

## Incidence and risk for Bone Cement Implantation Syndrome after hemiarthroplasty

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### Abstract

**Background:** Bone Cement Implantation Syndrome (BCIS) is a highly under-reported rare fatal complication of cementation, characterized by hypoxia, hypotension, cardiac arrhythmias, and cardiac arrest. With aim to alert surgeons about rare, but serious harm due to BCIS and its risk, clinical features, preventive measures and management, we evaluated the incidence and risk factor associated for BCIS in cemented hemiarthroplasty for fractures around hip.

**Material & Methods:** All patients of fracture neck of femur or intertrochanteric, operated with cemented hemiarthroplasty, who sustained BCIS during or within 24 hrs of the cementation, were included in the study. The BCIS was diagnosed, when the patient had hypoxia (SpO<sub>2</sub> <94%) or fall in systolic blood pressure > 20mm. These patients were evaluated for presence of risk factors like age, sex, osteoporosis, use of diuretics, poor preexisting physical reserve, pre-operative cardiopulmonary function etc.

**Results:** In 430 patients of cemented hemiarthroplasty done for fractures around hip, 13 sustained BCIS. The mean age in these patients was 84.3 years. Severity was grade 1 in 7 patients, grade 2 in 4 patients and grade 3 in 2 patients. All the patients of the grade 1 and grade 2 were revived successfully, whereas none of the patients of the grade 3, could be revived. Age and poor cardiac reserves were most commonly associated with BCIS.

**Conclusion:** BCIS is a rare, preventable, fatal complication of cementation which can be diagnosed early by constant monitoring. Management is supportive and prevention is best way, by surgical modification with modern cementing techniques, especially in high risk patients.

**Keywords:** Bone cement, Cement implantation syndrome, Hemiarthroplasty

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### Introduction

Fractures around hip in elderly are very common injury, which are usually treated by hemiarthroplasty. Owing to the poor quality of bone in these elderly patients and osteoporosis, this prosthesis is commonly fixed to bone with the help of bone cement. Thus cemented hemiarthroplasty, is a routine surgery done for fractures around hip in elderly patients.

Cemented prosthesis is not free of complications. Bone Cement Implantation Syndrome (BCIS) is among one of the complications which is the most fatal complication of cementation [1]. BCIS has no agreed definition. An adverse, sudden, cardiovascular event, characterized by hypoxia, hypotension, unexpected loss of consciousness, cardiac arrhythmias, and cardiac arrest or combination of these, occurring within minutes of cementation,

prosthesis insertion, joint reduction or occasionally, tourniquet deflation while cemented bone surgery can be referred as 'Bone Cement Implantation Syndrome' (BCIS) [2,3]. Although it is most commonly associated with hip arthroplasty, but it can also occur during cementation in other procedures like knee arthroplasty, shoulder arthroplasty or even during kyphoplasty [4,5]. We conducted this study to evaluate the incidence and risk factors associated for the above catastrophic event and to educate the surgeons regarding risks, clinical features, preventive measures and management of BCIS occurring during hemiarthroplasty.

### Material and methods

This prospective study is done at our center in all patients of hip fractures either neck of femur or intertrochanteric treated by cemented hemiarthroplasty in last 5 years. The study was approved by the institutional ethical review committee.

All patients of fracture neck of femur or intertrochanteric, operated between 2014 to 2019 with cemented hemiarthroplasty, who sustained BCIS during or within 24 hours of the cementation, were included in the study. The BCIS was diagnosed, when the patient had hypoxia (SpO<sub>2</sub> <94%) or fall in systolic blood pressure > 20mm, intra-operatively after cementation or postoperatively within 24 hours of cementation [2]. Thus any patients having hypoxia and hypotension which may be presented clinically as only transient confusion or as fulminant cardiovascular changes, which may proceed to arrhythmias, shock or cardiac arrest, were included in the study. The patients whose intraoperative and post-operative event was uneventful were excluded from the study.

All patients were operated only after optimizing the patient and obtaining medical and pre-anaesthetic clearance. Written informed consent was also obtained for all patients for cemented hemiarthroplasty by bipolar prosthesis. The hemiarthroplasty was done by standard posterior approach in lateral position under spinal anaesthesia in all the patients. The episodic hypotension following the spinal anaesthesia was well treated and

the patient's haemodynamic parameters were well maintained and made stable before the procedure.

Femoral canal preparation was done as per the standards. In all the cases, after head extraction and gradual rasping of the femur canal was done. Following this femoral canal was prepared by thorough lavage followed by drying of canal, remove small debris and application of cement restrictor. The prepared cement after mixing was inserted into the femoral canal in a retrograde manner over a suction catheter to suck trapped air, with help of a cement gun. The cement so inserted was pressurized by the hand and inserted appropriate sized bipolar prosthesis. Any patient sustaining hypotension or hypoxia during this period and after this for 24 hours was labelled as BCIS. The BCIS was graded as per Donaldson severity classification, grading into grade 1 as moderate hypoxia (SpO<sub>2</sub> <94%) or fall in Systolic blood pressure >20%, grade 2 as severe hypoxia (SpO<sub>2</sub> <88%) or fall in Systolic blood pressure >40% and grade 3 having cardiovascular collapse which required CPR [2].

Any patients sustaining the BCIS, during cementation intra-operatively were intubated and ventilated with 100% oxygen after sealing the surgical site. Cardiopulmonary resuscitation with administration of cardiac massage, CPR, crystalloid, vasopressors like adrenaline and atropine and supportive treatment was done to revive the patient. Patients sustaining BCIS in postoperative period were admitted in ICU, and connected to ventilator. Vasopressors, inotropics and cardiopulmonary resuscitation along with shock or defibrillator were given when needed. Patients who could not be saved underwent autopsy to confirm diagnosis of BCIS.

All those patients who sustained BCIS were evaluated for the presence of risk factors age, sex, osteoporosis, use of diuretics, poor preexisting physical reserve, pre-operative cardiopulmonary function, pre-existing pulmonary hypertension, bony metastases, presence of pathologic fracture, type of fracture, any previously instrumentation of

femoral canal and type of stem used in hip arthroplasty.

## Results

A total of 430 patients of fracture neck of femur or intertrochanteric femur treated by cemented hemiarthroplasty were operated at our centre during last five years and included in the study. Out of these patients, only 13 patients sustained BCIS in our study. The mean age in these patients was 84.3 years (range 78 to 92 years). Out of the 13 patients, 11 were male and 2 were female.

BCIS as per Donaldson severity was grade 1 in 7 patients, grade 2 in 4 patients and grade 3 in 2 patients. All the patients of the grade 1 and grade 2 were revived successfully, whereas none of the patients of the grade 3, could be revived. All patients in grade 1 and all patients of grade 2 except one sustained the event in intraoperative period just after the cementing and insertion of prosthesis. In grade 3, out of the two patients, one sustained the event in intraoperative period i.e. during cementation, while the other patient sustained the BCIS episode after, 6 hours of the surgery. Thus total 11 patients had BCIS, intra-operatively during cementation and two had during the postoperative period.

Out of the 13 patients, 9 had fracture neck of femur and 4 had intertrochanteric fracture and none of the patients had a pathological fracture or bony metastasis. The mean preoperative cardiac output in these patients was 43.4 % (range 39 to 58). All patients had normal cemented bipolar prosthesis of 150 mm size length done in the previously unreamed femoral canal.

## Discussion

Cemented hemi-arthroplasty is a routinely done procedure for fractures around the hip. Bone Cement Implantation syndrome (BCIS) is a rare fatal complication of cementation, which is highly underestimated and under-reported, as patients who die intra-operatively, are less likely to be reported [6]. Hence, there are not many case series or formal trials published on this topic and only few cases are only reported [1,3,6-8]. Further

milder varieties of BCIS are not recognized at all or not systematically collected or published. Thus, due to this underreporting, there is lack of peer-reviewed literature available on this topic regarding incidence, accepted definition, clinical presentation and management recommendations. Hence we conducted this study to evaluate the incidence and risk factors associated with BCIS in 430 patients of cemented hemiarthroplasty done for patients of fracture around hip in a period of 5 years.

The aetio-pathophysiology of bone cement implantation syndrome (BCIS) is unknown with theories being proposed, like systemic toxic effects of methyl methacrylate, embolic episode, histamine release, complement activation, endogenous cannabinoid-mediated vasodilatation or combination of these, but none of them have been proven completely [9-12]. Patho-physiologically, the genesis of BCIS is high intramedullary pressure (often >300mmHg), generated by the expansion of exothermic sealed cement, between the prosthesis and bone, which forces "snow flurry", which contain fat, marrow, cement particles, air, bone particles, and aggregates of platelets and fibrin into blood circulation. The embolic snow flurry within the circulation causes mechanical and mediator release changes via histamine, complement activation, endogenous cannabinoids, vasoactive or pro-inflammatory substances, thrombin and tissue thromboplastin etc, which manifests typical cardiovascular and hemodynamic changes of BCIS [2,9-14].

Numerous patient-related risk factors implicated in the genesis of BCIS include old age, male sex, osteoporosis, use of diuretics, poor preexisting physical reserve, impaired cardiopulmonary function, pre-existing pulmonary hypertension, patent foramen ovale, atrial-septal defect, bony metastases and concomitant hip fractures, particularly pathological or intertrochanteric fractures [2,3,6]. Patients with a previously un-instrumented femoral canal and long-stem hip arthroplasty appear to be associated with a higher incidence of BCIS [15]. We found in our series of 430 cases of cemented hemiarthroplasty, 13 sustaining BCIS, and BCIS was associated with high incidence in

higher age, male gender and poor cardiac reserve patients.

Due to differences in patient's risk factors, susceptibility and response and mediator based effect of BCIS, the degree of cardiovascular compromise is not necessarily proportional to the degree of the embolic load [16,17]. Hence there is wide spectrum of clinical presentation from milder transient hypoxia, hypotension or confusion to fulminant cardiovascular changes, which may proceed to arrhythmias, shock or cardiac arrest. Depending to SpO<sub>2</sub> and fall in systolic pressure Donaldson proposed a severity classification, grading BCIS into three grade, grade 1 as moderate hypoxia (SpO<sub>2</sub> <94%) or fall in Systolic blood pressure >20%, grade 2 as severe hypoxia (SpO<sub>2</sub> <88%) or fall in Systolic blood pressure >40% and grade 3 having cardiovascular collapse which required CPR [2]. In our series, grade 1 BCIS was seen in 7 patients, grade 2 in 4 patients and grade 3 in 2 patients.

First indication of clinically significant BCIS is fall in end tidal CO<sub>2</sub> concentration with dyspnoea or altered sensorium, followed by hypoxia and hypotension [18]. Invasive hemodynamic monitoring like oesophageal doppler, intraoperative pulmonary artery catheter or transoesophageal echocardiography can detect impending BCIS at an earlier stage than standard hemodynamic monitoring, but they are not routinely used and where not used by us as well [3,6,8,17,18].

Since amount of debris present in the femoral canal is finite, BCIS is a reversible time-limited process with ceiling effect, which can recover within minutes, even from large embolic loads, if hemodynamic stability is maintained by supportive therapy [19]. The supportive management includes administration of 100% oxygen with airway control, aggressive fluid therapy resuscitation & avoid volume depletion, inotropics and vasopressors [2,6,8]. Prophylactic use of antihistaminics or steroids for treatment of cement embolism could not be found in the literature search [7]. With supportive treatment, we were able to revive

all our grade 1 and grade 2 patients, but none of the grade 3 patients could be revived.

Prevention of BCIS is better, and various intraoperative surgical measures can reduce the risk of BCIS. These include medullary lavage, good haemostasis before cement insertion, prevent excessive cement pressurization, using low toxicity monomeric cement, minimizing the length of the prosthesis, vacuum cement mixing, retrograde application with cement gun with a suction catheter, intramedullary plug and venting the medulla [2,3,6,8]. Except for vacuum mixing and venting a hole, we follow all the other modern cementing techniques to minimize BCIS in all our case of cemented hemiarthroplasty.

Multidisciplinary clinical guidance for both anaesthetists and surgeons are issued by National Patient Safety Agency (NPSA) 2009, regarding the use of bone cement during hip arthroplasty, highlighting the joint decision-making, team-working and careful intra-operative monitoring, especially in high risk patients. Further, all hip fracture surgeries should be undertaken or directly supervised by experienced anaesthetists and surgeons, ideally on planned lists, with full involvement of anaesthesia team in the preoperative planning, allowing proper investigation and pre-optimization. All members should be aware of the problem and if severe reaction or cardiopulmonary arrest occurs, everyone should be aware of their defined roles in resuscitating the patient [20].

## Conclusion

BCIS is a rare preventable complication of bone cementation characterized by hypotension, hypoxemia, bradycardia, unconsciousness and even cardiac arrest, especially in high risk patients. Constant monitoring and early diagnosis during and after bone cementation is crucial in determining the outcome. Management includes surgical modification with modern cementing techniques and supportive measures along BLS and ACLS guidelines. Further registry-based or multicenter studies are needed on the topic for patient safety.

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