Biomechanical characteristics of head injuries from falls in children younger than 48 months

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ABSTRACT

Background A fall-height threshold is important when evaluating the likelihood of structural head injury or abusive head trauma. This study investigates witnessed falls to correlate the fall characteristics with the extent of injury.

Method Case–control study of children aged ≤48 months who attended one hospital following a fall from <3 m (10 ft), comparing cases who sustained a skull fracture or intracranial injury (ICI) with controls, who had minor head injuries. Characteristics included: the mechanism of injury, surface of impact, site of impact to the head and fall height.

Results Forty-seven children had a skull fracture or ICI, while 416 children had minor head injuries. The mean fall height for minor head injuries was significantly lower than that causing skull fracture/ICI ($p<0.001$). No skull fracture/ICI was recorded in children who fell <0.6 m (2 ft), based on the height of the head centre of gravity. Skull fractures/ICI were more likely in children aged ≤12 months ($p<0.001$) from impacts to the temporal/parietal or occipital region ($p<0.001$), impacts onto wood ($p=0.004$) and falls from a carer's arms, particularly when on stairs ($p<0.001$). No significant difference was reported between the mean fall heights of children who had a simple skull fracture (n=17) versus those who had a complex fracture or ICI (n=30).

Conclusions An infant is more likely to sustain a skull fracture/ICI from a fall above a 0.6 m (2 ft) threshold, based on the height of the head centre of gravity, or with a parietal/temporal or occipital impact. These variables should be recorded when evaluating the likelihood of skull fracture/ICI.

What is already known on this topic?

- Head injury is a frequent cause of hospital admission in young children, most commonly due to falls.
- The majority of head injuries presenting to hospital are minor.
- The factors that influence the severity of head injury in domestic falls are poorly understood.

What this study adds?

- Among children younger than or equal to 48 months who had sustained a fall, skull fracture/intracranial injury (ICI) was *significantly* associated with:
  - a fall height >0.6 m, based on the head centre of gravity
  - age ≤12 months
  - impacts to the parietal/temporal or occipital area
  - fall from a carer's arms
  - impacts onto wood.
- It is suggested that clinical decision making will be informed by determining: the age of the child, the distance fallen by the head (fall height), the point of impact of the head and the impacted surface.

INTRODUCTION

Whether as a result of accident or physical abuse, head injury causes significant mortality and morbidity in infants and young children.[1] An estimated 280/100 000 children are admitted to hospital every year with head injury in the UK.[2] Parslow *et al*[1] concluded that falling was the most common cause of intracranial injury (ICI) in young children admitted to intensive care units (38%), followed by motor vehicle collisions (30%) and assaults (16%).[1]

Head-injury severity and its relationship to fall height are extensively debated within the scientific literature, particularly for a 'low-height fall' and the precise definition of a short or low-height fall varies across studies.[3–13] Injury outcomes range from simple skull fracture[6 8 14] to ICI,[3 4 9–12] while some studies describe the potential for fatality.[5 15–17] The variation in fall-height thresholds may arise because fall heights are estimated from an incident description, without consideration of the child's actual posture prior to falling. Thus, the height through which the head has fallen is not considered. The literature suggests that head-injury severity is influenced by a child's age, the impact surface and the anatomical site of head impact[3 18–20] together with the fall height. The proposed fall-height thresholds for ICI vary from 0.91 m (3 ft) to 1.52 m (5 ft).[3–13]

This study investigates the correlation between head-injury severity and fall dynamics in children younger than or equal to 48 months who presented to hospital. The analysis focused on falls from <3 m (10 ft) within a domestic environment, to represent low falls and to contrast with the 'high falls' (ie, >10 ft) defined elsewhere.[7 11 13] This study aimed to evaluate the association between the fall characteristics and skull fracture or ICI, identified from neuroimaging. Such an analysis has the potential to identify fall-height thresholds that would cause skull fracture/ICI, to inform clinical practice and to assist in refining the accuracy of biomechanical simulations.

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METHOD

This case–control study compared the characteristics of domestic falls causing skull fracture/ICI in children younger than or equal to 48 months, with a control group of children who sustained a minor head injury.

Cases were defined as children with structural cranial or intracranial damage, as per the Public Health Observatory England's definition.[21] These children had cranial CT that identified a skull fracture or ICI that included brain or extra-axial injury. While head injuries in children are a common cause for hospital attendance, only 6%–15%[2] of all such admissions have a skull fracture/ICI. An extended period of data collection was required to ascertain consecutive cases of children who had sustained these injuries from a fall that was witnessed by a person able to describe the injurious event, and where this was accepted as a plausible explanation by the assessing clinician. A member of the research team identified these cases from the University Hospital of Wales Radiology or Paediatric Intensive Care Unit databases (1 January 2002–10 October 2012).

Controls were ascertained prospectively and consecutively from children assessed at the emergency department (ED) in the same hospital between May and October 2011. These children had sustained a *minor* head injury from a fall, witnessed by a person able to describe the injurious event and where this was accepted as a plausible explanation by the assessing clinician. A child was classified with a *minor* head injury when: an infant had a Glasgow Coma Score (GCS) of 15, or an older child had a GCS ≥14 and no additional factors that would warrant a CT scan (based on the UK National Institute of Health and Care Excellence head-injury guidelines[22]), or a child had a normal head CT scan. Children who had indicators for a head CT scan, according to national guidelines,[22] but did *not* undergo one, were excluded due to the potential for unidentified skull fracture/ICI. Any case in which child abuse was suspected was fully investigated by a multidisciplinary child protection team. Cases were included in the dataset only if abuse was firmly excluded.

A pro forma was developed to ensure consistent data collection (see online supplementary appendix 1). Data were collected, detailing the activity and position of the child immediately before and after a fall, the fall height (defined as the height of the surface from which the child had *fallen*), the impacted surface material and the object from which the child had fallen. The reported site of impact or the anatomical location of the cutaneous bruise or swelling was used to inform the likely impact site. Additional data included the age, gender, neurological symptoms, GCS and results of radiological investigations (skull X-ray, CT, MRI). Parents of control subjects were asked to describe the object from which the child had fallen, including an estimated fall height (EFH) by using a height chart as a visual aid. Cases were given a unique case identifier, strictly anonymised and data entered on to a password-protected database for further analysis.

The causes of the head injuries were categorised according to the Injury Database manual (as adopted by the European Union[23]) and then recategorised as falls from: standing or sitting, a moving object, a raised surface, down stairs, while being carried by a carer or in a child product such as a car seat (additional analysis was performed if the carer was descending stairs). For all cases, the object fallen from and the estimated height were extracted from available case notes and defined as the 'documented fall height' (H_f). The child's position prior to falling enabled calculation of the vertical distance through which the head had travelled. The position of the head centre of gravity (CoG) was estimated based on 50th percentile head measurements,[24] cadaveric CoG head measurements reported by Loyd *et al*[25] and 50th percentile sitting and standing heights.[26] This additional 'body-position measurement' was added to the H_f when the position of the child was clearly documented (standing, sitting, crawling), to account for the height of the head CoG (H_{HCoG}) and was ascertained retrospectively. In cases where the position of the child was not documented, an imputation strategy was used to estimate the lowest and greatest possible fall heights. For the lowest fall heights, the head height was assumed to be equivalent to the H_f, which was integrated into the H_{HCoG} calculation. For the greatest possible fall heights, the child was assumed to be in a standing position; this variable was defined as H_{HCoGM}. Both imputations were combined with cases where the position of the child was known.

Thompson *et al*[3] completed 'at-home investigations' of incidents described at an ED, and found that the *estimated* fall heights given by parents overestimated the *true* fall height. Therefore, based on their findings,[3] an extra variable—EFH—was calculated, to account for inaccurate parent/carer fall-height estimations. A series of biomechanical calculations were made (table 1) to seek correlation with the extent of head injury.

Table 1 Mathematical equations used to calculate variables and analyse the biomechanical data

Characteristic	Acronym	Equation number	Equation
Documented fall height	H_f	N/A	N/A
Estimated fall height	EFH	Equation 1	$EFH = H_f \times 0.718 + 0.11736$
Height of head centre of gravity *(where position of child unknown, fall height assumed to be equal to documented height)*	H_{HCoG}	Equation 2	$H_{HCoG} = H_f + X_{HCoG}$
Height of head centre of gravity *(where position unknown, head height assumed to be fall height plus standing height)*	H_{HCoGM}	Equation 3	$H_{HCoGM} = H_f + X_{HCoG}$
Injury risk probability	P(x)	Equation 4	$P(x) = \frac{1}{1 + e^{-(a+bx)}}$
Estimator of goodness of fit of logistic regression	EB	Equation 5	$EB = \frac{1}{n}\log((\prod_i Y_i)(\prod_j (1 - Y_j)))$

X_{HCoG}—height of head centre of gravity relative to body position. Only added if position of the child is clearly documented.[24–26]
P(x)—probability based on x, e (exponential), a (constant of logistic model), b (constant of logistic model), n (number of accidental cases), Y_i (predictors of injured cases), Y_j (predictors of uninjured cases).
N/A, not applicable.

Data analysis

Population studies,[3 16] where a fall height had been related to head-injury severity, were used to inform a power calculation to test the hypothesis that fall height is significantly different between falls that cause minor head injury and skull fracture/ICI. An initial minimum sample size of 50 cases with skull fracture/ICI was indicated with α set at 0.05 and a power >80%.

Comparison of the mean and minimum H_{HCoG} fall height was performed, considering children with minor head injury and those with a skull fracture/ICI. Analyses were conducted to determine if there was any correlation between the fall height and the likelihood of skull fracture or ICI.

A series of analyses was performed to identify correlations between the biomechanical variables describing the 'accident environment' and the consequent head injury. These analyses were conducted to identify any differences in biomechanical characteristics between those children who sustained a simple fracture versus those who sustained a complex fracture (multiple, depressed, basilar or diastatic fracture), or ICI with or without a fracture.

Injury-risk probability between cases and controls, in terms of H_{HCoG} and H_{HCoGM}, was investigated using a modified maximum likelihood regression model (equation 4, table 1).[27] The 'goodness of fit' of the model (EB) was assessed using the log likelihood (equation 5, table 1).[27] Statistical differences between cases and controls were assessed using the Student's t test or the Mann–Whitney U test for non-parametric data and the χ^2 test for categorical variables. Continuous variables are presented as mean±SD. Logistic regression was used to further evaluate the subgroups of the categorical variables (mechanism of injury, impact surface and site impact). The logistic regression reference category for injury mechanism was a fall from a standing height; for impact surface, it was a fall onto carpet; and for site of impact, it was a forehead impact.

All statistical tests were two-sided and the type 1 error rate was set to 0.05 for statistical significance. SPSS V.20 (IBM, 2010, PASW Statistics) was used for the analysis of the data.

RESULTS

This study compares 47 children who sustained a skull fracture/ICI with 416 controls with minor head injury. Twenty-four children had a simple skull fracture; of which, seven had a coexisting ICI. Nineteen had complex fractures, seven of which had depressed fractures, six multiple fractures, four bilateral fractures and three fractures that crossed a suture line (children had multiple fracture types). Overall, 21 children had ICI, 76.2% (16/21) had an isolated extra-axial haemorrhage and 23.8% (5/21) had more than one extra-axial haemorrhage or intracerebral injury.

Gender did not differ significantly between the two groups (p=0.642); however, *age* was influential (table 2), with a significantly greater proportion of children with a skull fracture/ICI aged ≤12 months (p<0.001). There was a significant difference in the likely *site of impact* between children with minor head injury and those with skull fracture/ICI (p<0.001). Logistic regression showed that parietal/temporal and occipital impacts were significantly associated with a skull fracture and/or ICI compared with forehead impact (table 2).

The *mechanism* most commonly associated with a minor head injury was a fall from a standing or sitting height (table 3). The logistic regression revealed that the likelihood of a skull fracture/ICIs was significantly greater as a result of a fall from a persons arms when being carried, particularly when carried on stairs compared with a fall from standing or sitting height (ie, a fall that occurred when the child was standing or sitting on the floor).

Table 2 Comparison of clinical and demographic characteristics in cases and controls

	Cases: skull fracture or ICI (n=47)/n (%)	Controls: minor head injury (n=416)/n (%)	p Value (χ^2) OR (95% CI)
Gender			p=0.642
Male	30 (63.8)	251 (60.3)	1.2 (0.6–2.2)
Female	17 (36.2)	165 (39.7)	
Age group (months)			p<0.001
Infants (≤12 months)	36 (76.6)	100 (24.0)	10.3 (5.1–21.1)†
Toddlers (13–48 months)	11 (23.4)	316 (76.0)	
Site of soft tissue injury/impact	n=(52)*	n=(444)*	p<0.001
Forehead	5	209 (47.1)	Reference
Parietal or temporal	33 (63.5)	22 (5.0)	62.7 (22.2–177)†
Occipital	12 (23.1)	41 (9.2)	12.2 (4.1–36.6)†
Vertex	0 (0)	7 (1.6)	2.5 (0.1–50.3)
Face	0 (0)	110 (24.8)	0.2 (0–3.1)
No visible injuries recorded	2	55 (12.4)	1.5 (0.4–8.0)

*Total number of cases differs due to some cases having more than one site of impact.
†Denotes significance.
ICI, intracranial injury; n, number of cases.

The impact surface was significantly different between those with a minor head injury and those with a skull fracture and/or ICI (p<0.001). The logistic regression showed that only an impact onto wood significantly increased the likelihood of skull fracture/ICIs, compared with a carpet impact. Of interest, a greater proportion of minor head injuries were the result of impacts onto concrete than for those causing skull fracture or ICI (37.9% vs 17.1%). However, these minor head injuries were mainly from impact to the forehead (57.5% (46/80)) as a consequence of a fall from standing height (41.2% (33/80)) and in children aged >12 months (81.3% (65/80)). The skull fracture/ICI cases for impacts onto concrete were to the parietal/temporal area (n=4/7, 57.1%) as a result of a fall from a carer's arms (n=3/7, 42.9%) and in children aged ≤12 months (n=5/7, 71.4%).

A fall height was documented for 133 falls (108 minor, 25 with skull fracture/ICI; table 3). Of these falls, 70.7% (94/133) were from a raised surface (mean H_f=0.66±0.29 m) and 17.3% (23/133), while being carried (mean H_f=0.92±0.49 m). The imputation was applied for 11 cases and 39 controls where the position of the child's head was not recorded. Children with a minor head injury fell from a mean height=0.62±0.31 m; a statistically lower height (p<0.001) than those with a skull fracture/ICI (1.09±0.36 m). The mean H_{HCoG} for those children with a skull fracture/ICI was 1.14±0.37 m, which was significantly greater (p<0.001) than minor-head-injury cases (mean H_{HCoG}=0.89±0.43 m; table 3). Using H_{HCoG}, no skull fracture/ICI cases were sustained from a height of <0.6 m (2 ft), as can be seen in figure 1.

The logistic regression curve shows the *probability* of sustaining a skull fracture/ICI based on H_{HCoG} and H_{HCoGM} for the range of heights reported for children with skull fracture/ICI

Table 3 Biomechanical characteristics influencing the severity of head injury in children aged ≤48 months experiencing a fall

Characteristic	Cases: skull fracture ±ICI/n (%)	Controls: minor head injury/n (%)	p Value (χ^2) OR (95% CI)
Mechanism of injury	(n=47)	(n=416)	p<0.001
Fall from standing or sitting height	2	199 (47.8)	Reference
Fall from moving object	0	18	2.1 (0.1–46.6)
Fall from raised surface	15 (31.9)	136 (32.7)	11 (2.5–48.8)*
Fall while being carried	14 (29.8)	19 (4.6)	73.3 (15.5–347)*
Fall down stairs or steps	3	42 (10.1)	7 (1.1–43.8)*
Fall while being carried on stairs	13 (27.2)	2	646.7 (84.2–4967.4)*
Surface impacted	(n=41)	(n=211)	p<0.001
Carpet	14 (34.1)	72 (37.1)	Reference
Laminate	6 (14.6)	43 (20.4)	0.7 (0.3–2.0)
Wood	7 (17.1)	6 (2.8)	6.0 (1.7–20.6)*
Concrete	7 (17.1)	80 (37.9)	0.45 (0.2–1.2)
Tile	5 (12.2)	9 (4.3)	2.8 (0.8–9.8)
Lino/vinyl/PVC	2 (5%)	1 (0.5%)	10.3 (0.9–121.3)
Biomechanical variable	(n=25) Mean (SD)	(n=108) Mean (SD)	
H_f, m	1.09 (0.36)	0.62 (0.31)	p<0.001
H_{HCoG}, m	1.14 (0.37)	0.89 (0.41)	p<0.001
H_{HCoGM}, m	1.47 (0.47)	1.15 (0.39)	p=0.001
EFH, m	0.90 (0.26)	0.56 (0.22)	p<0.001

*Denotes significance.
EFH, estimated fall height; H_f, documented fall height; H_{HCoG}, height of head centre of gravity *(where position of child unknown, fall height assumed to be equal to documented height)*; H_{HCoGM}, height of head centre of gravity (*where position unknown, head height assumed to be fall height plus standing height*); n, number of cases; PVC, polyvinyl chloride.

(figure 2). The *probability* of sustaining a skull fracture/ICI is estimated as 50% when H_{HCoG}=1.54 m (5 ft) (95% CI 1.41 to 1.69 m) (figure 2) and negligible when H_{HCoG}=0.6 m (2 ft). Based on H_{HCoGM}, the 50% probability increased to a height of 1.77 m (5 ft 10 inches) (95% CI 1.64 to 1.93 m).

No significant difference was identified in the age, site of impact, surface impacted or mechanism of injury among the 17 children who sustained a simple fracture only versus the 30 who sustained complex fracture or an ICI with or without a fracture (p>0.149). The mean H_{HCoG} for children with a simple skull fracture was 1.12 m while those with a complex fracture, or ICI with or without a fracture, equated to 1.16 m. This is not a significant difference (p=0.77).

DISCUSSION

This study demonstrates that the likelihood of a child aged 48 months or younger sustaining a skull fracture or ICI was increased in children aged 12 months or younger by an impact to the temporal/parietal or occipital region or when the H_{HCoG} exceeded 0.6 m (2 ft). These findings define a fall-height-injury threshold for the head of 0.6 m (2 ft), above which, the likelihood of skull fracture or ICI increases.

Previous studies have attempted to define fall-height thresholds for serious head injury in children.[4–7,11 15 16] In this study, no skull fracture/ICI occurred from an H_{HCoG} <0.6 m (2 ft), which is proposed as a potential threshold for the risk of sustaining a skull fracture/ICI. This threshold corresponds with existing experimental infant cadaver drop test data, from which, it can be inferred that a skull-fracture threshold exists between 0.3 m (1 ft)[28] and 0.82 m (2 ft 8 inches).[29 30] No skull fractures/ICI were reported from 0.3 m (1 ft) in this dataset.[28] While 42% of infant cadavers exhibited a skull fracture from a 0.82 m fall,[29 30] it is noteworthy that 0.82 m exceeds the 0.6 m (2 ft) threshold for skull fracture/ICI proposed in this study. Thomas

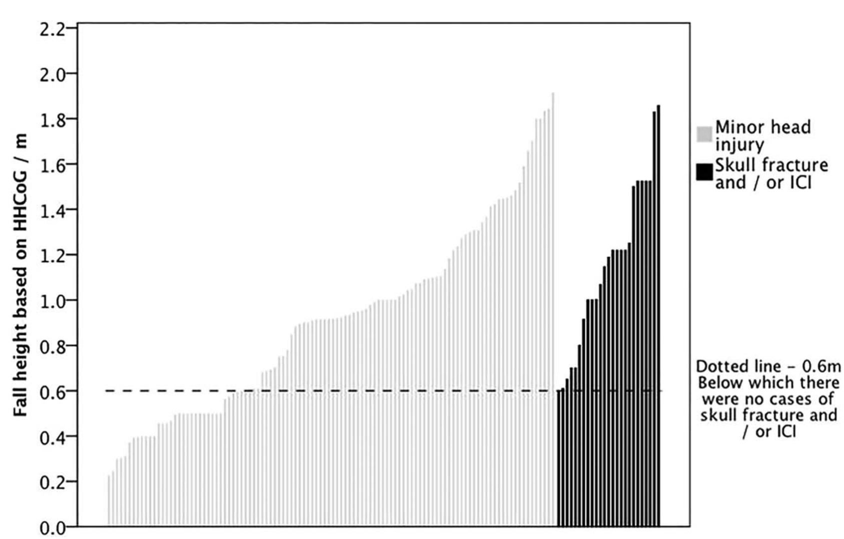

Figure 1 Height of head centre of gravity (H_{HCoG}) for minor head injury, skull fracture or ICI (intracranial injury) resulting from falls in children ≤48 months of age.

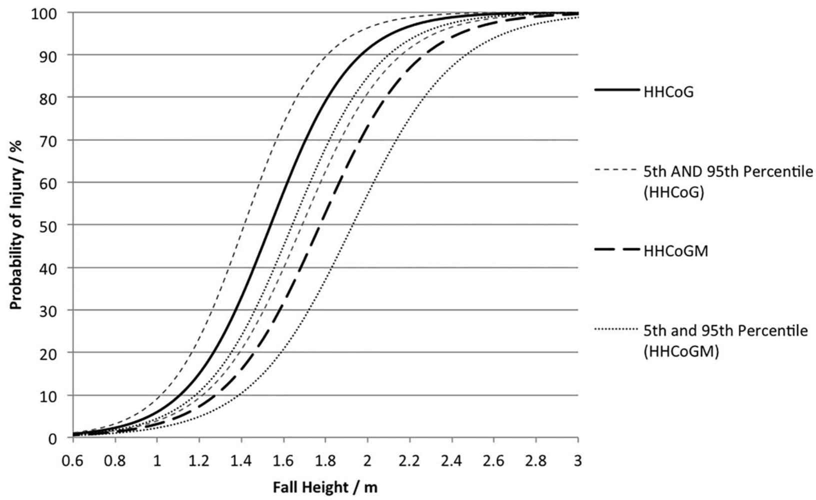

Figure 2 Logistic regression curve illustrating the probability of sustaining a skull fracture or ICI (intracranial injury) based on the height of head centre of gravity (H_{HCoG}) for the range of heights reported, including an imputation for maximum possible height of the head for cases where the position of the child was unknown (H_{HCoGM}).

et al[31] identified significant differences in the fall height of ≤2 years olds sustaining a skull fracture/ICI (compared with control cases), with 0.5 m reported as the lowest fall height for a skull fracture/ICI and a mean height equalling 1.32 m (95% CI 1.03 to 1.6 m). The authors did not, however, describe the fall-height calculations or consider the child's position, which may explain the differences in the results.

Published studies have also identified thresholds to define 'short' or 'low-height' falls based on the height of the surface fallen from[11 23 32] or the head height,[4] including: 0.91 m (3 ft),[11 12 14] 1 m (3 ft 3in),[9] 1.22 m (4 ft)[4–6 10] or 1.52 m (5 ft).[7] This variation may be due to an inconsistent interpretation of what constitutes a low fall (eg, a fall from a sofa or bed has been classified as <0.91 m (3 ft) to <1.22 m (4 ft)[4 6 9 11–14]). This variation and the pragmatic thresholds chosen within the studies limit a direct comparison of data. These studies all recorded simple skull fractures from falls below their defined 'low' fall-height thresholds. However, the actual fall heights were not documented, and it was unclear as to the exact height at which injury occurred. Leventhal *et al*[33] documented skull fractures from falls <0.61 m (2 ft), although the fall-height definition lacked clarity.

Almost one-third (29.8%) of those children sustaining a skull fracture/ICI in this study fell from a carer's arms at a mean height of 0.92 m (3 ft). While this figure is consistent with previous literature,[11] there was a range of EFHs associated with such fall scenarios (from >0.9 m (3 ft) to >1.2 m (4 ft)[4 11 33]). This type of fall may constitute a complex fall that involves translational and rotational accelerations on the head, which may affect injury severity.

Temporal, parietal and occipital impacts were significantly associated with skull fracture/ICI. While published studies confirm that the most common accidental fractures are parietal,[33] the site of impact has not previously been systematically recorded. Additionally, the most common epidural haemorrhage has been recorded in the temporal or temporal/parietal area.[34]

In this study, a skull fracture/ICI from a fall was more likely in infants (≤12 months of age). This is consistent with previous studies[11 20 33] where an age-related susceptibility of children sustaining serious head injury from a low-height fall has been documented. Ibrahim *et al*[11] reported that an *infant* was more likely to be hospitalised than a toddler, have a soft tissue injury and a skull fracture from a fall of <0.91 m (3 ft).[11]

Impact surface significantly affected head-injury severity, which is consistent with anthropomorphic test device studies.[18 35–38] A greater proportion of minor head injuries was the result of impacts onto concrete. This counterintuitive result may be due to a complex interplay of factors, such as the child's age, height fallen, impacting surface and the anatomical site of impact. Indeed, the majority of falls onto concrete were frontal impacts, falls from standing and were older children; all features associated with minor head injuries, and would, thus, go some way to support this theory. The relatively high propensity of concrete surfaces being related to minor head injuries may also be due to parental anxiety, with an increased likelihood to seek clinical reassurance when a child falls onto concrete.

This study was limited by the relatively small number of children with a skull fracture/ICI identified on CT scan as a result of falls, with only 47 presenting to a regional paediatric unit serving a population of approximately 465 000 over a 10-year period. This resulted in fewer numbers than predicted by the power calculation. While this did not preclude statistically significant results from a univariate analysis, a multivariate analysis of the relevant contribution of each of these features would require a much larger dataset of young infants in particular. Data were limited by the quality of recording in case notes[33] or the failure of the clinician to record the fall height in the cases, meaning comparisons such as the position of the child prior to the fall could not be assessed in all cases. Where data were missing, the lowest and highest possible H_{HCoG} were calculated to provide a logistic regression curve range. The resulting probability calculations give estimates that could be applied in clinical practice to guide decisions about the likelihood of skull fracture or ICI based on the EFH of the head, for example, the *probability of* sustaining a skull fracture/ICI is estimated as 50% when H_{HCoG}=1.54 m (5 ft) (95% CI 1.41 to 1.69 m). The heights used in this study were those reported by carers, which is a methodology consistent with previous literature. Cases of minor head injury were those seen at the ED, and represented children whose parents were sufficiently concerned to attend hospital, and will likely not reflect all minor head traumas that this population sustain.

This study highlights some key variables that influence the likelihood of a skull fracture and/or ICI in young children. These variables should be recorded when evaluating head injuries. Clinicians should pay particular attention to recording: the anatomical site of impact, the nature of the surface impacted, the height of any item from which the child fell and the position of the child prior to the fall. An estimation of the distance between the vertex of the head could be made for the child using prototype chart for the 50th percentile child (see online supplementary appendix 2) in conjunction with the child's height from standard height and sitting charts, thus, enabling estimation of H_{HCoG}. The logistic regression curve (figure 2) has the potential to give the likelihood of skull fracture or ICI for an estimated H_{HCoG}.

CONCLUSION

In falls among children younger than or equal to 48 months, skull fracture/ICI was *significantly* associated with:

- a fall height where the head centre of gravity was >0.6 m
- age ≤12 months
- impacts to the parietal/temporal or occipital area
- fall from a carer's arms
- falls onto wood.

Thus, when children present with a head injury, the child's age, area of skull impacted, the height of the head prior to falling and the surface landed on must be recorded together with the child's position prior to the fall. These variables ultimately have the potential to inform clinical decision making when assessing young children with a head injury and, in the longer-term, assist with the development of biomechanical thresholds and models.

Contributors JH conceptualised and designed the study, designed the data collection instruments, collected and analysed the data, drafted the initial manuscript and revised and approved the final manuscript as submitted. SM conceptualised and designed the study, coordinated and supervised data collection, critically reviewed the manuscript and approved the final manuscript as submitted. MJ conceptualised and designed the study, reviewed and revised the manuscript, critically reviewed the manuscript and approved the final manuscript as submitted. PT conceptualised and designed the study, reviewed and revised the manuscript and approved the final manuscript as submitted. AK conceptualised and designed the study, coordinated and supervised data collection, critically reviewed and edited the manuscript and approved the final manuscript as submitted.

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Patient consent Obtained.

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Data sharing statement Data from this study is stored on a database, and is available on request.

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