Secondary cement injection technique reduces pulmonary embolism in total hip arthroplasty

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Abstract

Purpose Cardio-pulmonary damage due to embolism is a feared complication of cemented hip arthroplasty and can be fatal. Embolic events result from an increased intramedullary pressure during cement and stem insertion and can lead to extrusion of bone-marrow elements into the circulation. To reduce embolism and at the same time achieve an ideal cement mantle, the cement injection stem has been designed. In contrast to conventional stems where cement applied before stem insertion (primary cementing technique), the cement injection stem is positioned first and only then is the cement injected via the stem in a volume- and pressure-controlled fashion (secondary cementing technique).

Methods A randomised trial with 30 patients was performed to evaluate whether this technique is able to reduce embolic events. Patients either received a conventional cemented stem (primary cementing technique) or a cement injection stem (secondary cementing technique). Embolic events were recorded by transesophageal echocardiography at six specific points during the operation and classified from grade 0 to grade 3.

Results Significantly fewer grade 2 and 3 embolic events were observed in patients receiving the cement injection stem using the secondary cementing technique. Moreover, in the conventional group all patients (100 %) had at least one grade 3 embolus whereas only 20 % with the secondary cementing technique had an embolic event of grade 3.

Conclusion Secondary cement insertion via the cement injection stem is able to reduce severe embolic events significantly. The technique offers a more gentle cementing technique and therefore appears especially beneficial for patients of advanced age and/or with pre-existing cardio-pulmonary comorbidities.

Introduction

Although cemented stems have recently been used less often, they still account for more than 37 % in Australia, 51 % in the United Kingdom and more than 75 % in Sweden [1–3]. Reasons are the good long-term results [1, 4, 5], the cost effectiveness [6], the high stability in osteoporotic bone and the advantage of full postoperative weight bearing [7, 8], which is especially important for elderly people. However, one disadvantage of cemented total hip arthroplasty (THA) is the incidence of embolism with cardiopulmonary distress [9–14]. In most patients, it is usually non-fatal, characterised by hypoxia and/or hypotension and occurs around the time of cementation, stem insertion or reduction of the joint [14]. However, in some patients it causes serious cardiovascular changes which may produce arrhythmias, shock or cardiac arrest [14] and potentially death [15–17]. Cemented THA has a higher intraoperative mortality rate than uncemented THA [16, 17]. And as all large studies only report the operative

Study design High-quality randomized controlled trial - Level I

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mortality rate, it is also assumed that the non-fatal events are underreported [14].

It is believed that the embolic events are a result of the increased intramedullary pressure, leading to extrusion of bone marrow elements with embolisation of the cardiovascular system [18]. Several methods have been introduced to reduce the incidence of embolism [10, 18, 19], but the problem is not yet solve.

A novel approach is the cement injection stem, which uses a secondary cementing technique [20, 21]. In contrast to primary cementing techniques, the cement injection stem is placed in the femur directly after preparation of the medullary cavity. After this the cement is injected around the cement injection stem (secondary cementing technique) in a volume and pressured controlled way. Simultaneously, the stem allows the outflow of intramedullary debris through a drainage canal in the stem. As a result, intramedullary peak pressures are avoided, which should result in a reduced spill-over of debris into the circulation as a consequence.

To evaluate the efficiency of the system, this study compared the incidence of cardiac embolism between a conventional cemented stem (primary cementing technique) and the cement injection stem (secondary cementing technique).

Materials and methods

Secondary cementing technique and cement injection stem

The cement injection stem (Aesculap, Tuttlingen, Germany) (Fig. 1a) was designed to achieve an exact position of the implant, produce an optimal cement mantle and avoid undesired high intramedullary peak pressures. To achieve these aims, the cement injection stem uses a secondary cementing technique (SCT). In contrast to the primary cementing technique (PCT) where cement is injected before stem insertion, in SCT the stem is placed into the femur after the usual preparation of the medullary cavity and before cement is applied.

The optimal position of the stem is achieved by a proximal collar and a bioresorbable distal cement restrictor. Both keep the implant exactly in the centre of the prepared cavity and lead to a uniform distribution of the cement mantle around the stem (Fig. 1a, b). Cement is injected through an integrated short-length canal and fills the medullary cavity from proximally to distally (Fig. 2). Fluid and air remaining in the medullary space are drained through a special drainage canal. The canal is integrated into the stem, starts at the very distal side of the implant and drains intramedullary fluid and air to the proximal side of the implant.

Cement injection is achieved with a cement injector which produces a constant cement volume flow rate. Superfluous

Fig. 1 a Cement injection stem. b Postoperative radiograph of the cement injection stem

cement can escape via two calibrated cement valves in the proximal collar of the stem. The system (cement applicator, leakage channels, cement) is designed to achieve a constant cement flow, resulting in a defined penetration into the spongy bone and a high quality cement mantle. At the same time the system only causes a moderate intramedullary pressure and avoids high peak pressures. When the intramedullary pressure is reported as 2,000 mmHg (266.6 kPa), which is needed to achieve a sufficient cement penetration [21, 22], the cement injector switches off. In contrast to conventional stems, the stem cannot alter its position during curing of the cement as it is stabilised by the proximal collar and the distal cement restrictor.

Cement and cement applicator

The cement applicator (Aesculap, Tuttlingen, Germany) is custom-designed for the cement injection stem and injects the cement after connection to the stem at a controlled volume flow rate. At the end of the cementing process (approximately 30 seconds) the applicator stops automatically at a pressure of 2,000 mmHg (266.6 kPa). The cement used for injection over the cement injection stem is Osteopal® (Heraeus Medical GmbH, Wehrheim, Germany).

Study group

The study group comprised 30 patients who were assigned into two groups (Table 1). From this collective, 15 patients

Fig. 2 Cement flow during application via the cement injection stem. The femoral cavity is filled from proximally to distally. Extravasated material, blood and irrigation fluid can leave the cavity through the centrally seated drainage canal

received a conventional stem (MS-30, Zimmer, Warsaw, USA) using the primary cementing technique (PCT) and 15 patients received a cement injection stem (Aesculap, Tuttlingen, Germany) using the secondary cementing technique (SCT). Randomisation was done on the operation day by one person not involved in the surgery. The study protocol was approved by the ethics committee of the university, and before starting all patients were informed in detail about the study and signed an informed consent.

Clinical study protocol

All patients were operated upon between June 2002 and July 2003 by the senior surgeon (VJ) following a standardised intraoperative procedure as follows. Joint replacement was performed through a modified minimally invasive Hardinge approach in the supine position. All patients received the same cementless cup (Screwcup SC, Aesculap, Tuttlingen, Germany). Jet lavage for irrigation of the medullary cavity and vacuum cement mixing was the same in both groups. All patients received general anaesthesia and transoesophageal

echocardiography (TEE) was recorded on a videotape by one anaesthetist using a transesophageal 5-mHz sonic probe placed on the right atrium in the longitudinal section. TEE was performed at six defined points as previously reported [11, 13]: 1 = skin incision (control), 2 = insertion of the cementless cup, 3 = femoral cavity opening, 4 = stem insertion (SCT)/ cement injection (PCT), 5 = cement injection (SCT)/ stem insertion (PCT), 6 = joint reposition. Patients were monitored postoperatively on the intensive care unit for 24 hours.

TEE analysis and grading

TEE was video recorded and analysed off-line by a blinded team consisting of one anaesthetist and one orthopaedic surgeon. Incidents were classified after established criteria [11, 13]: Grade 0: no emboli or small echogenic particles, Grade 1: a cascade of fine emboli, the right atrium or ventricle are partially opacified, Grade 2: a cascade of fine emboli or embolic masses with a diameter < 5 mm, Grade 3: emboli mixed with large embolic masses with a diameter > 5 mm.

Statistics

Statistical analysis was performed by SAS (Version 8, SAS Institute, Cary, North Carolina, USA). The Mann-Whitney U test was used for group comparison. A p-value <0.05 determined significance. Graphs were created with SigmaPlot (Version 8.02, Systat Software GmbH, Erkrath, Germany).

Results

Pulmonary embolism

Significant differences between the two groups were observed for grade 2 and grade 3 embolic events, but not for grade 1 (Table 2, Fig. 3a–c). A higher degree of grade 2 events was found for the conventional cementing technique

Table 1 Demographic patient data presented as mean $\pm$ standard deviation (SD)

Characteristics	Conventional group (primary cementing technique) <i>n</i> =15	Cement injection group (secondary cementing technique) <i>n</i> =15
Gender	M=8 / F=7	M=12 / F=3
Age (years)	73.9 $\pm$ 4.4	72.1 $\pm$ 12.3
Weight (kg)	75.7 $\pm$ 3.4	88.5 $\pm$ 14.5
Height (cm)	163.5 $\pm$ 8.1	171.0 $\pm$ 8.2
Physical status: ASA I-IV	0:5:9:1	1:10:4:0

M male, *F* female

at all measured points, except for skin incision (point 1) and cup implantation (point 2) (Fig. 1b). The events were significantly higher during stem insertion/ cement injection (point 4) ($p<0.001$) and relocation of the joint (point 6) ($p<0.024$). Similarly, more and longer grade 3 events were observed for the conventional cementing technique at points 3, 4, 5 and 6 (Fig. 3c). The events were significantly higher during stem insertion/ cement injection at point 4 ($p<0.035$) and point 5 ($p<0.001$) and also were significantly higher during reposition at point 6 ($p<0.001$).

The maximum embolic event per person in the cement injection group (SCT) was grade 1 in 47 % (7/15), grade 2 in 33 % (5/15) and grade 3 in 20 % (3/15). In contrast, in the conventional group (PCT) all patients (100 %; 15/15) experienced at least one grade 3 embolic event.

Regarding the measurement points, embolic events were not observed at the control point (point 1: skin incision) and only very few during implantation of the cup (point 2). Substantially more events were recorded during opening of the medullary cavity (point 3), but without statistical significance between the two groups. In contrast, during injection of cement and insertion of the stem (points 4 and 5) clearly more embolic events occurred in the conventional group (PCT) than in the cement injection stem group (SCT). The highest prevalence of embolic events was seen in both groups during relocation of the hip (point 6). And again, the embolic events grades 2 and 3 were significantly higher in the PCT than in the SCT group ($p<0.024$, $p<0.001$).

Operation and complications

No complications occurred in either group during surgery. The operation time showed no difference between the groups (70.4 ± 11.4 min PCT vs. 70.5 ± 6.8 min SCT). Intraoperatively one female patient was diagnosed (TEE) with an open foramen ovale, which did not however result in any complication. Postoperatively one patient of the conventional group developed confusion and reduced peripheral oxygen saturation of unknown origin, but completely recovered

within 48 hours. Three patients in the conventional group were diagnosed (duplex-ultrasonography) with deep vein thrombosis (distal popliteal vein) 72 hours after surgery. All of them resolved without complications.

Discussion

Embolism is a feared complication during cemented THA which can lead to cardio-pulmonary distress [9] and even can end fatally. The intraoperative mortality rate for cemented THA has been reported to be approximately 0.1 % [15–17]. It increases if cemented THA is performed for an intracapsular (0.2 %), intertrochanteric (1.6 %) or a pathological fracture (4.3 %) [17]. The embolic events are a result of the increased intramedullary pressure and occur predominantly during cement and stem insertion, which leads to a spill-over of bone marrow content into the circulation [23]. Several techniques have been introduced to reduce this extrusion. Vacuum drainage at the proximal femur or a distal venting hole have been suggested [12, 13, 19], but are controversial as they might result in a higher intra- and postoperative fracture risk and a longer operation time [12, 18]. Modern cementing techniques, including vacuum cement mixing and jet lavage [24], have been found to be effective, but still are not without issues.

In this randomised study we have shown that by the use of the SCT, the incidence of embolism can further be reduced and is clearly less than modern PCT. In particular long and severe grade 3 events can be significantly reduced and were barely seen in the SCT group. Similarly, grade 2 incidents occurred to a lesser degree with SCT than with PCT at all relevant recording points. With the SCT, grade 2 emboli only occurred during cement injection and during reposition, but still were clearly less than for the PCT. This clear reduction of severe events can directly be attributed to the secondary cementing technique which produces a constant cement application with an intramedullary peak pressure limit. In contrast, for conventional primary cementing techniques

Table 2 Duration and degree of embolic events in both groups presented as mean $\pm$ standard deviation (SD)

Event(s)	Conventional group (primary cementing technique)			Cement injection group (secondary cementing technique)		
	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
1=skin incision	0 $\pm$ 0	0 $\pm$ 0	0 $\pm$ 0	0 $\pm$ 0	0 $\pm$ 0	0 $\pm$ 0
2=cup insertion	20.5 $\pm$ 45.1	3.6 $\pm$ 13.9	0 $\pm$ 0	15.8 $\pm$ 41.7	0 $\pm$ 0	0 $\pm$ 0
3=opening femoral cavity	45.7 $\pm$ 67.8	33.6 $\pm$ 70.7	0.3 $\pm$ 0.5	74.3 $\pm$ 94.7	3.1 $\pm$ 8.6	0.2 $\pm$ 0.6
4=stem/cement	18.0 $\pm$ 37.9	56.3 $\pm$ 63.3 ^a	0.4 $\pm$ 0.7 ^a	22.5 $\pm$ 41.7	2.0 $\pm$ 7.7 ^a	0 $\pm$ 0 ^a
5=cement/ stem	93.7 $\pm$ 160.2	53.3 $\pm$ 108.2	1.1 $\pm$ 1.6 ^a	78.9 $\pm$ 80.6	35.7 $\pm$ 62.5	0 $\pm$ 0 ^a
6=joint reduction	109.9 $\pm$ 166.7	92.7 $\pm$ 120.2 ^a	2.3 $\pm$ 2.1 ^a	152.2 $\pm$ 173.0	32.5 $\pm$ 69.2 ^a	0.1 $\pm$ 0.3 ^a

^a Significance ($p<0.05$) between primary and secondary cementing technique

Fig. 3 Embolic events at six defined measurement points for the primary cementing group (PCT) and secondary cementing group (SCT) (mean $\pm$ SEM). **a** Grade 1. **b** Grade 2. **c** Grade 3. (*significance $p < 0.05$)

intramedullary peak pressures of up to 5,250 mmHg have been reported [18, 25, 26]. As the intramedullary pressure is likely to correlate positively with the number of embolic events [23], high peak pressures increase the risk of cardio-pulmonary damage. However, to reach the recommended cement mantle of 2–5 mm in all areas [24], a pressure of approximately 2,000 mmHg is assumed to be sufficient [21, 22]. Besides, Kapoor et al. could show that a constant pressure, even though lower, is more important than a high peak pressure [27]. Both can be reliably and safely realised with the cement injection stem. A constant cement flow is achieved by the controlled volume flow rate application and the special valves. This avoids peak pressures, but still achieves sufficient pressure up to 2,000 mmHg, resulting in a good and stable cement mantle [20].

Despite the clear reduction in severe embolic events, grade 1 events were observed to a similar extent as the conventional group. The reason is that the SCT also needs an adequate pressure for a sufficient cement penetration into the trabecular bone. However, grade 1 events rarely lead to critical cardio-pulmonary damage. Pitto et al. showed that in 120 cemented THAs, grades 2 and 3 resulted in hypotension, hypoxemia, decrease of end-tidal CO₂ levels and increase of pulmonary shunt values, whereas the symptoms were not present in grade 1 embolism [12]. As many patients undergoing cemented THA are of an older age and have more co-morbidities with a higher ASA score [2], the SCT might offer a more gentle cementing procedure for this group. This is underscored by a study where patients with severe systemic diseases and an ASA classification of III or IV were not only affected more severely during surgery, but the effect also lasted over the postoperative period [12]. Similar observations were reported for ventilation and perfusion rates in patients undergoing cemented THA [9, 28, 29]. Thus, the benefit of the SCT might be even greater for patients with a higher intraoperative complication and morbidity risk as often seen for femoral fractures [17, 30]. Furthermore, an advantage of the SCT is that the operation time is not prolonged as reported for other techniques [12].

Embolic events in this study were most pronounced during relocation of the joint. This has been described before [13, 31] and is attributed to the operation procedure during stem insertion [18], which results in a clearly reduced or even ceased blood flow [32]. During joint reposition, when the leg is stretched again, and the temporarily occluded femoral vein is re-opened, the newly formed thrombi are washed out [18]. This effect was also observed in our study, but with significantly higher grade 2 and 3 events in the conventional PCT group. In contrast, clearly fewer grade 2 and barely any grade 3 events were observed in the SCT group, confirming the lower extrusion rate of bone-marrow elements with this technique.

An obvious limitation of the new cement injection stem is that long-term survival rates are still pending. However, the conventional stem from which the cement injection stem is derived has shown good mid-term survival rates [33, 34]. Furthermore, the cement mantle produced by the secondary cementing technique has been found to be effective [20, 21], and an in-vivo long-term fatigue test has shown that the cement mantle was comparable or even significantly better than the conventional cemented stem [20].

This randomised study has demonstrated that the use of a cement injection stem with a secondary cementing technique results in a definite reduction of embolism. In this respect, the cement injection stem appears to be a promising design, especially in patients of advanced age, with femoral fractures and/or with cardio-pulmonary comorbidities.

Conflict of interest Development of the cement injection stem was supported by Aesculap.

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