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Background

Around 60,000 planned total hip replacements*1 and 60,000 repairs of hip fractures are carried out annually in the UK. The mortality rate following partial hip replacement following fracture treatment is ten times higher than that following a planned hip replacement. Patients undergoing surgery after fracture are older, generally more ill and are in need of an emergency operation. The mortality rate is significantly higher if surgery is delayed more than 48 hours.

The most common cause of sudden intra-operative death during arthroplasty is the occurrence of venous embolisation of fat and marrow contents. This phenomenon is exacerbated by poor patient preparation, dehydration and significant co morbidities and is associated with instrumentation of the canal and finally cement insertion. At the time of arthroplasty, embolism can occur when cement is used but has also been reported with cementless implants.

In this country, around half of total hip replacements (THR) are done using bone cement (data are not collected on use of cement for hip fracture repair) with 30 per cent being uncemented and the remainder either hybrid or resurfacing procedures. This has gradually decreased in the last few years, but practice appears to relate to the individual preferences of clinicians. Internationally rates vary, from around three per cent in Canada to around 85 per cent in Sweden for the year 2005/2006.

A recent UK study underlined the effectiveness of techniques to reduce risks for patients undergoing hip fracture repair, following best practice in cementing technique. The need for action to reduce risks was highlighted in the Chief Medical Officer’s Annual Report (2007).

Review of evidence of harm from reporting systems

Reporting and Learning System (RLS) Data

The NHS Reporting and Learning System (RLS) was established by the National Patient Safety Agency (NPSA) to provide a national database of incidents relating to patient risks and harm. Interpretation of data from the RLS should be undertaken with caution. As with any voluntary reporting system, the data are subject to bias. A proportion of incidents which occur are not reported and those which are reported may be incomplete having been reported immediately and before the patient outcome is known.†

Following a reported incident of a patient death relating to use of bone cement in hip surgery in January 2008, a search of the patient safety incidents held within the RLS was undertaken and updated to the end of October 2008. A total of 1185 incidents were identified using a variety of search terms, seeking problems ‘on the table’ during orthopaedic surgery. These were reviewed individually to confirm whether they could be related to bone cement implantation syndrome. Cases were excluded where harm occurred after the perioperative period; where other kinds of complications were involved; where the procedure was performed on the knee or where use of cement or uncemented procedure was not specified. Thirty-six incidents were identified for further analysis.

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* Reporting to the National Joint Registry (NJR) is not mandatory and the suggested compliance rate for 2006 is 79 per cent, figures are therefore likely to be under-representative of actual procedures undertaken.
† The RLS was established in October 2003 and all NHS organisations were able to report to the RLS by 1 January 2005. It is important to note the volume of reports received by the RLS has increased since inception and as the RLS is a voluntary reporting system, the data may not be representative of the rates of incidents across England and Wales. Data are based on the date that incident became available for analysis. All incidents since the inception of the RLS are included.

www.npsa.nhs.uk/patientsafety/alerts-and-directives
Analysis of the data identified 24 patient deaths during hip surgery where bone cement was used. Most of these related to repair of hip fracture (hemiarthroplasty), often as emergency admissions (see Table 1). A further six patients suffered severe harm and most of these related to hemiarthroplasty. It is widely understood that patients undergoing hemiarthroplasty are likely to be frail elderly patients with higher risks of general post-operative death. Sample reports include:

“Patient having cemented hip prosthesis inserted for fractured neck of femur. Cement inserted and prosthesis being hammered into place when patient became bradycardiac 40 / min. Unresponsive to atropine. Loss of Palpable pulse with PEA cardiac arrest. CPR commenced and continued for 20 minutes and no response to treatment. Patient died.”

“Patient was having an operation for a right cemented [name of prosthesis]. Patient went into asystole when cement put into hip joint.”

“During procedure when introduction of cement the patients condition deteriorated. Patient died at 21:10.”

The search also identified one reported death during the perioperative period where use of un-cemented prostheses was explicitly stated, but no further details were available about the nature of the death (i.e. whether due to fat embolism or not).

Because of the voluntary nature of the reporting system, RLS data cannot be used to assert the relative risks of cemented versus un-cemented techniques. However, a pattern has emerged of reported incidents relating to deaths and severe harm from use of bone cement, while few similar incidents have been reported in relation to un-cemented procedures.

Table 1: Incidents resulting in death or severe harm during a hip procedure, cement use and type of procedure – NPSA data

<table>
<thead>
<tr>
<th>Degree of Harm</th>
<th>Procedure</th>
<th>Cement use</th>
<th>Uncemented</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cemented</td>
<td>Uncemented</td>
<td></td>
</tr>
<tr>
<td>Deaths</td>
<td>Hemiarthroplasty</td>
<td>17</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Arthroplasty (THR)</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>24</td>
<td>1</td>
<td>25</td>
</tr>
<tr>
<td>Severe Harm</td>
<td>Hemiarthroplasty</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Arthroplasty (THR)</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>6</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Grand Total</td>
<td></td>
<td>30</td>
<td>1</td>
<td>31‡</td>
</tr>
</tbody>
</table>

Table 1: Incidents resulting in death or severe harm during a hip procedure, cement use and type of procedure – NPSA data

| Base: all incidents involving severe harm or patient death during hip procedures in the RLS up to 31 October 2008 |

Medicines and Healthcare Products Regulatory Authority (MHRA) Data

The MHRA adverse incident database includes records of 20 patient deaths and four serious reactions in the UK (between 2000 and 2008) associated with the use of bone cement in hemiarthroplasty or total hip replacement. These were reported from different sources including hospitals, manufacturers and coroners. From date and location of incident, none appear to be duplicates of those reported to the RLS, although none were reviewed individually and not all may

‡ Data are based on the date that incident became available for analysis. All incidents since the inception of the RLS are included. The degree or harm may have been changed upon review to match the text description of the incident.
be attributable to this phenomenon. MHRA data also includes facilities in Scotland and the independent sector, which is broader than incidents reported to the RLS.

Table 2: Incidents resulting in death or severe harm with use of cement during hip procedure – MHRA data (2000-2008)

<table>
<thead>
<tr>
<th>Degree of harm</th>
<th>Procedure</th>
<th>Cemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>Hemiarthroplasty</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Arthroplasty (THR)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>20</td>
</tr>
<tr>
<td>Severe Harm</td>
<td>Hemiarthroplasty</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Arthroplasty (THR)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>4</td>
</tr>
<tr>
<td>Grand Total</td>
<td></td>
<td>24</td>
</tr>
</tbody>
</table>

[Note: Excludes two severe incidents which appear to be caused by response to Gelofusine]

Strategic Executive Information System (STEIS) Data – Serious Untoward Incidents (SUIs)

STEIS data collecting SUIs reported in England by trusts to Strategic Health Authorities from 2005 to end of October 2008 were reviewed and two deaths were reported related to the use of cement during hemiarthroplasty. In addition there were five deaths post hip replacement reported but in all cases other causes were cited such as cerebral vascular accident (stroke).

NHS Litigation Authority (NHSLA) Data

The NHSLA database was searched for incidents relating to hip cement. Nineteen incidents were found that cited ‘hip cement’ as part of the claim detail. This included incidents that occurred on or after 1 April 1995 and were reported to the NHSLA before 30 September 2008. However, none of these incidents involved death or adverse reaction.

National Joint Registry (NJR) Data

The NJR§ allows the entry of untoward intra-operative events to be reported and in 625 cases (one per cent) an untoward event was reported. None appear to mention problems with bone cement and they are all around complications relating to the insertion of the prosthesis e.g. calcar crack, fracture of the femoral shaft, trochanteric fracture, etc. Compared with previous years, the reported pattern of untoward intra-operative events has largely remained the same.

National hip fracture database

In September 2007, the British Orthopaedic Association and the British Geriatric Society launched the National Hip Fracture Database (NHFD). This is a web-based audit for England and Wales that builds on the work of a number of large scale hip fracture audits across the UK and is supported by the National Clinical Audit Support Programme (NCASP). This aims to promote best practice in

§ The National Joint Registry (NJR) was set up by the Department of Health and Welsh Assembly Government to collect information on all hip and knee replacement operations and to monitor the performance of replacement hip and knee joints (implants). Trusts are asked to register all details of total hip and knee replacements in England and Wales, but the NJR does not collect information on repair of hip fracture.

**Review of effectiveness, harm and evidence-based guidance**

**Literature review**

A review was undertaken of evidence relating to the effectiveness and safety of procedures during hip surgery and of current national guidance.

A recent meta-analysis by Ahn et al (2008) pooled the results from 11 prospective and retrospective studies that compared results between cemented and uncemented femoral implant fixation methods (n=2613 hemiarthroplasties). Relative risks of post-operative outcomes for peri-operative (<1 month), intermediate mortality (<3 months) and long-term mortality (≥6 months), complications and pain were similar between both groups. Only blood loss and operative time were reduced in the uncemented groups and these results reached statistical significance. The revision rate was lower for the cemented cohort (p=0.01). A second meta-analysis by Morshed et al (2007) compared cemented and uncemented total hip replacements. No significant benefit was seen in one method over the other in terms of failure. A Cochrane review of existing clinical trials by Parker and Gurusamy in 2006 found limited evidence that cementing a prosthesis in place reduced post-operative pain and led to better mobility. The authors however cautioned that “because of the limited number of patients studied, it is not possible to determine if any adverse effects of cement offset these advantages.”

In terms of evidence of harm, there is some data on the risks of intraoperative death during cemented hip arthroplasty and hemiarthroplasty. For instance, one US study reviewed over 38,000 total joint arthroplasties; 23 intraoperative deaths occurred, all during cemented procedures, whilst no intraoperative deaths occurred in more than 12,500 patients who had a non-cemented procedure. The same pattern was indicated in a survey of trauma centres in Wales, in one year, 15 intraoperative deaths during hemiarthroplasty occurred in 847 patients having a cemented prosthesis, and no intraoperative deaths occurred in 328 patients having non-cemented prostheses. A recent audit of 9,082 cemented procedures carried out in the UK since 1988 identified only one intraoperative death; this single intraoperative death was consistent with fat embolism and the authors concluded that the risks of sudden death during cemented total hip replacement using best surgical and anaesthetic practice was therefore ‘nearly zero’.

A recent comprehensive review provides a good summary of current evidence and notes that “there is no widely accepted definition (of bone cement implantation syndrome) and a paucity of recommendations for the avoidance and management of this syndrome.”

Other ‘grey literature’ worldwide includes the notification of five intraoperative deaths following use of cemented hip arthroplasty in Pennsylvania.

**National Institute for Health and Clinical Excellence (NICE)**

In March 2000, NICE issued guidance based on a technology appraisal on the selection of prostheses for primary total hip replacement. This supported the use of cement (largely around longevity of prosthesis, based on a 10 year benchmark, and pain and discomfort to the patient). The NICE appraisal was scheduled for review in July 2005, but this was deferred because of the lack of new comparative data. This is due for further review.
NICE guidance is currently at an early stage of development for hip fracture repair, with guidelines expected in 2011. Other relevant work relates to mini-incision surgery for total hip replacement in 2006\textsuperscript{14}, but does not advocate the use of one technique over another.

**Scottish Intercollegiate Guidelines Network (SIGN)**

SIGN published guidance in 2002\textsuperscript{15} on the prevention and management of hip fracture in older people. The authors reviewed the use of cement for hemiarthroplasties and concluded that the use of bone cement had been associated with intra-operative morbidity and proposed methods to reduce this, such as intramedullary lavage and modern cementing techniques. However, they identified evidence that uncemented stems were associated with more thigh pain and poorer overall function. The recommendation within this guideline was therefore that "cement should be used when undertaking hemiarthroplasty, unless there are cardiorespiratory complications."

**MHRA**

The MHRA has not published specific safety information on this topic.

### Evidence supporting particular actions

Guidance produced by the Patient Safety Advisory in Pennsylvania\textsuperscript{12} includes detailed advice on minimising risks by aggressive lavage and suction of the femoral canal before the procedure, as well as preoperative screening for patients at risk and intraoperative anaesthetic monitoring among other interventions.

Further work is needed in this country to review evidence on the most effective surgical and anaesthetic techniques to reduce risks. However, existing evidence appears to support the following actions listed in the Rapid Response Report as immediate actions which clinical teams can consider to minimise harm.

1. **Identifying patients at risk**

   There is some evidence around particular patients at risk and factors to consider, such as patient’s cardiopulmonary reserve.\textsuperscript{9} It has been shown in animal models that the use of either cement or inert bone-wax produces significantly more dysfunction and the amount of pulmonary fat emboli was ten times greater at autopsy.\textsuperscript{16} This reinforces the need for greater caution for patients with pre-existing cardiopulmonary dysfunction.\textsuperscript{11}

2. **Anaesthetic technique**

   There is good evidence on the need for monitoring hydration and vigilance by anaesthetic team at the point of inserting prostheses.\textsuperscript{9,17,18}

3. **Surgical technique**

   a) **Lavage and use of cement restrictor/plug**

   There is good evidence that conducting thorough, pulsatile, high pressure, high-volume lavage and brushing and drying of the intramedullary canal of the femoral shaft to remove tissue prior to cement insertion reduces risk of fat embolism.\textsuperscript{9,19}
Evidence suggests that use of cement restrictor may cause less physiological disturbance\(^2\) and supports the use of bone plug.\(^2\)

b) Use of suction catheter

Evidence is available on suctioning technique and use of catheters.\(^2\)

c) Mixing cement in a vacuum and using cement gun

A randomised-controlled trial of 60 patients revealed severe embolic events and intra-operative pulmonary impairment in patients who had a femoral component fixed with the use of conventional cementing techniques. This risk was reduced when using cement if the bone-vacuum cement technique was used (and for uncemented techniques).\(^1\)

There is also longstanding evidence on the benefits of using cement guns.\(^2\)

d) Communication with anaesthetist

There is no specific evidence around communication at the point of insertion.

These recommended actions have been identified in discussion with anaesthetic and surgical professional bodies. There is still a need for thorough review of evidence on most effective surgical and anaesthetic techniques, but available evidence suggests support for these immediate actions while awaiting a final review.

### Summary and conclusion

The NPSA has identified a number of deaths and cases of serious harm relating to patients undergoing hip surgery where cement has been used. The vast majority of these relate to patients undergoing emergency hemiarthroplasty following hip fracture.

The relative safety and effectiveness of cemented and uncemented prostheses for different procedures are complex clinical questions. Although there are still areas of uncertainty, there is a growing body of evidence on best practice to mitigate risk. The national database on hip fracture to monitor activity and trends, and forthcoming NICE guidelines on hip fracture repair to clarify evidence-based practice, are important initiatives to ensure patient safety and quality. In the meantime, the NPSA through the accompanying Rapid Response Report provides a reminder to clinical staff of risks and highlights surgical and anaesthetic techniques, based on best available evidence, to minimise risks to patients.
References

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