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## *Executive summary*

# A randomised controlled trial of prehospital intravenous fluid replacement therapy in serious trauma

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# Executive summary

## Introduction

The initiation of intravenous fluid replacement in injured patients at the accident scene is becoming a routine procedure. It has been assumed that early volume replacement in a bleeding patient will result in the patient arriving at hospital in a better haemodynamic state than if no fluids are given. However, some non-randomised studies of trauma patients and one quasi-randomised study of patients with severe bleeding injuries have begun to cast doubt on this assumption.

In the UK most on-scene fluid therapy is given by ambulance-service paramedics acting in accordance with their protocols. We therefore conducted a pragmatic study to compare the effects of two different fluid protocols, one usually with fluid administration and one usually without, used by paramedics.

## Methods

With approval from 16 local research ethics committees, paramedics in two ambulance services were randomly allocated to one of two treatment protocols for the prehospital use of intravenous fluids in adult trauma patients.

- Protocol A: intravenous fluids were adminis-tered at the incident scene to all adult trauma patients who under current procedures the paramedic would consider starting on intravenous fluids.
- Protocol B: fluids were withheld until arrival at hospital, unless the time to hospital was likely to be over 1 hour.

Paramedics who had been qualified for at least 1 year were randomised to an initial treatment protocol using a simple random-number generator. Approximately half way through the trial the paramedics were crossed over to the alternative protocol.

Trauma patients aged 16 years or over who died or stayed in hospital for three or more nights and who were attended by a paramedic crew randomised to a treatment protocol were included in the study. Patients with burns, poisoning, asphyxiation, minor uncomplicated skin or skeletal injuries, isolated fractured neck of femur, or who were pregnant were excluded.

Death, complications, general health status (measured using the Short Form with 36 items (SF-36) questionnaire), processes of care and costs were measured up to 6 months post-incident.

## Data collection

Characteristics of the incidents, the patients and their injuries, and the crews attending were taken from: ambulance-service dispatch records and patient report forms; hospital accident and emergency (A&E), inpatient and administrative records; and from coroners' records. Death was assessed from hospital and coroners' records at 6 months post-incident, and all survivors identified within 7 months of their accident ($n = 878$) were sent a follow-up questionnaire, which included the SF-36 health status questionnaire, and asked about use of healthcare services.

## Results

In total 1309 patients were entered in the study: 699 (53.4%) were treated by paramedics operating protocol A and 610 (46.6%) were treated by paramedics operating protocol B.

The randomisation worked well and there were no significant differences between treatment groups in incident characteristics, ambulance performance times, or patient or injury characteristics, apart from slightly more moderate or severe head injuries in the protocol A group (25.3% versus 20.3%).

Protocol compliance was poor, with only 31% of protocol A patients receiving prehospital fluids and only 80% of protocol B patients not given fluids. The estimated odds ratio for being given prehospital fluids when treated by protocol A compared to protocol B was 2.09 (95% confidence interval (CI), 1.53 to 2.81).

### Mortality

There were 73 deaths within 6 months in the 699 patients in the protocol A group (10.4%), and 60/610 (9.8%) in the protocol B group. Thus the crude odds ratio for deaths when managed by protocol A was 1.07 (95% CI, 0.73 to 1.54).

Excluding 26 patients whose cause of death may not have been trauma related, the odds ratio was 1.04 (95% CI, 0.69 to 1.55). Excluding 17 patients who may have been dead on arrival of the ambulance at the scene the odds ratio was 1.04 (95% CI, 0.70 to 1.53).

Adjustment for age, injury severity and whether the patient was unconscious at the scene did not significantly alter these odds ratios.

### Complications

A total of 106 patients were identified from hospital notes as having at least one of eight major complications (adult respiratory distress syndrome, sepsis, acute renal failure, coagulopathy, wound infection, pneumonia, fat embolism or pulmonary embolism). The proportions with recorded complications were similar in the two groups: 60/699 (8.5%) in the protocol A group versus 46/610 (7.5%) in the protocol B group.

### Health status

A total of 878 questionnaires were sent to patients, and 559 (64%) usable replies were received. The response rate was similar in the two groups (62.9% versus 64.6%). In all eight dimensions of the SF-36 health status measure patients who had been managed by paramedics operating protocol A reported better average health than did patients in the protocol B group. However, none of the differences were at a level considered clinically important and only for one of the eight dimensions was the difference statistically significant.

### Composite outcomes

No significant differences in outcome were found between the two protocol groups in terms of patients who either died or had serious complications, nor for patients who either died or had known poor health.

### Subgroups

Subgroups of patients were defined on eight characteristics (ambulance service area, whether a doctor was on scene, paramedic–patient contact time, injury severity, whether taken to theatre for emergency surgery, type of injuries, type of area, and whether the patient was treated before or after protocol cross-over). There was no evidence of any difference in mortality rates or composite outcomes between any subgroups, or between protocols within any subgroup.

### Time to A&E department

The analysis suggests that patients given fluids spent 12–13 minutes longer at the accident scene than did patients not given fluids. However, because only one-quarter of patients were given fluids, and the specific protocol used made little difference to this, average on-scene times were largely unaffected by protocols.

## Costs

In the prehospital and immediate-care phase (including A&E treatment), the mean costs of the protocol A and protocol B groups were £419 and £416, respectively. This small difference reflects two small and offsetting effects of protocol B: reduced on-scene time ($p = 0.08$) and increased use of blood in the A&E department ($p = 0.03$). There were no other statistically significant differences in costs, with the mean total costs being £2706 and £2678 in the protocol A and protocol B groups, respectively ($p = 0.52$).

## Conclusions

This study does not support the idea that protocols recommending fluid administration do harm in blunt trauma patients. Previous studies have shown that, even though the initiation of intravenous fluids by paramedics seems to be associated with an increased risk of death, this may not be remediable by altering fluids protocols. It is possible that either giving fluids early does no harm, or that only one-quarter of patients are given fluids, and thus the specific protocol used makes little difference to this proportion. Ambulance services should therefore concentrate on avoiding unnecessary delays and speeding up transfer to definitive care in hospital rather than concentrate on their fluids protocols.

### Recommendations for future research

- The relationship between the time taken by paramedics on scene and outcome in blunt trauma may be the critical issue, and this needs investigation.
- One way of avoiding on-scene delay is to start fluid infusion in the ambulance en route to hospital, but further research into the advantages and difficulties of this approach is needed.
- Any future research in the UK into the benefits in blunt trauma patients should compare strict no-fluids protocols (as would be operated by technicians) rather than discretionary protocols. Ways of separating out the effect of fluid infusion and on-scene time delays should be sought.
- The fluids issue remains unresolved. It is not just a problem for prehospital care but also for care prior to definitive surgery. Is the giving of intravenous fluids appropriate in A&E departments? Do the same arguments about the time taken to reach theatre or pretheatre resuscitation apply, and if so can a trial to prevent fluid resuscitation in blunt trauma patients prior to arrival in theatre be organised?

## Publication

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# NHS R&D HTA Programme

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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