RAPID

Fast pain relief for hip fracture: A study with paramedics

Jenna Bulger[1], Alan Brown[2], Bridie Evans[1], Greg Fegan[1], Simon Ford[3], Katy Guy[3], Sian Jones[2], Leigh Keen[4], Ashra Khanom[1], Ian Pallister[3], Nigel Rees[4], Ian Russell[1], Anne Seagrove[1] and Helen Snooks[1]

1 Swansea University, 2 Patient representatives, 3 Abertawe Bro Morgannwg University Health Board, 4 Welsh Ambulance Services NHS Trust

j.k.bulger@swansea.ac.uk

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Background

Hip fracture is an extremely painful injury for which patients are usually given opiates for pain relief in prehospital care, if anything; the literature suggests that the pain relief is unsatisfactory. Opiates have several side effects which the elderly cohort at particular risk of hip fracture are susceptible to. These side effects affect patients' general health and recovery. Fascia Iliaca Compartment Block (FICB) is a procedure which provides local anaesthetic to the hip area, and is routinely undertaken by clinicians in the emergency department for patients with hip fracture, but it has not been fully evaluated for use by paramedics at the scene of 999 calls.

Aim

Our aim was to to assess the feasibility of undertaking a fully powered, multi-centre randomised trial to test the clinical and cost-effectiveness of paramedics providing FICB for patients who have fractured a hip at the scene of their injury.

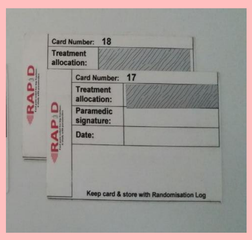
Methods

Paramedic training

Considering available resources and methods used in previous trials in this field (Dochez et al 2014, McRae et al 2015), our training package incorporated: E-learning; group face-to-face sessions led by a consultant anaesthetist; and attending the local hospital in pairs, where they are observed administering FICB by an anaesthetist, with the observing paramedic providing critique to the performing paramedic

Randomisation

Paramedics randomly allocated patients to trial arms using custom made scratchcards



Consent

A paramedic research support officer approached patients within ten days of their injury to discuss consent to follow up in the trial

Data collection and follow up

We collected the following routinely available outcomes from ambulance and hospital records: mortality, pain scores, medications administered by paramedics, on-scene time, time to surgery, and length of hospital stay. We sent patients who had provided consent to take part in the trial follow up questionnaires which included a quality of care monitor; SF-12; and the Rivermead Mobility Index at one and six months. We tested mortality and health related quality of life (using SF-12) as primary outcomes.

Analysis

We assessed our results against the following progression criteria:

1. Ability to recruit ten paramedics to the trial
2. Paramedic recognition of hip fractures has a sensitivity of 75% or more and a positive predictive value of 85%
3. At least 50% of intervention participants receive the intervention
4. At least 60% of recruited participants consent to follow up
5. Follow up data for primary outcomes can be collected for 70% or more of patients
6. Mean patient satisfaction in intervention group is at least 80% of patient satisfaction in the control group
7. Clinicians are in equipoise about safety and effectiveness of paramedic-administered FICB
8. Balance of Serious Adverse Events between groups

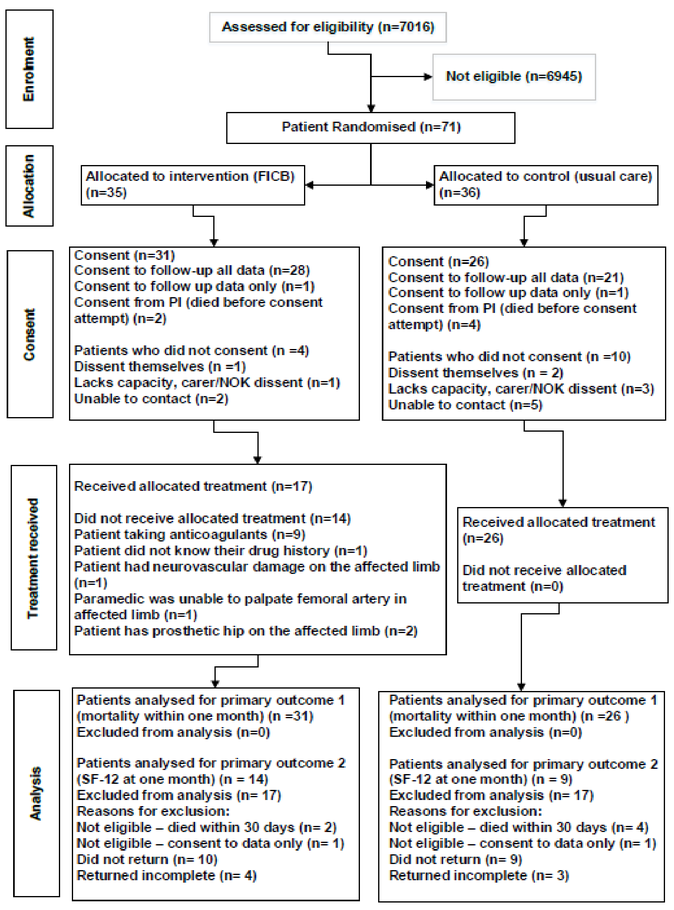
Results

Nineteen paramedics completed their training and randomly allocated 71 patients to the trial (35 intervention vs 36 control). Fifty-seven (80%) patients consented to follow up (31 intervention vs 26 control), with 17 patients in the intervention group receiving FICB (55%) – there were 14 patients with contraindications (the use of anticoagulants being the most common, n=9).

The participants' baseline characteristics were similar between trial arms. Paramedics were able to recognise hip fractures with acceptable accuracy – a sensitivity over 75% and positive predictive value over 85%. We recorded a routinely collected mortality status for all patients, but capturing our patient reported primary outcome (health related quality of life using SF-12) was less successful – approximately 60% of one month questionnaires and 70% of six month questionnaires were returned.

Patient satisfaction with the care they received from paramedics in the intervention arm was 97% of that in the control arm. The only outcome which was statistically significantly different between trial arms was the administration of morphine – patients in the control arm were twice as likely to receive morphine as those in the intervention arm (80% vs 40%). There was approximately a nine day difference in length of stay between trial arms, with those in the intervention arm having shorter admissions on average, though this was not statistically significant. Paramedics spent around five minutes longer with patients in the intervention group, though again, this was not a statistically significant difference.

Three patients in the intervention arm and four in the control arm experienced SAEs. The only SAE assessed as being related to the intervention was local anaesthetic toxicity, which was successfully treated with the antidote, Intralipid, on scene.



	Experimental	Usual Care
N	31	26
Mean age in years, range	81.5, 63.6 – 101.4	82.2, 68.3 – 91.8
Female, n (%)	25 (80.6%)	20 (76.9%)
Time of paramedic attendance		
06:00 - 17:59 n (%)	18 (58.1%)	15 (57.7%)
18:00-05:59 n (%)	13 (41.9%)	11 (42.3%)

	Hip or femoral fracture on X-Ray	No hip or femoral fracture on X-Ray	Total
Recruited	49	8	57
Not recruited	15		
Total	64		
Sensitivity (49/64) 76.6%; PPV (49/57) 86%			

	Experimental	Usual Care
Patients with SAEs	3	4
Details	Local anaesthetic toxicity (n=1) Sepsis and bowel obstruction (n=1) Died within 7 days of injury (n=1) (Community acquired pneumonia)	Blood transfusion (n=1) Dialysis and ITU admission due to rhabdomyolysis (n=1) Died within 7 days of injury (n=2) (Heart failure, pulmonary oedema)

	Experimental	Usual Care	Difference (95% CI)
Mortality, n	18	13	
Died within six months % (n)	5.56% (1)	30.77% (4)	-25.21 (-52.44 to 2.02)
SF-12 - One month, n	14	9	
Physical Health mean (SD)	30.14 (7.14)	36.29 (10.19)	-6.15 (-13.64 to 1.35)
Mental Health mean (SD)	40.59 (12.87)	34.43 (15.13)	6.16 (-6.08 to 18.40)
SF-12 - Six months, n	4	2	
Physical Health mean (SD)	34.15 (10.04)	42.64 (14.91)	-8.49 (-36.02 to 19.05)
Mental Health mean (SD)	44.31 (18.40)	57.80 (4.55)	-13.48 (-52.19 to 25.22)
Satisfaction with care, n	20	13	
Mean (SD)	3.37 (0.42)	3.47 (0.51)	-1.00 (-0.43 to 0.23)
Rivermead Mobility Index - One month, n	18	12	
Mean (SD)	5.22 (3.23)	6.67 (3.28)	-1.44 (-3.93 to 1.04)
Rivermead Mobility Index – Six months, n	7	4	
Mean (SD)	8.29 (3.25)	9.75 (2.50)	-1.46 (-5.75 to 2.82)
Mean difference in pain score, n	23	14	
Mean (SD)	3.74 (2.71)	4.14 (2.74)	-0.40 (-2.28 to 1.47)
Medications administered by the study paramedic, n	31	26	
Entonox % (n)	3.23% (1)	3.85% (1)	-0.62 (-10.28 to 9.04)
Paracetamol % (n)	51.61% (16)	80.77% (21)	-29.16 (-52.37 to 5.94)
Morphine % (n)	41.94% (13)	80.77% (21)	-38.83 (-61.88 to -15.79)
Ondansetron % (n)	35.48% (11)	23.08% (6)	12.41 (-10.96 to 35.77)
Time study paramedic spent with patient (from attendance at scene to arrival at ED), n	31	26	
Mean in minutes (SD)	79.77 (28.25)	74.81 (22.58)	4.97 (-8.80 to 18.73)
Time from arrival at ED to anaesthetic room, n	25	17	
Mean in minutes (SD)	2069.84 (1693.58)	2044.71 (1319.27)	25.13 (-962.65 to 1012.92)
Length of hospital stay, n	29	21	
Mean in days (SD)	17.69 (15.18)	26.81 (24.81)	-9.12 (-20.51 to 2.27)

Conclusion

RAPID met all of its pre-specified progression criteria. An application for funding for a multi-centre, fully-powered trial will therefore be submitted to the National Institute of Health Research Health Technology Assessment Programme. This will test the safety, clinical and cost effectiveness of paramedic administered FICB in prehospital care.

This project was funded by Health and Care Research Wales, through their Research for Patient and Public Benefit funding call (1003). The views and opinions expressed are those of the authors and do not necessarily reflect those of Health and Care Research Wales or the National Health Service.