Incidence, associated risk factors and cumulative risk scores: a retrospective chart review of a single center's experience with bone cement implantation syndrome in a low and middle income country, South Africa

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Abstract

Background: Cemented arthroplasty is appropriate management for displaced neck of femur fractures. However, it is associated with Bone Cement Implantation Syndrome (BCIS), characterized by a drop in systemic blood pressure, hypoxia, unexpected loss of consciousness, and cardiovascular collapse. This study aimed to quantify the incidence of BCIS in a low and middle income country (LMIC), to compare whether similar risk factors exist as compared to high income countries. It also aimed to assess whether cumulative risk factors were associated with severe grades of BCIS.

Methods: A retrospective chart review analyzed consecutive adult patients undergoing cemented arthroplasty between January 2016 and July 2017 at Addington Hospital, KwaZulu-Natal, South Africa. The lowest blood pressure and oxygen saturation at defined points were compared to baseline readings, and patients were graded as grade 1, 2 or 3 BCIS. Records were analyzed for the presence of risk factors, of which 16 were identified and compared to the occurrence of BCIS. Factors deemed statistically significant were combined and a cumulative risk score was compared to the grades of BCIS.

Results: The total incidence of BCIS was 45.79%. The incidence of BCIS grade 1, 2 and 3 were 34.58%, 5.61%, and 5.61% respectively. Independent significant factors included ASA ≥3, hypertension, previous cerebral ischaemia, previous myocardial ischaemia, and renal failure. A statistically significant difference existed between various grades of BCIS and cumulative risk scores for each grade. The mean risk score for no BCIS, grade 1, 2 and 3 BCIS were 0.77 ± 0.75, 1.81 ± 1.15, 3.0 ± 0.63, and 3.5 ± 1.05 respectively.

Conclusions: This study reported the incidence of BCIS, risk factors associated with BCIS, and that cumulative risk factors increased the grade of BCIS. Grade 1 and grade 3 BCIS occurred more commonly in our institution than in the reported literature.

Background

Hemiarthroplasty and total hip arthroplasty are common and appropriate management strategies for displaced neck of femur fractures.[1] While the best method for implanted prosthesis fixation remains controversial, cement fixation of the femoral stem prosthesis with polymethyl methacrylate (PMMA) has been deemed superior, and cement use is therefore justified, in that it offers better long term viability, reduction in post-operative pain, and improved post-operative mobility, with quicker return to baseline function.[2-6]

Bone cement implantation syndrome (BCIS) is a well described complication of cemented arthroplasty.[9] It is associated with a series of characteristic clinical features, including a drop in systolic blood pressure >20 % from baseline, moderate hypoxia with oxygen saturation <94%, unexpected loss of consciousness, cardiovascular collapse requiring cardiopulmonary resuscitation, and, in some cases, death.[3,10] These can occur at the time of cement and prosthesis insertion, joint manipulation, or deflation of limb tourniquet, if used.[7]

The seminal classification of BCIS by Donaldson et al. grades the syndrome according to severity, as follows:[3]

- Grade 1: Moderate hypoxia (SpO_2 <94%) or a decrease in systolic arterial pressure >20%
- Grade 2: Severe hypoxia (SpO_2 <88%) or a decrease in systolic arterial pressure >40% or unexpected loss of consciousness
- Grade 3: Cardiovascular collapse requiring cardiopulmonary resuscitation.[3]

Severe grade BCIS would constitute grade 2 or 3.[11]

Olsen et al. reported the total incidence of BCIS, irrespective of grade, to be 28%, with incidences of grade 1, grade 2, and grade 3 to be 21%, 5.1% and 1.7% respectively.[11] A recent single centre study reported a day-of-surgery mortality rate to be 0.67%.12 In a large study, Pripp et al. demonstrated that 58% (95% CI 28% – 76%) of perioperative mortalities in the surgical

management of hip fractures were associated with cement use.[13] A retrospective review by Hossain et al. concluded that the 48 hour perioperative mortality following cemented hemiarthroplasty is around 1% (p<0.001), with an increased risk of perioperative death in cemented implant insertion, as compared to uncemented implant insertion.4 A further comparative between cemented and uncemented patients undergoing hemiarthroplasty by Olsen et al. showed that 28% of patients had symptoms of hypotension and hypoxia in the cemented group, versus 17% in the uncemented group (p=0.003). Furthermore, 7% of patients in the cemented group developed severe symptoms versus zero patients in the uncemented group(p=0.003).14 BCIS has been reported in as many as 74% (95% CI, 69.5% – 78.6%) of cancer patients following cemented arthroplasty, with occurrence of grade 1, 2, and 3 being 62.5%, 11%, and 0.5% respectively.[15]

Independent pre-operative risk factors for the development of BCIS, studied in high income countries, are reported to be increased age, American Society of Anaesthesia (ASA) scores of ≥3, chronic obstructive pulmonary disease or other pre-existing lung disease, medication with diuretics and warfarin, osteoporosis, pre-existing pulmonary hypertension, significant cardiac disease, and cancer, specifically pulmonary metastasis.[7,11,15] Surgical risk factors implicated include the use of long stem femoral prosthesis, having generated higher intermedullary pressures, pathological fractures, and intertrochanteric fractures.[7]

The etiology and pathophysiology of BCIS are not fully understood. Proposed theories exist for the mechanism of the syndrome. The embolic theory, which is most commonly accepted, suggests that during cementation, intramedullary contents such as bone fragments, fat, and fragments of PMMA, under pressures greater than 300mmHg as cement expands in the canal, are potentially forced into the systemic circulation, causing embolization of debris into the pulmonary vasculature.[7,16] The resultant mechanical damage to the vascular endothelium triggers vasoconstriction and inflammatory mediator release, as well as immune mediator release.[3] The ventilation/perfusion mismatch that ensues causes hypoxia, and the raised pulmonary vascular resistance leads to right ventricular dysfunction and circulatory collapse.[3] A case report of a patient undergoing cemented hemiarthroplasty, demonstrated, via transoesophageal echo, the presence of embolic mass from the main pulmonary artery to the inferior vena cava during circulatory collapse and cardiac arrest.[17] Emboli with significant pulmonary shunting have been demonstrated in 93% of patients with cement use.[18] However, not all patients develop clinically significant symptoms, which supports the theory that baseline characteristics may play a role in the ability of a patient to tolerate the embolic load produced during cementation. Post mortem findings have been able to demonstrate the presence of bone marrow elements in pulmonary vasculature, as well as adherent to endocardium, hepatic, and renal vasculature.[19] A less favoured theory suggests a type 1 hypersensitivity reaction to PMMA.[3] Higher concentrations of plasma histamine have been reported in patients with PMMA use.[20] However, due to similar clinical features, differentiation between the two theories is difficult in practice.

Anaesthetic strategies to prevent BCIS start with identification of the at risk patient, via a careful pre-operative assessment.[21] Risk factors which have been deemed to be significant should raise a red flag, triggering a high index of suspicion for the development of BCIS.

Intravascular optimization, via goal-directed therapy, has been shown to reduce perioperative mortality and shorten hospital stay.[22,23] However, it has little bearing on the grade of BCIS that ensues.[24]

Surgical strategies to prevent BCIS include intramedullary lavage, drying of the femoral canal, and ensuring adequate hemostasis prior to cementing.[3,7,25] Techniques such as cement gun use, and drilling of a distal venting hole results in a more even distribution of pressure and release of excessive pressure, reducing potential for embolization.[8,11]

Scope

While the incidence of the different grades of BCIS ranges significantly in the literature, to our knowledge, a study has not been performed to determine the incidence of the syndrome, as classified by Donaldson et al., in a South African setting.[3] Exploring the incidence in an LMIC, as well as comparing whether similar or different risk factors exist in LMIC populations as compared to HIC populations, will allow for refinement of peri-operative risk stratification and ultimately prevention of morbidity and mortality. This study therefore aimed to answer the following:

- What is the overall incidence and incidence of each grade of BCIS in a LMIC country and is this comparable to HIC?
- What independent pre-operative factors exist that may lead to the development of any grade of the syndrome in a LMIC population, and are these similar to those identified in HIC?
- Is the cumulative presence of factors deemed independently significant associated with an increased likelihood of severe grade BCIS?

Ethics approval

The study was approved by the University of KwaZulu-Natal Bioethics Research Ethics Committee. (Ref No. BE451/17)

Methods

Data Collection

A retrospective chart review was conducted. The review analyzed all consecutive adult patients undergoing cemented arthroplasty between January 2016 and July 2017 at Addington Hospital, KwaZulu-Natal, South Africa. Inclusion criteria was any patient undergoing cemented arthroplasty. Patients undergoing uncemented procedures, and those with incomplete medical and anaesthetic records were excluded.

Demographic information (age, gender), date of presentation, date of surgery, medical history and date of discharge were collated. Anaesthesia charts were reviewed for type of anaesthesia and ASA rating.

Blood pressure and oxygen saturation recordings were noted at three points: [1] prior to delivery of anaesthesia (baseline), [2] the lowest reading following cement implantation, and [3] the lowest reading post completion of surgery. Points [2] and [3] were then compared to point [1], and a percentage decrease from baseline readings was calculated. Documentation of circulatory collapse, resuscitative efforts, and outcomes were captured. This allowed for a classification of BCIS, as per the criteria outlined by Donaldson

et al., as well as a calculation of overall incidence and incidence of each individual grade of BCIS.

Factors identified in the patient records included age >65, ASA grade, gender, HIV status, hypertension, diabetes, cardiovascular disease, previous cerebral ischaemia, previous myocardial ischaemia, cardiac failure, pre-existing lung disease, renal failure (defined as a creatinine >150mmol/L or documented renal failure), impaired liver function tests, history of previous cancer, cerebellar disease, and thyroid disease. Once identified, these were compared to the occurrence of BCIS. Furthermore, those deemed independently significant were collated and assessed for a relationship between the cumulative risk score and the grades of BCIS.

Records of patients who died during the perioperative period were analyzed for identified risk factors, grade of BCIS, first warning sign following cementation, resuscitative efforts, outcomes, and post-mortem findings.

Statistical Analysis

Descriptive statistics were used to summarize demographic and clinical characteristics of the patients. Incidences were calculated as a percentage of total study population, and means were reported using two standard deviations.

Logistic regression reporting odds ratios (Chi-squared test) was performed with BCIS as the primary outcome to compare the presence of individual baseline characteristics and potential risk factors.This was done to determine whether an independent relationship existed between the various factors and the development of BCIS. A p value of ≤0.05 was considered statistically significant. Factors deemed significant on a univariate level were then combined to form a risk score. A Kruskal-Wallis-H test was conducted to determine if the cumulative risk score was different in the four grades of BCIS. Each grade of BCIS was then assessed for mean number of risk factors. Stata version 15 was used to analyze the data.

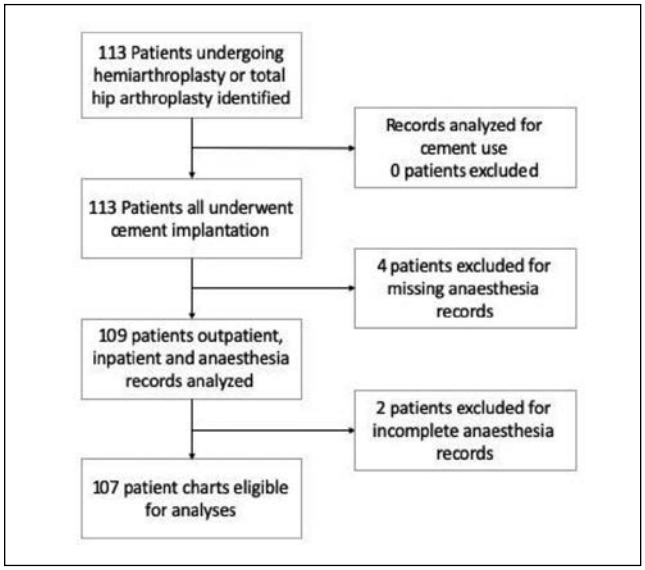

Figure 1. CONSORT diagram showing recruitment of patients.

Results

The medical records of 113 patients were reviewed. 107 patients were included, as per the consort diagram. (Figure 1)

The total incidence of BCIS of all grades was 45.79% (49/107). The incidence of BCIS grade 1, 2, and 3 were 34.58%, 5.61% and 5.61% respectively. A total of 5/107 (4.67%) were on-table deaths.

The baseline characteristics of patients presenting for cemented arthroplasty are presented in Table 1. The mean age of patients presenting for cemented arthroplasty was 72.98 years (±11.29), and 87 (81.30%) patients were 65 years or older. With regard to sex, 65 patients were female (60.75%) and 42 were male (39.25%).

Table 1. Baseline characteristics and Logistic regression reporting odds ratios, with BCIS as primary outcome.

Baseline	n (%)	No BCIS	BCIS	Odds Ratio, 95% CI	p-value
Gender					
Male	42 (39.25%)	23	19	0.96 (0.44 – 2.10)	0.93
Female	65 (60.75%)	35	30	1.03 (0.48 – 2.26)	0.93
Age					
≥65	87 (81.31%)	45	42	1.73 (0.63 – 4.76)	0.27
<65	20 (18.69%)	13	7		
ASA					
≥3	28 (26.17%)	7	21	5.46 (2.06 – 14.43)	0.0003
1-2	79 (73.83%)	51	28		
Hypertension					
Yes	72 (67.29%)	33	39	2.45 (1.24 – 7.03)	0.012
No	35 (32.71%)	25	10		
Cardiovascular Disease	5 (4.67%)	1	12	8.48 (2.30 – 48.20)	0.0001
Yes	102 (95.33%)	57	37		
No					
Previous Myocardial Ischaemia					
Yes	19 (17.76%)	1	18	33.09 (14.21 – 59.89)	0.001
No	88 (82.24%)	57	31		
Cardiac Failure					
Yes	5 (4.67%)	1	4	5.06 (0.54 – 46.92)	0.11
No	102 (95.33%)	45	57		
Diabetes					
Yes	37 (34.60%)	16	21	1.96 (0.88 – 4.41)	0.98
No	70 (65.42%)	42	28		
Pre-existing lung disease					
Yes	9 (8.41%)	3	6	2.56 (0.80 – 10.8)	0.19
No	98 (91.59%)	55	43		
Renal Impairment					
Yes	19 (17.76%)	3	16	8.89 (2.40 – 32.8)	0.001
No	88 (82.24%)	55	33		
Liver impairment					
Yes	5 (4.67%)	2	3	1.82 (0.29 – 11.40)	0.51
No	102 (95.33%)	56	46		
Cancer history					
Yes	3 (2.80%)	1	2	2.42 (0.21 – 27.59)	0.46
No	104 (97.20%)	57	47		
Cerebellar disease					
Yes	1 (0.09%)	0	1	1 (omitted)	-
No	106 (99.01%)	58	48		
Thyroid Disease					
Yes	2 (1.87%)	1	1	1.18 (0.07 – 1.90)	0.90
No	105 (98.130	57	48		
HIV positive					
Yes	4 (3.74%)	3	1	0.38 (0.10 – 4.97)	0.39
No	103 (96.26%)	55	48		

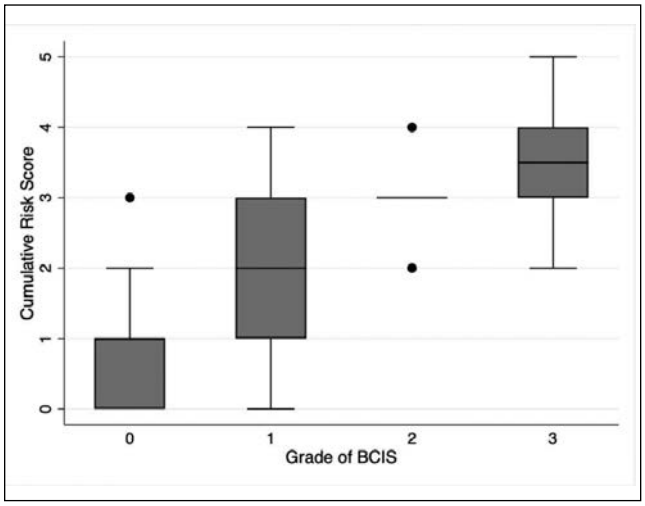

Figure 2. Box plot showing cumulative risk scores for grades of BCIS.

A total of 29 patients (27.10%) had an ASA classification ≥3. A total of 13 baseline medical factors along with age ≥65, gender and ASA classification ≥3 were accepted for analyses. The mean delay to surgery was 5.21 (±2.95) days, and the mean post-surgical days in hospital was 4.20 (±3.30) days. A total of 4 patients underwent general anaesthesia and the remaining underwent regional anaesthesia, with the mean intrathecal dose of 0.5% bupivacaine being 2.31 mL (±0.33 mL).

The results of the logistic regression reporting odds ratios with BCIS of any grade as the primary outcome are displayed in Table 1. Of the 16 analyzed characteristics, a total of 5 factors have been shown to be statistically significant for the development of BCIS. These are ASA ≥3 (OR 5.46, 95% CI 2.06 – 14.43, p = 0.0003), hypertension (OR 2.45, 95%CI 1.24 – 7.03, p 0.012, previous cerebral ischaemia (OR 8.48 95%CI 2.3- - 48.20, p = 0.0001), previous myocardial ischaemia (OR 33.09 95%CI 14.21 – 49.98, p = 0.001), and renal impairment (OR 8.89 95% CI 2.40 – 32.8, p = 0.001).

The 5 identified independent risk factors were further analyzed for their cumulative relationship with the various grades of BCIS. A Kruskal-Wallis-H test showed that there was a statistically significant difference in the cumulative risk scores between the 4 groups, $\chi 2$ (2) = 39.13, p = 0.0001. The mean cumulative risk scores for no BCIS, grade 1, 2, and 3 were 0.77 ± 0.75, 1.81 ± 1.15, 3.0 ± 0.63, and 3.5 ± 1.05 respectively. The minimum, median, and maximum risk scores for each grade of BCIS are represented in Figure 2.

A total of 8 peri-operative deaths occurred. The all cause peri-operative mortality was therefore 8.41%, with 6 (5.6%) deaths being related to grade 3 BCIS. There were 5 on-table deaths, 1 death on day 2 post-surgery in ICU, and 2 deaths on day 1 post-surgery in the ward. A summary of their peri-operative course is displayed in Table 2. Of the 5 on-table deaths, 4 were over the age of 65, and 4 displayed significant pre-operative comorbidities, including hypertension, previous myocardial ischaemia, previous cerebral ischaemia, and renal impairment. All 5 patients were classified as ASA ≥3. There were 5 patients who developed circulatory collapse at the time of cement and femoral stem insertion and 1 at the time of wound closure. First warning signs included a drop in oxygen saturation, confusion, and a decrease in blood pressure. While all patients received appropriate resuscitative efforts, only 1 patient was successfully resuscitated and admitted to ICU. However, she died on day 2. A post-mortem performed on two of the patients reported multiorgan failure as a cause of death. The other patients did not receive post-mortems.

Discussion

To our knowledge, a study investigating the incidence of BCIS, and grading according to Donaldson et al. had not yet been done in a South African setting.[3] The results indicate that grade 1 BCIS is common, with grade 2 and grade 3 occurring less commonly.

The incidence of BCIS varies greatly across the literature. A similar study conducted by Olsen et al. reported the total incidence of BCIS, irrespective of grade to be 28%, with incidences of grade 1, grade 2, and grade 3 to be 21%, 5.1%, and 1.7% respectively.[11] This study showed the total incidence of BCIS to be 45.79%, with grade 1 and grade 3 BCIS occurring in 34.58% and 5.60% of the study population, respectively. These are significantly higher than the incidence reported by Olsen et al. This study reported a similar incidence of grade 2 BCIS of 5.60%. The mortality rate following the development of grade 3 BCIS was 5.60% and is significantly higher than the on-table mortality rate of 0.26% reported by Tan et al.[12] The possible reasons for a higher incidence in this study are three-fold: firstly, Olsen et al.'s study population was ten-fold higher than this study population. Secondly, all arthroplasty performed by the institution in this study utilized cement. In other institutions, consideration to offer patients non-cemented arthroplasty would have resulted in patients at risk of BCIS being selected out of the study population, therefore reducing the incidence of all grades of BCIS, particularly, the incidence of the higher grades of BCIS. This can be further substantiated in more recent work by Olsen et al., which demonstrated that 28% of patients undergoing cemented arthroplasty developed symptoms of hypotension and hypoxia, versus 17 % in the uncemented group, with 7% of patients developing severe symptoms, compared to 0% in the uncemented group.[14] Finally, the hospital in this study is a regional hospital in a LMIC, which would cater for patients with significant risk factors, and a proportion of low risk patients may have been managed at the district hospital level.

Independent pre-operative factors that have been shown to increase the incidence of BCIS in this study include ASA score ≥3, hypertension, previous cerebral ischaemia, previous myocardial ischaemia, and renal impairment. Similarly Olsen et al. have reported ASA score of 3 or 4 as an independent risk factor for high grade BCIS.[11] This demonstrates that similar risk factors exist for the development of BCIS in HIC and LMIC population groups.

Cardiac disease has been reported as a risk factor by Olsen et al., and substantiates the association of hypertension and previous myocardial ischaemia found in this study.[14] Two known mechanisms for peri-operative myocardial infarction are acute coronary syndrome and imbalanced supply-demand relationships in patients with long-standing coronary artery disease.[26] Patients with hypertensive disease or previous myocardial ischaemia would be intolerant of sudden changes in hemodynamics. Qi et al. demonstrated significant changes in haemodynamics during cementation, with decreases in systolic blood pressure

Table 2. Baseline characteristics and Logistic regression reporting odds ratios, with BCIS as primary outcome

Patient	Age/ Sex	On table death	Delay to surgery	Risk score	Significant co-morbid illness	Anaesthesia	Preceding event	First warning sign	Resuscitation	BCIS Grade	Post-mortem
1	63 Male	yes	5 days	4	HTN, CVI, CF, COPD, renal/liver impairment, cerebellar disease	Spinal1.8ml 0.5% bupivacaine + 10mcg fentanyl	Cement and Femoral stem insertion	Decrease in SpO_2, confusion	IV fluids, Intubation, CPR, vasopressor inotropes	3	Multi-organ failure
2	71 Female	yes	9 days	3	HTN, previous MI, DM	CSE: 1ml spinal 0.5% bupivacaine + 9ml epidural 0.5% bupivacaine	Cement and Femoral stem insertion	Decrease in SpO_2	IV fluids, intubation, CPR vasopressor inotropes	3	Not done
3	77 Female	yes	5 days	2	HTN	Spinal: 2.6ml 0.5% bupivacaine	Cement and Femoral stem insertion	Decrease in SpO_2, decreased LOC	IV fluids, vasopressor	3	Not done
4	90 Female	yes	8 days	4	HTN, previous MI, DM, COPD, RF	Spinal: 2.5ml 0.5% bupivacaine	Wound closure	Decreased blood pressure	IV fluids, vasopressor	3	Not done
5	91 Female	no	1 day	1	Nil	Spinal: 2ml 0.5% bupivacaine	n/a	n/a	found unresponsive in ward day 1 post op	0	Not done
6	80 Female	no	2 days	2	HTN, previous CVA	Spinal: 1.8ml 0.5% bupivacaine + 2.5mcg sufentanil	n/a	n/a	No: found unresponsive in ward day 1 post op	2	Not done
7	84 Male	no	1 day	3	HTN, CVS disease, DM, RF	Spinal: 2.2ml 0.5% bupivacaine	n/a	Increasing inotrope requirements	Yes: IV fluids, inotropes Demised day 2 ICU	3	Multi-organ failure
8	78 Female	yes	3 days	3	HTN, CVS disease, previous MI, CF	Spinal: 2.2mls 0.5% bupivacaine	Cement and femoral stem insertion	Decrease in SpO_2 and LOC	IV fluids, inotropes	3	Done – report lost

Hypertension (HTN), Cerebrovascular Ischaemia (CVI), Cardiac failure (CF), Chronic obstructive pulmonary disease (COPD), Myocardial Ischaemia (MI), Diabetes Mellitus (DM), Renal Failure (RF), Combined Spinal Epidural (CSE), Loss of consciousness (LOC), Intravenous (IV), Cardiopulmonary resuscitation (CPR)

of 10-20mmHg and Clark et al. demonstrated a 33% transient reduction in cardiac output during cementation.[9,10] It is therefore understandable why hypertensive disease and previous myocardial ischaemia may increase the risk for BCIS. Previous cerebral ischaemia, identified as a significant factor in this study, has not been analyzed in similar research. Since hypertension is a known risk factor for the development of cerebral ischemia, the apparent link to the development of BCIS may be due to the underlying hypertensive vascular disease.[27] Renal impairment, identified as an independent risk factor in this study, was also identified as an independent risk factor in a more recent study by Olsen et al.[14]

Despite the large burden of disease that HIV disease places on LMIC populations, no significant higher risk for the development of BCIS was identified in the HIV positive patients, as compared to the HIV negative patients.

To our knowledge, no other study exists investigating the relationship between cumulative risk factors and grade of BCIS. We report a statistically significant difference between the cumulative number of independent risk factors and the grade of BCIS, with a significantly greater mean number of risk factors being present for the more severe grades of BCIS, that being 3 and 3.5 for grades 2 and 3 respectively. The Association of Anaesthetists of Great Britain and Ireland recommend a three-stage process to reduce the incidence of morbidity and mortality associated with BCIS. Their process aims to identify patients that are at high risk for cardiorespiratory compromise.[21] Our findings suggest that patients with a risk score ≥ 3 would significantly increase the risk for the development of grade 2 and 3 BCIS. This finding supports the safety guidelines outlined by Griffiths et al., allowing for appropriate identification of patients at risk for the development of grade 2 and 3 BCIS, assessment of the appropriateness and necessity for cement use, as well as preparation for the prevention and management of the syndrome, should it occur. It aids in appropriate planning for post-operative placement and monitoring of these patients, by pre-operatively securing high dependency facilities.

Limitations

The study was conducted in a district hospital, in a low to middle income country, South Africa. This therefore limits the generalizability of the results. Due to the retrospective study design, data collection was limited to existing data in medical records. Absent data regarding surgical techniques could therefore not be considered. Moreover, anaesthesia provider- and surgeon-related factors such as case volume or experience were not taken into account. Post-mortems are not consistently performed. This study has been limited by its small scale and cohort of patients. Finally, by virtue of the hospital being regional in nature, expected well patients may have been managed at district level, and their outcomes therefore not included in the study.

Recommendations

It is recommended that larger multicentre studies be done in LMIC populations to validate the findings presented. Despite the limitations of this study, it is recommended that the risk score as described be used as a starting point for awareness of patients at risk of developing BCIS, such that they can be appropriately risk stratified.

Conclusion

This study reported the incidence of the various grades of BCIS, and the risk factors associated with the development of BCIS in patients undergoing cemented arthroplasty at a single centre in KwaZulu-Natal, South Africa. This study also reported that cumulative risk factors increase the grade of BCIS that occurs. Grade 1 and grade 3 BCIS occurred more commonly in our institution than in the reported literature. Significant pre-operative factors for the development of BCIS are hypertension, previous myocardial or cerebral ischaemia, renal impairment, and ASA score ≥3. These are noted to be consistent with findings in high income countries.

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