Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma (Review)

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[Intervention Review]

Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

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ABSTRACT

Background

Ultrasonography is regarded as the tool of choice for early diagnostic investigations in patients with suspected blunt abdominal trauma. Although its sensitivity is too low for definite exclusion of abdominal organ injury, proponents of ultrasound argue that ultrasound-based clinical pathways enhance the speed of primary trauma assessment, reduce the number of computed tomography scans and cut costs.

Objectives

To assess the efficiency and effectiveness of trauma algorithms that include ultrasound examinations in patients with suspected blunt abdominal trauma.

Search methods

We searched the Cochrane Injuries Group's Specialised Register, CENTRAL, MEDLINE, EMBASE, CINAHL, publishers' databases, controlled trials registers and the Internet. Bibliographies of identified articles and conference abstracts were searched for further elligible studies. Trial authors were contacted for further information and individual patient data.The searches were last updated in January 2008.

Selection criteria

Studies: randomised controlled trials (RCTs) and quasi-randomised trials (qRCTs). Participants: patients with blunt torso, abdominal or multiple trauma undergoing diagnostic investigations for abdominal organ injury. *Interventions*: diagnostic algorithms comprising emergency ultrasonography (US). *Controls*: diagnostic algorithms without US ultrasound examinations (for example, primary computed tomography [CT] or diagnostic peritoneal lavage [DPL]). *Outcome measures*: mortality, use of CT and DPL, cost-effectiveness, laparotomy and negative laparotomy rates, delayed diagnoses, and quality of life.

Data collection and analysis

Two authors independently selected trials for inclusion, assessed methodological quality and extracted data. Where possible, data were pooled and relative risks (RRs), risk differences (RDs) and weighted mean differences, each with 95% confidence intervals (CIs), were calculated by fixed- or random-effects modelling, as appropriate.

Main results

We identified four studies meeting our inclusion criteria. Overall, trials were of moderate methodological quality. Few trial authors responded to our written inquiries seeking to resolve controversial issues and to obtain individual patient data. We pooled mortality data from three trials involving 1254 patients; relative risk in favour of the US arm was 1.00 (95% CI 0.50 to 2.00). US-based pathways significantly reduced the number of CT scans (random-effects RD -0.52, 95% CI -0.83 to -0.21), but the meaning of this result is unclear. Given the low sensitivity of ultrasound, the reduction in CT scans may either translate to a number needed to treat or number needed to harm of two.

Authors' conclusions

There is currently insufficient evidence from RCTs to justify promotion of ultrasound-based clinical pathways in diagnosing patients with suspected blunt abdominal trauma.

PLAIN LANGUAGE SUMMARY

No evidence in favour of using ultrasound to aid diagnosis of patients with a 'blunt' injury to the abdomen

Many people admitted to hospital after an injury have 'blunt' (that is, not penetrating) damage to the abdomen. Doctors treating these patients need to know whether the organs within the abdomen have been injured. Ultrasound scans are believed to help diagnose the patient's condition. In this review, the authors looked for studies that compared death rates in patients with an abdominal injury where ultrasound was used to aid diagnosis with death rates where no ultrasound was used. They also looked for evidence that ultrasound use could reduce the need to carry out other more complex and more expensive diagnostic tests. However, very few trials have been done and the authors conclude there is insufficient evidence to justify the use of ultrasound as part of the diagnosis of patients with abdominal injury.

BACKGROUND

Description of the condition

The exact prevalence of blunt abdominal injury among trauma admissions is unclear. Data from the German Polytrauma Registry suggest a prevalence of 20% (Bardenheuer 2000). However, the prevalence reported in the international literature ranges from 6% to 65% (Stengel 2003). In Australia, according to the South Western Sydney Regional Trauma Registry Report 1995 to 1999, mortality attributable to abdominal trauma can be reliably estimated at 10% (Sydney report 2003).

The detection of closed abdominal injury remains a challenge for the trauma team, especially when there is multiple trauma. Both false-positive and false-negative findings bear the risk of severe complications. The clinical problem is the poor reliability of the physical signs and symptoms that indicate the presence of visceral lesions (Jones 1983; Prall 1994) and subsequent abdominal distension, especially in intubated or comatose patients. In one autopsy study (Hodgson 2000a) 43% of abdominal injuries were missed during primary screening in an emergency department.

Description of the intervention

Among the diagnostic tools available, diagnostic peritoneal lavage (DPL) has remained the standard initial diagnostic investigation for more than 20 years. Although regarded as a safe technique with high sensitivity (Amoroso 1999; Hodgson 2000b), it has a significant false-positive rate (EAST 2003). This exposes the patient to the risk of an unnecessary laparotomy. In a retrospective analysis the incidence of short-term complications caused by neg-

ative laparotomy was 43% (mainly pneumonia) in patients with associated extra-abdominal injuries, and 20% in patients with no associated extra-abdominal injuries (Morrison 1996).

Helical computed tomography (CT) is widely considered as the diagnostic imaging standard in the trauma setting (Jhirad 1998; Linsenmaier 2002; Livingston 1998). Even though, in specialised trauma centres, it is now possible to schedule patients rapidly for abdominal or whole-body CT scanning (Rademacher 2001; Wintermark 2002), one might argue that haemodynamically critical patients should not undergo a diagnostic procedure that takes, on average, 30 minutes. New-generation, multi-slice CT machines only partly solve this problem; the reduction in examination time is somewhat offset by the increased time required for data processing and multiplanar reconstruction. For children, routine CT might lead to considerable radiation exposure (Ruchholtz 2002). Moreover, CT might be neither an available nor an affordable tool for routine trauma investigation in low-volume centres, rural areas, or developing countries.

In 1968, Holm set the framework for using ultrasonography in the trauma setting (Holm 1968). Ultrasonography is a quick, non-invasive, repeatable and nevertheless, inexpensive tool that has emerged as a key component of diagnostic algorithms and clinical pathways (Baka 2002; Boulanger 2000). At the trauma bay ultrasonography is mainly used in terms of focused assessment of sonography for trauma (FAST) to detect the presence of free fluid as an indicator of organ injury (Scalea 1999). However, the prevalence of organ injury without accompanying free fluid ranges from 5% to 37% (Yoshii 1998).

In a systematic review and meta-analysis of the scientific literature (Stengel 2001) we have previously demonstrated that ultrasound has an excellent specificity but rather low sensitivity (below 90%) regardless of the chosen endpoint (that is, free fluid or organ injury). This means that a positive sonogram proves the presence of intraperitoneal injury, whereas a negative sonogram fails to confidently exclude traumatic organ lesions. A recent cohort study has reported a surprisingly low 42% sensitivity for ultrasound (Miller 2003). A major criticism of this study was that findings considered false-negative encompassed a broad range of minor and possibly trivial lesions that were unlikely to harm patients.

Outcome assessment following severe trauma is now a subject of active research. Basically, two dimensions of outcome can be defined: quantity and quality of life. A major goal of in-hospital care of the abdominally injured is to reduce both early mortality (due to intra-abdominal bleeding) and late mortality. The latter is today usually the result of inflammatory complications such as systemic inflammatory response, multi-organ failure, adult respiratory distress syndrome (ARDS) or nosocomial infections. A key part of improving outcomes is reducing the rate of missed injuries. Interventions should be effective (in terms of diagnostic precision) and efficient (in terms of invasiveness, potential harms, time consumption and resource use).

Every effort should be made to reduce morbidity by avoiding non-therapeutic laparotomy, unnecessary invasive procedures (that is, DPL) and procedures that expose patients to the potential risks with, for example, intravenous contrast agents and radiation exposure (Scheck 1998). This is of considerable importance in women of childbearing age, in whom it is difficult to exclude pregnancy in an unconscious patient.

Regarding quality of life (QoL), little experience has been gained with validated instruments in the setting of abdominal trauma. One such instrument which has, however, been used in some studies is the Hanover Score for Polytrauma Outcome (HASPOC). This is a two-part instrument that comprises elements of the Glasgow Coma Outcome Scale (GOS), the Short Form 12 (SF-12) assessment tool, the Musculo-Functional Assessment (MFA), the Merle d' Aubigné Score, the Tegner Activity Score and a modified Frankel Score (Stalp 2002). Another recently developed scoring system is the Polytrauma Outcome (POLO) chart, which contains parts of the Short Form 36 (SF-36) and the EUROQOL questionnaire (Pirente 2002).

Why it is important to do this review

The ideal and most widely applicable diagnostic approach for primary trauma assessment is still an issue of debate. Thus, evidence is needed as to the effectiveness of the strategy of using ultrasound in diagnostic investigations of patients with suspected blunt abdominal injury.

OBJECTIVES

To study whether diagnostic algorithms using ultrasonography at the emergency department reduce the mortality and morbidity of patients with suspected blunt abdominal trauma and improve functional and health-related outcomes.

The following hypotheses were tested:

- the use of ultrasonography in trauma algorithms is associated with reduced mortality compared with algorithms that do not involve a sonographic examination;
- algorithms that include emergency ultrasonography reduce the incidence of missed injuries;
- some patient subgroups (that is, children, hypotensive trauma victims) derive greater benefit from ultrasound diagnosis than others;
- patients who are scheduled to algorithms involving emergency ultrasonography recover with favourable measures of quality of life;
- ultrasonography reduces the rate of non-therapeutic laparotomies;

- ultrasound decreases the frequency of invasive procedures, such as diagnostic peritoneal lavage or modalities that are associated with exposure to radiation or potentially allergenic contrast agents (that is, computed tomography);
- ultrasound-based clinical pathways are cost-effective.

METHODS

Criteria for considering studies for this review

Types of studies

We considered randomised and quasi-randomised controlled trials that compared trauma algorithms with ultrasonography, alone or in combination with other established diagnostic tests (that is, computed tomography [CT], diagnostic peritoneal lavage [DPL], clinical monitoring), to algorithms without the use of ultrasound. Trials were included irrespective of blinding, number of patients randomised, and language of the article.

Types of participants

Haemodynamically stable or unstable patients with suspected blunt abdominal trauma as a single injury or an injury accompanying multiple trauma. Studies investigating patients with stab wounds and gunshot wounds were excluded.

Types of interventions

Diagnostic algorithms including ultrasonography either to detect free intra-abdominal fluid (focused assessment of sonography for trauma [FAST]) or organ injury, including follow-up ultrasound examinations performed by radiologists, non-radiologist clinicians or ultrasound technicians, alone or in combination with subsequent confirmatory tests.
Any algorithm that uses only other established diagnostic tests (i.e. CT, DPL, clinical monitoring).

Types of outcome measures

Primary outcomes

- overall mortality (as a proportion of patients)

Secondary outcomes

- mortality attributable to abdominal injury (i.e. rupture of solid and hollow organs, vascular injury)
- functional and health-related measures of outcome (i.e. SF-12, SF-36, POLO chart, HASPOC, Activities of Daily Living [ADL])
- rates of missed injuries with and without surgical consequences (as defined by the results of subsequent laparotomy/laparoscopy, autopsy, follow-up examinations during hospital stay or necessity for re-admission following discharge because of false-negative findings)
- non-therapeutic laparotomy rates (i.e. negative laparotomy performed for false-positive findings of index tests, including misclassification of organ injury that, by intra-operative judgement, would have been suitable for conservative treatment)
- short-term (until discharge) and long-term morbidity (i.e. SIRS, ARDS, sepsis, nosocomial pneumonia, wound infection, abdominal compartment syndrome)
- frequency of DPL procedures
- frequency of CT exams
- time spent at the trauma bay (emergency department) until surgery, admission to the intensive care unit or peripheral wards or ambulation
- duration of intensive care unit (ICU) stay (days)
- length of hospital stay (days)

Search methods for identification of studies

There was no language or publication restriction applied to any component of the search strategy.

Electronic searches

The following databases were searched:
- CENTRAL (*The Cochrane Library* issue 1, 2008)
- MEDLINE (1966 to January 2008),
- EMBASE (1980 to January 2008),
- The Cochrane Injuries Group's Specialised Register (January 2008),
- CINAHL (the Cumulative Index to Nursing and Allied Health Literature) (1980 to January 2008),
- Current Controlled Trials (to January 2008)

The detailed search strategies are presented in Appendix 1.

Searching other resources

The following publisher's databases were searched:
- SpringerLink (including the journals Abdominal Imaging, World Journal of Surgery, European Journal of Trauma, Chirurg, Unfallchirurg, Radiologe, Emergency Radiology, European Radiology)

- ThiemeConnect (including the journals Aktuelle Traumatologie, Zentralblatt für Chirurgie, RöFo Fortschritte auf dem Gebiet der Röntgenstrahlen und der bildgebenden Verfahren, Ultraschall in der Medizin)
- Lippincott Williams and Wilkins (including the Journal of Trauma, Annals of Surgery, Critical Care Medicine, Shock, Journal of Computer Assisted Tomography)
- CCMed (a database of German language medical journals)

Web-based resources including:

- The Radiological Society of North America-RSNA (covering the journals Radiology and Radiographics as well as the RSNA Index to Imaging Literature)
- Google

Handsearching

Abstracts presented to the following international scientific societies were handsearched:

- Society for Academic Emergency Medicine (1999 to 2007)
- Deutsche Gesellschaft für Chirurgie (published in Langenbecks Arch Surg Suppl and Dtsch Ges Chir Kongress Bd 1997 to 2007)
- Deutsche Gesellschaft für Unfallchirurgie (published in Hefte zur Unfallheilkunde and Hefte zu der Unfallchirurg 1997 to 2007)
- Deutsche Röntgen-Gesellschaft (published in RöFo 1999 to 2007)
- Deutsche Gesellschaft für Ultraschall in der Medizin (1999 to 2003)
- The American Association for the Surgery of Trauma (1999 to 2006)
- The Eastern Association for the Surgery of Trauma (1999 to 2008)

We scanned reference lists of all relevant articles for further trials.

Author queries

Authors of potentially relevant abstracts were asked to provide full information using a data extraction form. We also asked for individual patient data, where possible. We contacted authors of relevant articles to enquire if they had information on any past, present or future studies.

Data collection and analysis

Selection of studies

Two authors (DS, KB) assessed titles or abstracts of all studies identified by the initial search and excluded clearly non-relevant studies. Full text articles were obtained for potentially relevant studies and any studies with unclear methodology. All these studies were assessed by two authors as to whether they met the inclusion criteria for this review, their method of randomisation or quasi-randomisation, and their adequacy of allocation concealment. Disagreements on inclusion were resolved by discussion and, if necessary, by scrutiny by an independent third author (FP).

Data extraction and management

Two authors independently extracted the results of each included paper on a data extraction sheet. Disagreements were resolved by discussion.

Assessment of risk of bias in included studies

Each included trial was read independently by two authors for the following aspects of internal and external validity.

A. Was the assigned treatment adequately concealed prior to allocation?
2 = method did not allow disclosure of assignment;
1 = small but possible chance of disclosure of assignment or unclear;
0 = quasi-randomised or open list/tables.
B. Were the outcomes of patients/participants who withdrew described and included in the analysis (intention to treat)?
2 = withdrawals well described and accounted for in analysis;
1 = withdrawals described and analysis not possible;
0 = no mention, inadequate mention, or obvious differences and no adjustment.
C. Were the outcome assessors blinded to the results of the index test (i.e. ultrasonography) and/or reference tests and/or patient outcome?
2 = effective action taken to blind assessors;
1 = small or moderate chance of unblinding of assessors;
0 = not mentioned or not possible.
D. Were the treatment and control group comparable at entry?
2 = good comparability of groups, or confounding adjusted for in analysis;
1 = confounding small or mentioned but not adjusted for;
0 = large potential for confounding, or not discussed.
E. Were care programmes, other than the trial options, identical?
2 = care programmes clearly identical;
1 = clear but trivial differences;
0 = not mentioned, or clear and important differences in care programmes.
F. Were the inclusion and exclusion criteria clearly defined?
2 = clearly defined;
1 = inadequately defined;
0 = not defined.
G. Were the interventions clearly defined?

2 = clearly defined interventions are applied with a standardised protocol;
1 = clearly defined interventions are applied but the application protocol is not standardised;
0 = intervention and/or application protocol are poor or not defined.

H. Were the outcome measures used clearly defined (by outcome)?

2 = clearly defined;
1 = inadequately defined;
0 = not defined.

I. Was the surveillance active, and of clinically appropriate duration?

2 = active surveillance and appropriate duration;
1 = active surveillance, but inadequate duration;
0 = surveillance not active or not defined.

Data synthesis

Mean differences and 95% confidence intervals were calculated for continuous variables. For dichotomous outcomes, relative risks (RRs) and risk differences (RDs) with 95% confidence intervals were calculated. We used MetaView statistical software in RevMan 4.2.5 to pool the effect measures within a fixed-effects or random-effects model, where appropriate.

To evaluate the between-study variability we tested for heterogeneity of results. We planned sensitivity and subgroup analyses (children, hypotensive patients, use of ultrasound as a primary versus subsequent work-up modality, follow-up examinations, operator experience). To control for possible publication bias, we aimed to test for funnel plot asymmetry.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

The search delivered 377 citations of studies investigating the use of ultrasound in trauma. Since ultrasound findings prompted different forms of further investigation, care programmes varied between groups. We did not judge this difference a flaw but a desired observation indicating effectiveness (that is, a change in doctor's decisions) and efficiency (a change in health-related outcomes) of ultrasound-based clinical pathways.

Most studies examined the diagnostic accuracy of ultrasonography to detect free intraperitoneal fluid or organ damage. (Readers interested in the problem of efficacy [accuracy] will find a diagnostic meta-analysis including a QUOROM flowchart depicting the study selection procedure in Stengel 2003.) We identified nine studies that compared the effectiveness and efficiency of ultrasound-based clinical pathways to algorithms that did not incorporate ultrasound examinations. Four of these (Branney 1997; Healey 1996; Hesse 1999; McKenney 2001) compared cohorts of patients admitted before and after introducing ultrasound as a screening tool and were excluded from further analysis.

Of the five remaining trials, two used a randomised format (Melniker 2006; Rose 2001). Another randomised trial (Navarrete-Nav. 1996) sought to prove the superiority of early computed tomography over multimodal procedures (including bedside ultrasound) to clear suspected chest and abdominal trauma. As a consequence of a recent letter to the editor responding to an evidence-based emergency medicine note (Vance 2007), this trial was dropped from the current version of the review, because it was not clear how many patients underwent which types of diagnostic interventions in the control arm.

Two other studies enrolled patients in a quasi-randomised fashion. The suitable algorithm was defined by ultrasound availability: ultrasound on weekdays from 8am to 5pm; no ultrasound on weekdays from 5pm to 8am and on weekends (Arrillaga 1999) or the presence of one of the investigators (Boulanger 1999). Since no patient had the opportunity to influence the date of injury, we considered these methods proper allocation at random.

Risk of bias in included studies

In general, details of the study populations were sparse or missing. One of the randomised trials (Rose 2001) met some of our design standards. Patients were assigned by a computer-generated list, although it was not clear whether concealment was maintained (trial author reply to clarify this issue is pending). Sample-size considerations called for 50 patients in each group to detect a 20% difference in CT scan use between groups. A secondary outcome (30-minute difference in time to laparotomy) mandating inclusion of 420 patients was mentioned in the methods section of the original paper. However, no data were provided on this endpoint. A flowchart sketched the study profile according to the CONSORT-recommendations.

The Sonography Outcomes Assessment Program (SOAP)-1 Trial (Melniker 2006) is a randomised clinical trial to assess the effect of point-of-care, limited ultrasonography (PLUS). At the time of the first review, economic data gathered from 115 participants had been published as an abstract (Melniker 2004). Mean hospital charges for the PLUS arm were $13,841 (95% CI US$11,170 to $16,512) and $33,512 (95% CI $10,465 to $56,559). A press release (http://www.diagnosticimaging.com/dinews/2003060301.shtml, June 2003) reported a significantly decreased mortality in the experimental arm (6.3% versus 8.1%), a reduced ICU length of stay (2.1 days versus 3.2 days), and a reduced use of CT. We did not receive a response to our letter to the research team. In the meantime, some of the results have been published in full. Although the trial authors had laudable

and honest goals, the original article is difficult to interpret. Of 525 patients screened, 262 were randomised and only 217 were included in the final analysis, which contradicts the intended intent-to-treat principle. All continuous measures were presented as means, medians, and interquartile ranges, and the lack of standard deviations did not allow for including the study in the pooled analysis. Composite complications including death were abstracted from the medical record, thus addressed in a retrospective fashion. Individual complication rates were neither tabulated nor indicated in the text. We will try to contact the trial authors again to ask for more details.
In contrast, the quasi-RCTs thoroughly described patient selection criteria and interventions, but provided too few demographic data to estimate the degree and direction of bias. No attempts were made to control for effect modification by multivariate analysis. One of these trials (Boulanger 1999) addressed a large number of endpoints (the number of extra tests, laparotomy rates, mortality, accuracy, diagnostic time and costs).

Effects of interventions

Owing to the small sample of studies eligible for this review, we did not explore publication bias.

Results in each comparison category are shown in the MetaView summary analysis.

Mortality

Data were available from three studies (Arrillaga 1999; Boulanger 1999; Melniker 2006). There was no evidence of a difference in mortality; random-effects RR = 1.00 (95% CI 0.50 to 2.00). No data were provided on mortality attributable to abdominal injuries, missed abdominal injuries or adverse events caused by any of the diagnostic tests or negative laparotomy.
(The mortality outcome for Melniker 2006 also included complication rate, however the data were included since events such as hemorrhagic shock, septic shock, and multisystem organ failure are potentially life-threatening).

Use of computed tomography (CT) scans

Data were pooled from all four trials, showing significant heterogeneity (I^2 = 98.4%). Ultrasound-based algorithms reduced ordering of CT scans by 50%; the random-effects RD = -0.52 (95% CI -0.83 to -0.21).

Use of diagnostic peritoneal lavage (DPL)

Two studies (Arrillaga 1999; Boulanger 1999) reported data on the use of DPL; ultrasound-based algorithms reduced the number of DPL procedures by 6% (95% CI -0.11 to -0.02).

Cost-effectiveness analysis

Two studies that aimed to estimate costs exhibit inconclusive results.
In Boulanger 1999 the ultrasound pathway proved superior to the control arm. We did not attempt to pool these results.
In Melniker 2006 mean hospital charges for the PLUS arm were US$10,600 (interquartile range [IQR] US$5,700 to 19,000) and US$16,400 (IQR US$6,700 to 43,600) for non-PLUS patients.

Laparotomy

Data from three studies were combined for this endpoint (Boulanger 1999; Melniker 2006; Rose 2001). There was no evidence of a difference in laparotomy rates with ultrasound-based algorithms (fixed-effects, RD = 0.00, 95% CI -0.04 to 0.04).

Other secondary outcomes

We did not identify any RCTs or quasi-RCTs that explored the impact of ultrasound-based clinical pathways on other health-related outcomes such as quality of life. In a quasi-RCT (Boulanger 1999) ultrasound reduced the mean time from arrival to hospital to completion of the diagnostic algorithm from 151 minutes (95% CI 127 to 174) to 53 minutes (95% CI 48 to 58). In this study subjects undergoing ultrasound had a 60% reduced relative risk of delayed recognition of intra-abdominal trauma (mainly small bowel lacerations). Two non-therapeutic laparotomies were performed in each group.
In Arrillaga 1999, another quasi-RCT, mean length of stay and mean ICU days did not differ between groups. In this study, ultrasound significantly reduced the median disposition time from 80 minutes during weekdays, and 92 minutes during weekends, to 20 minutes in both cases.
In the SOAP-trial (Melniker 2006), the time from ED arrival to OR transfer was significantly shorter in the ultrasound-group (median interval 60 [IQR 41 to 70] versus 157 [IQR 90 to 178] minutes).

DISCUSSION

Following early enthusiasm for the use of emergency ultrasound to disclose abdominal injury after blunt trauma, there is an increasing awareness of its limitations. There is no doubt that a positive sonogram (either for free fluid or organ injury) proves the presence of intraabdominal damage. However, it is debatable whether identifying injured patients is a significant problem for trained emergency department teams. Given its poor overall sensitivity, ultrasound cannot be used to rule out abdominal injury (Emery 2001; Miller 2003).

We have to admit that in the first published version of this review, we had mistakenly shifted the denominators in the study

published by Boulanger 1999. Also, the inclusion of the study Navarrete-Nav. 1996 may have been not suitable because of a primary hypothesis which does not meet the question of interest. However, after correcting for these mistakes, the key message of this review remains not only similar, but may even be more alarming. It is troubling that an intervention regarded as a diagnostic standard has been so poorly evaluated. It is open to debate whether the reduction in CT scans is beneficial, or exposes patients with blunt trauma to a higher risk.

The observed reduction in CT scans might, in part, reflect a false sense of security; physicians are well advised to insist on admission and clinical monitoring, regardless of a negative sonogram. There is some evidence that repeated examinations enhance ultrasound sensitivity (Nunes 2001). Although scientific data are sparse, scheduled follow-up examinations have established themselves in clinical practice because of their feasibility. However, if there is a high pre-test probability of abdominal injuries, contrast-enhanced computed tomography still represents the diagnostic modality of choice.

Ultrasound-based algorithms are often assumed to have merits in shortening the primary trauma assessment, triaging patients more precisely, avoiding unnecessary interventional procedures, and reducing costs. However, such assumptions are hardly supported by the available scientific data. Apart from a significant reduction in the frequency of ordering CT scans, we found no beneficial effect of ultrasound on patient-centred endpoints. Divergent results prevented pooling of data for most endpoints of interest.

Of note, two studies of higher methodological quality (Boulanger 1999; Rose 2001) showed only a marginal reduction in CT frequency. Thus, it is open to debate whether abdominal ultrasound measurably affects the doctor's decision to order definitive diagnostic tests.

The meaning of the slightly increased relative risk of mortality in the ultrasound arm of two quasi-randomised trials (Arrillaga 1999; Boulanger 1999) is not straightforward and susceptible to residual confounding. Patients in this group might have been more severely injured, haemodynamically unstable and considered unsuitable for CT imaging more frequently. Although similar ISS values were noted in both groups, no information was provided on abbreviated injury scales (AIS) for abdominal damage. Thus, imbalances between patient groups cannot be excluded.

AUTHORS' CONCLUSIONS

Implications for practice

The current evidence from randomised trials focusing on patient-centred outcomes, do not provide sufficient evidence to inform policy on the use of ultrasound-based clinical pathways in the initial diagnostic investigation of patients with blunt abdominal trauma. Given the low sensitivity of ultrasound, clinical practice guidelines must be scrutinised for the value of ultrasound examinations within established trauma algorithms. Despite a lack of diagnostic accuracy, the results of this review suggest minor efficiency of ultrasonography in the trauma setting (that is, its impact on clinical decision making, and anticipated patient benefits).

Implications for research

Given the biological plausibility of disclosing organ damage by ultrasound, there is still a need for high-quality randomised or cluster-randomised trials to examine the efficacy of ultrasound-based clinical pathways in diagnosing patients with suspected blunt abdominal injury. Specifically, researchers must respect and report demographic variability and follow-up policies.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Arrillaga 1999

Methods	Quasi-RCT (algorithm used was based on the daytime and weekday availability of ultrasound). Location: Community Hospital, Level-I-Trauma Center, South Carolina, USA. Recruitment period: 9 months. Adequacy of concealment: 0. Intent-to-treat: 0 Blinding: 0 Comparability of treatment groups at entry: 1 Comparability of care programmes: 0 Definition of inclusion and exclusion criteria: 1 Description of interventions: 1 Definition of outcomes: 2 Duration of surveillance: 0 (not defined)
Participants	Inclusion criteria: consecutive patients with suspected blunt abdominal trauma (not specified). 331 enrolled (US 105, no US 226). US group: mean age 38.1 (SD 22.7) years, mean ISS 13.0 (SD 11.6), 62% males. No US group: mean age 33.6 (SD 18.6) years, mean ISS 13.4 (SD 9.7), 69% males
Interventions	a. Clinical examination, focused ultrasound for free fluid, further management depended on sonograms and hemodynamical stability b. Clinical examination, CT in stable and DPL in unstable subjects
Outcomes	1. Number of diagnostic tests (CT, DPL). 2. Mortality. 3. Morbidity (not specified). 4. Length of stay. 5. Diagnostic accuracy. 6. Total costs.
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Boulanger 1999

Methods	Quasi-RCT (algorithm used was determined by date of admission). Location: University Hospital, Kentucky, USA. Recruitment period: October 1995 to August 1997. Adequacy of concealment: 0. Intent-to-treat: 1. Blinding: 0. Comparability of treatment groups at entry: 2. Comparability of care programmes: 0. Definition of inclusion and exclusion criteria: 2. Description of interventions: 2. Definition of outcomes: 2. Duration of surveillance: 1.
Participants	Inclusion criteria: victims of blunt trauma, older than 16 years of age, resuscitated by trauma service, no clinical indication for laparotomy, unreliable or equivocal abdominal examination. 706 enrolled (US 460, no US 246). US group: mean age 38.4 (SD 17.6) years, mean ISS 23.3 (SD 12.8), 73% males. No US group: mean age 40.2 (SD 18.2) years, mean ISS 22.8 (SD 11.3), 73% males
Interventions	a. Clinical examination, focused ultrasound for free fluid, further management depended on sonograms and hemodynamical stability. b. Clinical examination, CT in stable and DPL in unstable participants.
Outcomes	1. Time from arrival to the completion of diagnostic algorithm. 2. Number of diagnostic tests (CT, DPL). 3. Mortality. 4. Laparotomy rates. 5. Diagnostic accuracy and number of significant injuries. 6. Total costs.
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Melniker 2006

Methods	RCT: Location - three level-1 trauma centers, New York Methodist Hospital, Maricopa Hospital, Phoenix, Jackson Memorial Hospital, Miami, USA
Participants	Inclusion criteria: patients presenting with any one of a mechanism of injury (energy reportedly delivered to the torso), symptomatology (complaint of chest, abdominal, or pelvic pain), or physical findings (chest, abdominal, or pelvic tenderness) suspicious of torso trauma Exclusion criteria: Patients or patient proxies who were unable to provide consent and those requiring immediate transfer to the operating suite were excluded

Melniker 2006 (*Continued*)

Interventions	a. Diagnostic interventions that the initial evaluating physician, under ordinary circumstances, would use to evaluate torso trauma patients plus 4-view FAST assessment b. Ordinary diagnostic interventions to evaluate torso trauma
Outcomes	1. Time from ED arrival to direct transfer to operative care in minutes (sample size calculations: 40% reduction, 90% power, alpha 5%). 2. Use of CT of the torso 3. Hospital length of stay in days 4. Composite complications (rate of hemorrhagic shock, septic shock, multisystem organ failure, or death) based on CPT or ICD codes found in the medical record 5. Total charges in 2003 US dollars
Notes	Of 525 patients screened, 81 went directly to OR, 136 lacked consent, 262 were randomized, and 217 were analyzed

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Rose 2001

Methods	RCT. Location: University Hospital, California, USA. Recruitment period: November 1997 to November 1998. Adequacy of concealment: 1. Intent-to-treat: 1. Blinding: 0. Comparability of treatment groups at entry: 2. Comparability of care programmes: 1. Definition of inclusion and exclusion criteria: 2. Description of interventions: 2. Definition of outcomes: 2. Duration of surveillance: 1.
Participants	Inclusion criteria: patients 18 to 75 years old meeting critical trauma triage criteria after blunt injury, defined by the American College of Surgeons Subcommittee of trauma. 212 randomised (US 105, no US 107), 208 analysed (4 dropped because of incomplete data). US group: mean age 40.0 (SD 19.5) years, mean ISS 9.9 (SD 12.4), 61% males. No US group: mean age 39.0 (SD 16.8) years, mean ISS 9.8 (SD 8.8), 63% males
Interventions	a. Standard standard trauma management plus focused ultrasound for free fluid (none, small, moderate, large) with 15 minutes of arrival by experienced doctors. b. Standard trauma management.
Outcomes	1. Difference in abdominal CT scan use (sample size calculations: 20% difference, 80% power, two-tailed alpha 5%). 2. 30-minute difference in time to laparotomy.

Rose 2001 (*Continued*)

Notes	Trial was stopped at 215 participants because US was recognised as standard practice and did not allow for further patient recruitment

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Branney 1997	Comparison of prospectively collected ultrasound data (August 1995 to October 1995) with a historical cohort admitted before instituting ultrasound-based clinical pathways (August 1994 to October 1994)
Healey 1996	Comparison of prospectively collected ultrasound data (May 1994 to August 1995) with a historical cohort admitted before instituting ultrasound-based clinical pathways
Hesse 1999	Comparison of prospectively collected ultrasound data (1990 to 1994) with a historical cohort admitted before instituting ultrasound-based clinical pathways (1986 to 1990)
Ma OJ	Comparison of ultrasound accuracy and the request of CT scans among physicians with minor, moderate and high skills in performing FAST
McKenney 2001	Comparison of prospectively collected ultrasound data (January 1995 to June 1995) with a historical cohort admitted before instituting ultrasound-based clinical pathways (January 1993 to June 1993)
Navarrete-Nav. 1996	Trial intended to prove the superiority of computed tomography over multiple diagnostic interventions including ultrasound

DATA AND ANALYSES

Comparison 1. Mortality

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Relative risk of mortality	3	1254	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.50, 2.00]

Comparison 2. Use of computed tomography (CT)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Difference in CT frequency	4	1462	Risk Difference (M-H, Random, 95% CI)	-0.52 [-0.83, -0.21]

Comparison 3. Use of diagnostic peritoneal lavage (DPL)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Difference in DPL frequency	2	1016	Risk Difference (M-H, Random, 95% CI)	-0.06 [-0.11, -0.02]

Comparison 4. Cost-effectiveness

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Direct costs per patient (US$)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only

Comparison 5. Laparotomy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Laparotomy rate	3	1131	Risk Difference (M-H, Fixed, 95% CI)	Not estimable

Comparison 6. Reduction in diagnostic time

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean reduction in diagnostic time (minutes)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Comparison 7. Delayed diagnoses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Risk of delayed diagnosis	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Comparison 8. Non-therapeutic laparotomy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Risk of non-therapeutic laparotomy	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Comparison 9. Duration of hospital stay

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean length of stay (days)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Comparison 10. Intensive care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean ICU days	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Analysis 1.1. Comparison 1 Mortality, Outcome 1 Relative risk of mortality.

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 1 Mortality

Outcome: 1 Relative risk of mortality

Study or subgroup	Ultrasound n/N	No ultrasound n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Arrillaga 1999	9/105	13/226		26.9 %	1.49 [0.66, 3.38]
Boulanger 1999	59/460	23/246		36.3 %	1.37 [0.87, 2.16]
Melniker 2006	23/111	40/106		36.8 %	0.55 [0.35, 0.85]
Total (95% CI)	**676**	**578**		**100.0 %**	**1.00 [0.50, 2.00]**

Total events: 91 (Ultrasound), 76 (No ultrasound)

Heterogeneity: $Tau^2 = 0.29$; $Chi^2 = 9.69$, df = 2 (P = 0.01); $I^2 = 79\%$

Test for overall effect: Z = 0.00 (P = 1.0)

Analysis 2.1. Comparison 2 Use of computed tomography (CT), Outcome 1 Difference in CT frequency.

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 2 Use of computed tomography (CT)

Outcome: 1 Difference in CT frequency

Study or subgroup	Ultrasound n/N	No ultrasound n/N	Risk Difference M-H,Random,95% CI	Weight	Risk Difference M-H,Random,95% CI
Arrillaga 1999	9/105	223/226		25.4 %	-0.90 [-0.96, -0.85]
Boulanger 1999	111/460	225/246		25.4 %	-0.67 [-0.73, -0.62]
Melniker 2006	53/111	85/106		24.7 %	-0.32 [-0.44, -0.20]
Rose 2001	37/104	54/104		24.5 %	-0.16 [-0.30, -0.03]
Total (95% CI)	**780**	**682**		**100.0 %**	**-0.52 [-0.83, -0.21]**

Total events: 210 (Ultrasound), 587 (No ultrasound)

Heterogeneity: $Tau^2 = 0.10$; $Chi^2 = 190.20$, df = 3 ($P<0.00001$); $I^2 = 98\%$

Test for overall effect: Z = 3.33 (P = 0.00086)

Analysis 3.1. Comparison 3 Use of diagnostic peritoneal lavage (DPL), Outcome 1 Difference in DPL frequency.

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 3 Use of diagnostic peritoneal lavage (DPL)

Outcome: 1 Difference in DPL frequency

Study or subgroup	Ultrasound n/N	No ultrasound n/N	Risk Difference M-H,Random,95% CI	Weight	Risk Difference M-H,Random,95% CI
Arrillaga 1999	3/105	15/226		46.7 %	-0.04 [-0.08, 0.01]
Boulanger 1999	5/460	21/225		53.3 %	-0.08 [-0.12, -0.04]
Total (95% CI)	**565**	**451**		**100.0 %**	**-0.06 [-0.11, -0.02]**

Total events: 8 (Ultrasound), 36 (No ultrasound)

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.22$, df = 1 (P = 0.14); $I^2 = 55\%$

Test for overall effect: Z = 2.71 (P = 0.0068)

Analysis 4.1. Comparison 4 Cost-effectiveness, Outcome 1 Direct costs per patient (US$).

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 4 Cost-effectiveness

Outcome: 1 Direct costs per patient (US$)

Study or subgroup	Ultrasound N	Mean(SD)	No ultrasound N	Mean(SD)	Mean Difference IV,Random,95% CI	Mean Difference IV,Random,95% CI
Boulanger 1999	460	156 (244)	246	540 (126)		-384.00 [-411.30, -356.70]
Subtotal (95% CI)	**0**		**0**			**0.0 [0.0, 0.0]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.0 (P < 0.00001)						

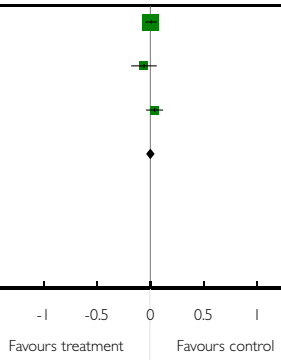
Analysis 5.1. Comparison 5 Laparotomy, Outcome 1 Laparotomy rate.

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 5 Laparotomy

Outcome: 1 Laparotomy rate

Study or subgroup	Ultrasound n/N	No ultrasound n/N	Risk Difference M-H,Fixed,95% CI	Weight	Risk Difference M-H,Fixed,95% CI
Boulanger 1999	35/246	62/460		60.1 %	0.01 [-0.05, 0.06]
Melniker 2006	29/111	34/106		20.3 %	-0.06 [-0.18, 0.06]
Rose 2001	12/104	8/104		19.5 %	0.04 [-0.04, 0.12]
Total (95% CI)	**461**	**670**		**100.0 %**	**0.00 [-0.04, 0.04]**
Total events: 76 (Ultrasound), 104 (No ultrasound)					
Heterogeneity: Chi^2 = 1.90, df = 2 (P = 0.39); I^2 =0.0%					
Test for overall effect: Z = 0.00 (P = 1.0)					



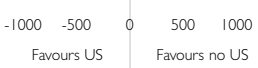
Analysis 6.1. Comparison 6 Reduction in diagnostic time, Outcome 1 Mean reduction in diagnostic time (minutes).

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 6 Reduction in diagnostic time

Outcome: 1 Mean reduction in diagnostic time (minutes)

Study or subgroup	Ultrasound N	Mean(SD)	No ultrasound N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
Boulanger 1999	460	53 (55)	246	151 (187)		-98.00 [-121.90, -74.10]
Subtotal (95% CI)	**0**		**0**			**0.0 [0.0, 0.0]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.0 (P < 0.00001)						
Test for subgroup differences: Not applicable						



Analysis 7.1. Comparison 7 Delayed diagnoses, Outcome 1 Risk of delayed diagnosis.

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 7 Delayed diagnoses

Outcome: 1 Risk of delayed diagnosis

Study or subgroup	Ultrasound n/N	No ultrasound n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Boulanger 1999	3/460	4/246		0.40 [0.09, 1.78]
Subtotal (95% CI)	**0**	**0**		**0.0 [0.0, 0.0]**
Total events: 3 (Ultrasound), 4 (No ultrasound)				
Heterogeneity: not applicable				
Test for overall effect: Z = 0.0 (P < 0.00001)				

Analysis 8.1. Comparison 8 Non-therapeutic laparotomy, Outcome 1 Risk of non-therapeutic laparotomy.

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 8 Non-therapeutic laparotomy

Outcome: 1 Risk of non-therapeutic laparotomy

Study or subgroup	Ultrasound n/N	No ultrasound n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Boulanger 1999	1/460	1/246		0.53 [0.03, 8.51]
Subtotal (95% CI)	**0**	**0**		**0.0 [0.0, 0.0]**
Total events: 1 (Ultrasound), 1 (No ultrasound)				
Heterogeneity: not applicable				
Test for overall effect: Z = 0.0 (P < 0.00001)				

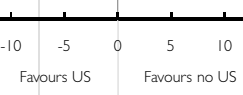
Analysis 9.1. Comparison 9 Duration of hospital stay, Outcome 1 Mean length of stay (days).

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 9 Duration of hospital stay

Outcome: 1 Mean length of stay (days)

Study or subgroup	Ultrasound N	Mean(SD)	No ultrasound N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
Arrillaga 1999	105	7.2 (9)	226	7.2 (10.1)		0.0 [-2.17, 2.17]
Subtotal (95% CI)	**0**		**0**			**0.0 [0.0, 0.0]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.0 (P < 0.00001)						
Test for subgroup differences: Not applicable						



Analysis 10.1. Comparison 10 Intensive care, Outcome 1 Mean ICU days.

Review: Emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma

Comparison: 10 Intensive care

Outcome: 1 Mean ICU days

Study or subgroup	Ultrasound N	Mean(SD)	No ultrasound N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
Arrillaga 1999	105	3.1 (7.1)	226	2.5 (5.1)		0.60 [-0.91, 2.11]
Subtotal (95% CI)	**0**		**0**			**0.0 [0.0, 0.0]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.0 (P < 0.00001)						
Test for subgroup differences: Not applicable						

APPENDICES

Appendix 1. Detailed search strategies

MEDLINE 1966 to January 2008

1 abdominal injuries
2 thoracic injuries
3 wounds, nonpenetrating
4 multiple trauma OR polytrauma
5 retroperitoneum
6 rupture
7 shock, traumatic
8 hemoperitoneum OR haemoperitoneum OR free fluid OR intraperitoneal fluid
9 spleen OR splenic
10 liver OR hepatic
11 accidents
12 accidents, traffic
13 seat belts
14 bicycling
15 motorcycles
16 ultras* OR echotomogr* OR sonogr*
17 focused assessment of sonography for trauma OR FAST OR emergency ultras*
18 (1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15) AND (16 OR 17)
19 randomised controlled trial OR randomized controlled trial
20 random allocation
21 double blind method
22 single blind method
23 (19 OR 20 OR 21 OR 22)

24 18 AND 23
EMBASE 1980 to January 2008
1 'intermethod comparison'/exp
2 'randomized controlled trial'/exp
3 'non invasive measurement'/exp
4 1 OR 2 OR 3
5 'peritoneal fluid'/exp
6 'hemoperitoneum'/exp
7 'spleen rupture'/exp
8 'spleen injury'/exp
9 'liver injury'/exp
10 'multiple trauma'/exp
11 'abdominal blunt trauma'/exp
12 'abdominal bleeding'/exp
13 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12
14 'peritoneum lavage'/exp
15 'clinical observation'/exp
16 'spiral computer assisted tomography'/exp
17 'diagnostic approach route'/exp
18 14 OR 15 OR 16 OR 17
19 'echography'/exp
20 'ultrasound scanner'/exp
21 'ultrasound transducer'/exp
22 19 OR 20 OR 21
23 4 AND 13 AND 18 AND 22

WHAT'S NEW

Last assessed as up-to-date: 18 February 2008.

Date	Event	Description
11 February 2008	New search has been performed	Review updated. New studies found and included/excluded.

HISTORY

Protocol first published: Issue 4, 2003

Review first published: Issue 2, 2005

Date	Event	Description
12 November 2007	Amended	Review amended. A shift in denominators was corrected based on the addition of one study (Boulanger 1999), another study was dropped from the analysis (Navarrete-Nav 1996), the results of a recent full-text

(*Continued*)

		publication of a former conference abstract (Melniker 2006) were included
9 February 2005	New citation required and conclusions have changed	Review first published.

CONTRIBUTIONS OF AUTHORS

Dirk Stengel was the principal investigator of this study, identified relevant literature, extracted and summarised data, and wrote the manuscript.

Kai Bauwens, Jalid Sehouli, and Franz Porzsolt assisted in literature retrieval and data extraction. Kai Bauwens co-reviewed eligible studies for methodological quality.

Grit Rademacher, Sven Mutze, and Axel Ekkernkamp discussed core ideas, and contributed to data interpretation.

All authors critically appraised the final version of this review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Department of Trauma and Orthopaedic Surgery at the Unfallkrankenhaus, Berlin, Germany.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Algorithms; Abdominal Injuries [*ultrasonography]; Emergencies; Randomized Controlled Trials as Topic; Wounds, Nonpenetrating [*ultrasonography]

MeSH check words

Humans