developing carcinogenesis. Further, it will enable clinicians treating patients who have received high levels of radiation to consider alternative modalities to manage the patient's injuries. It is assumed that every clinical investigation involving radiation is clinically indicated. There are occasions when the investigation may be undertaken as confirmatory exercise rather than being absolutely required, and thus could be forfeited. Further, there may be circumstances when given the high cumulative dose of radiation, alternative non-radiation based investigations could be undertaken.

The predictive value of ISS, age, length of hospital stay and AIS body region, 2 and 3, have been demonstrated to be reliable indicators of higher radiation exposure and consequential addition carcinogenesis risk. Paediatric patients below the age of 3.3 and with pelvic or limb injury had significant higher levels of radiation exposure. Thus, at the outset, patients could be identified who were likely to receive higher levels of radiation. The use of age and injury pattern could form the basis of local treatment guideline in considering alternatives, such as ultrasound or MRI to investigate/manage some of the patient's injuries.

### **Limitations of our study**

There are several limitations in this study that must be acknowledged. Firstly, this is a single centre study and does not capture investigations that may have

occurred to patients after repatriation to other hospitals. We estimate this would apply to a very small number of patients since our institution acting as a MTC follows the treatment of patients until discharge. Secondly, the results obtained would only be translatable to other centres if they operated similar protocols to our own centre.

Thirdly, our study looks at the generalised risk of carcinogenesis rather organ specific or actual occurrence. If patients were followed up to establish actual occurrence, the large number of confounding factors would make causation difficult to safely conclude. Fourthly, 44.2% of the values are predicted rather than the actual values of radiation exposure. Although this has the potential to bias the study as the values may either under or over-estimate the radiation exposure, given fluoroscopy was not recorded the figures are likely to be an underestimation. For example, if a patient underwent the insertion of a metal nail into their femur, they would be exposed to roughly 1mSv (32). In polytrauma patients who often undergo many surgical procedures of a similar nature, if not greater magnitude, in the 12 months following injury, this under estimation dose and risk is not insignificant.

When the clinical management was retrospectively reviewed following the scan, it was not possible to accurately establish the role the results of the scan had played in the patient's therapeutic management, which could be addressed with a prospective study.

In conclusion, the paediatric patient group treated at a Level 1 Trauma Centre received substantial additional radiation exposure as a result of radiological investigations, in the year following their accident to expose them to a median risk of 1:2,469, with the highest risk 1:338. This risk of carcinogenesis of the radiological examinations is over and above the general risk, related to both environment and individual patient factors. The ISS, length of hospital stay and the age/injury pattern can be used as predictors to identify patients who are likely to be exposed to increased amounts of radiation and thus alternative investigatory strategies can be adopted.

## Legends

Figure 1. Figure showing a categorisation of the ISS score and the cumulative radiation exposure.

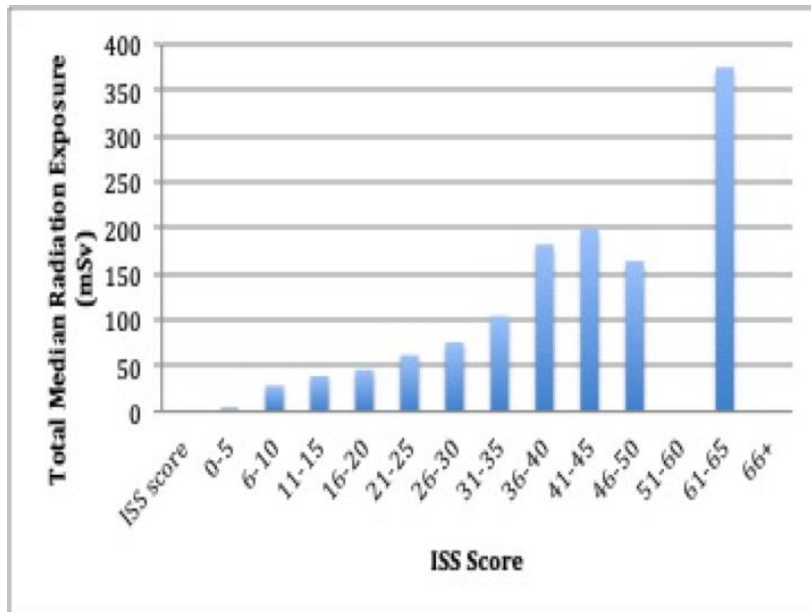


Figure 2. Graph showing the effect of age on the radiation dose received during 12 months following the index accident (The solid line representing the mean and the dotted line representing the Standard Deviation).

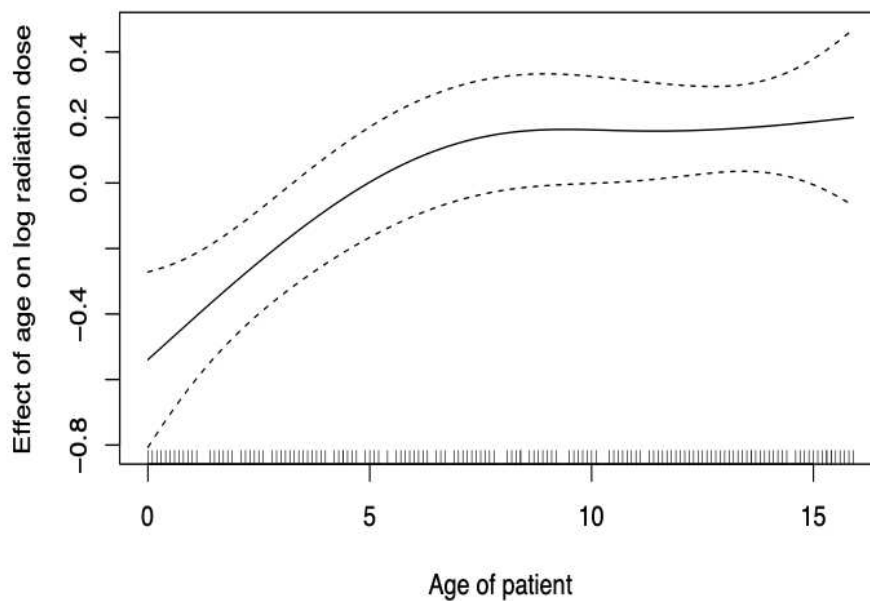
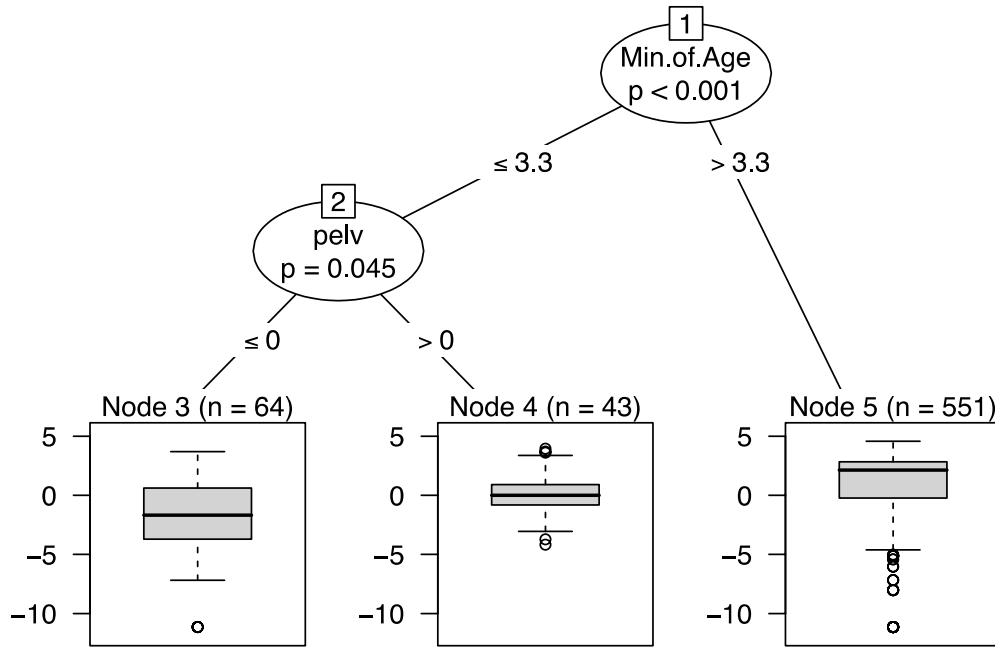




Figure 3. Diagram demonstrating the predictive model using AIS regions and the amount of radiation received during the 12 months following the index accident.



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