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General anesthesia and femoral nerve block versus spinal anesthesia for cemented hip arthroplasty in elderly patients: A randomized controlled trial

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ABSTRACT

BACKGROUND: Traumatic femoral fractures are a prevalent orthopaedic issue in elderly adults. General anaesthesia (GA) vs. spinal anaesthesia are still being discussed as the best anaesthetic method for cemented hip arthroplasty (SA). This study compared the impact of spinal anaesthesia versus general anaesthesia in combination with femoral nerve block on the mean arterial blood pressure (MAP) in patients having cemented hip arthroplasty operations.

AIM OF THE STUDY: To compare the impact of spinal anaesthesia on elderly patients undergoing cemented hip arthroplasty operations versus general anaesthesia in combination with femoral nerve block on mean arterial blood pressure.

PATIENTS AND METHODS: The study was registered at Pan African-Clinical Trial Registry.org with ID of (PACTR 202,111,575,647,784). At Ain Shams University Hospital, 60 patients receiving total hip arthroplasty were separated into two equal groups, each comprising 30 patients, for the purpose of this prospective randomised comparison study. Patients in Group (A) underwent spinal anaesthesia, while Group (B) received general anaesthesia together with an ultrasound-guided femoral nerve block.

RESULTS: This study showed that GA was associated with more stable readings of mean arterial blood pressure (MAP) after anesthesia induction and post cement implantation than SA (p-value = 0.04 and 0.038 respectively).

CONCLUSION: Patients who received general anesthesia (GA) had more stable hemodynamic parameters especially the mean arterial blood pressure (MAP) than those who received spinal anesthesia (SA).

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General anesthesia; spinal anesthesia; mean arterial pressure; Hip arthroplasty

1. Background

Elderly patients suffering from fracture femur usually have many age related physiological changes that can lead to hemodynamic instability [1].

The anesthetic management of such elderly patients undergoing hip arthroplasty, whether by general anesthesia (GA) or spinal anesthesia (SA) can dramatically enhance the perioperative results [2]. Many authors favoured the choice of GA as an anesthetic choice, providing more stable hemodynamics. Regional nerve block when combined with GA can provide more perioperative cardiovascular stability and better pain control [3,4].

On the other hand, numerous studies strongly support choosing SA over GA as it allows evaluation of mental status and dyspnea during arthroplasty [5]. However, this should be weighed against the need for a secured airway in the event of bone cement implantation syndrome (BCIS) [6].

Several causes, including the systemic absorption of methyl methacrylate, high pressure during cementing, fat and marrow embolism, exothermic reaction, allergic reaction, and release of endogenous mediators such histamine, have been proposed as explanations for BCIS [7].

AIM OF THE WORK: To compare the impact of spinal anaesthesia on elderly patients undergoing cemented hip arthroplasty operations versus general anaesthesia in combination with femoral nerve block on mean arterial blood pressure.

2. Materials and methods

At the hospitals affiliated with Ain Shams University, this prospective, randomised, comparative clinical study was carried out. As soon as the study received approval from Ain Shams University's Research Ethics Committee (FMASU MD92/2021), the study was registered at Pan African-Clinical Trial Registry.org with ID of (PACTR 202,111,575,647,784). A computer-generated random numbers table was used, a total of 60 patients were divided equally into two groups (group A and group B). Each group included 30 patients by block randomization method. Investigators were blinded, recording the intraoperative monitoring data and complications was done by a doctor not involved in

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the induction of anesthesia and ata was statistically analysed by a doctor who did not knew about the type of anesthesia in each group.

3. Patients selection criteria

Inclusion Criteria

a-Aged≥65 years old.

b- Patients scheduled for cemented hip arthroplasty for fracture femur.

Exclusion Criteria

a-Major spine deformities or multiple fractures.

b-Myopathy or coagulopathy.

c-Pre-operative cognitive dysfunction.

d-Chronic obstructive pulmonary disease with or without pulmonary hypertension with estimated right ventricular systolic pressure (RVSP) > 45 mmHg.

e-Renal dysfunction.

f-Known allergy to use medication or infection at the site of injection.

4. Sample Size calculation

Using PASS11 program, setting power at 80%, alpha error (α) at 5%, reviewing previous relevant study results Messina et al. [1] mentioned statistically significant differences when comparing general anesthesia (GA) group and spinal anesthesia (SA) group regarding the intra operative hemodynamics measured (20 minutes after starting surgery) as mean arterial blood pressure (MAP) was 97 ± 20 among SA group vs 78 ± 14 among GA group. These results indicate 30 patients per group are required for a sample size.

5. Study procedure

All patients were assessed preoperatively both clinically and by necessary investigations and were taught about Clock drawing test (CDT) to assess the cognitive function integrity [8], it is done by giving the patient a piece of paper with a pre-drawn circle on it and asking him to draw the numbers on the clock, then telling him to draw the hands to show a specific time, and giving one point if the task was completed correctly and zero points if the clock was not completed correctly. The patients were informed of the anaesthetic plan and were asked to sign a formal consent. In the operating room, a wide bore intravenous access was inserted, all patients were given 250 ml of crystalloid slowly intravenous and were fully monitored by non-invasive blood pressure, Echocardiogram (ECG), and pulse oximetry, capnogram for general anesthesia group, and urinary output (UOP). Group (A) Patients received GA combined with ultrasound guided femoral nerve block. GA induction was by preoxygenation, intravenous injection of Fentanyl 2 µg/kg, Propofol 1–2 mg/kg titration slowly to loss of verbal response, and rocuronium 0.6 mg/kg, then endotracheal intubation. Femoral nerve block was done under complete aseptic technique, the femoral nerve was visualized using a linear ultrasound probe (8–15 HZ) (Sonosite, M-Turboc, Global technology) placed on the femoral crease to view the femoral vessels and nerve as shown in Figure (1). An echogenic needle of 22 Gauge and 10 cm length was used to inject local anesthetic in plain from lateral to medial orientation.15 mL (75 mg) of 0.25% bupivacaine (sunnypivacaine, Sunny pharmaceutical, Egypt) was injected around the femoral nerve after a negative aspiration test.

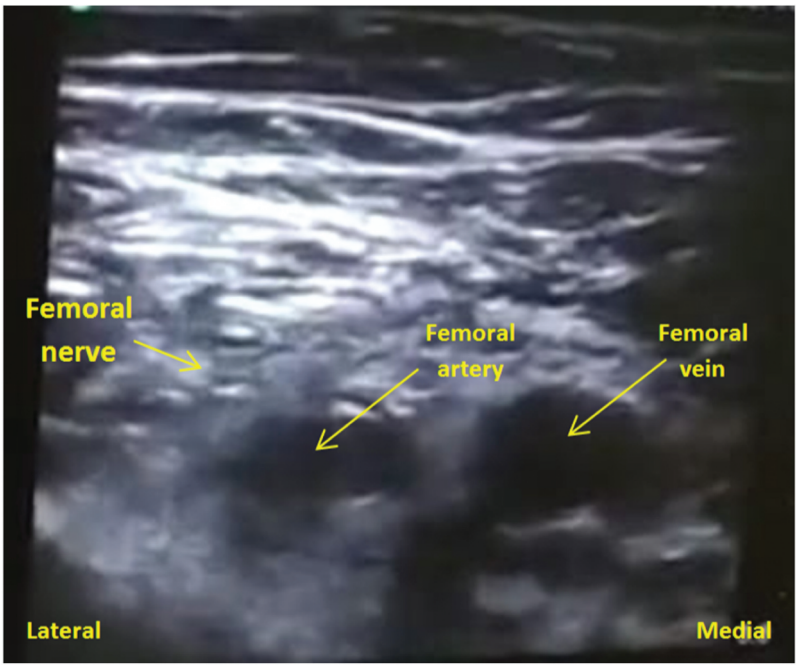

Figure 1. Ultrasound view of the femoral neuro vascular bundle.

Group (B) patients received SA, a 25-gauge Quincke spinal needle was used while the patient in the sitting or lateral position a total volume of 2.5 ml (12.5 mg) of 0.5% hyperbaric bupivacaine (sunnypivacaine, Sunny pharmaceutical, Egypt) was injected intrathecally under complete aseptic technique. Patients provided supplemental oxygen by nasal prongs. All patients of group (B) were assessed for spinal block progression and complications by checking the sensory block with pin prick test to ensure that the spinal block level was adequate for the surgery procedure (at T10). All patients were moved to PACU at the end of surgery and were followed for 24 hours postoperatively. Any undesired events and complication were recorded and managed according to international and local guidelines. All the patients were followed by:

(1) MAP (presented as mmHg) as a primary outcome, which was recorded after induction of anesthesia, pre-cement, and post-cement implantation.
(2) Heart rate (presented as beat/min) was recorded after induction of anesthesia, pre-cement, and 10 minutes after cement implantation.
(3) Mean hourly UOP (presented asml/hr) was measured for 24 hours preoperatively and for 24 hours postoperatively.
(4) Serum creatinine (presented as mg/dl) was measured preoperative and 24 hours postoperatively.
(5) CDT for cognitive function preoperative and 24 hours postoperatively.

6. Statistical analysis

Data were analyzed using Statistical package for Social Science (SPSS) version 22.0, Quantitative data were expressed as mean ± standard deviation (SD) or Median, and interquartile range (IQR) when indicated. Qualitative data were expressed as frequency and percentage.

The following tests were used:

Independent-samples t-test of significance was used when comparing between two means. Chi-square (X2) test of significance was used in order to compare proportions between two qualitative parameters. Mann Whitney U test: for two-group comparisons in no

n-parametric data. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: Probability (p-value). p-value ≤0.05 was considered significant. p-value ≤0.001 was considered as highly significant. p-value >0.05 was considered non-significant.

7. Results

In this randomised comparison study, 60 patients with cemented total hip arthroplasty were included and splited equally into two groups, 30 patients in each group: Patients in Group A had GA along with an ultrasound-guided femoral nerve block, while those in Group B received SA as shown in Figure (2).

Regarding demographic data and patient characteristics (in terms of age, sex, and ASA), no statistically significant differences was observed between the 2 groups (*p*-value>0.05) (Table 1).

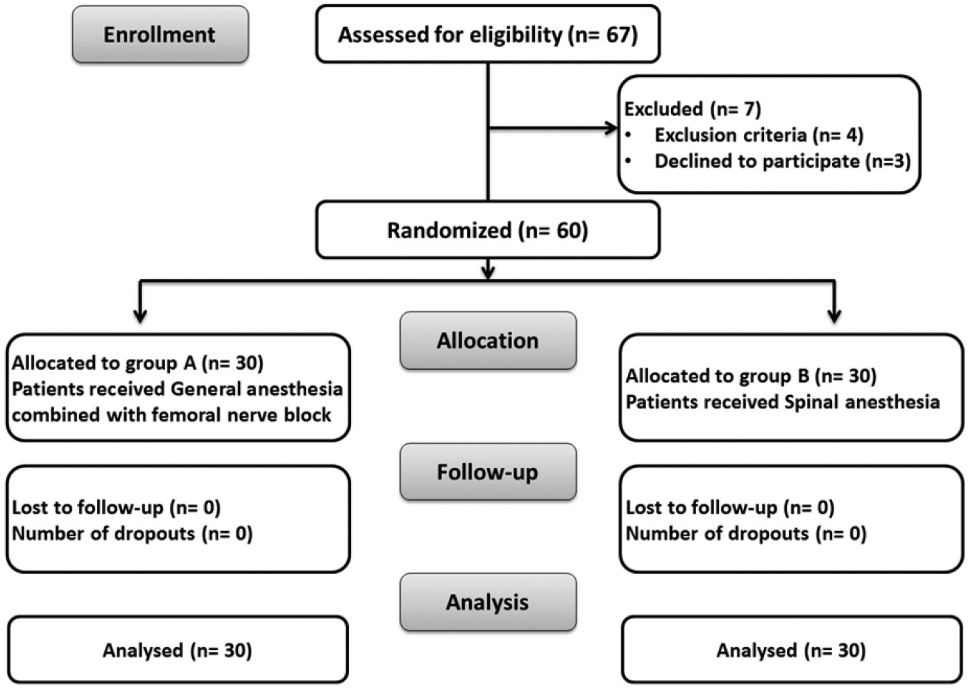

Figure 2. Consort flow diagram.

After induction and after cement installation, mean arterial blood pressure (MAP) decreased more in group B than in group A (*p*-value 0.05), although no statistically significant difference was observed before cement insertion (p-value > 0.05) (Table 2).

No statistically significant differences was observed between both groups as regards renal function which was assessed by the total urine output (UOP) (presented as ml/hr) per operative and postoperative in first and second days, and the serum creatinine measured once preoperatively and 24 hours postoperatively (*p*-value > 0.05) (Table 3).

When post-operative cognitive function was compared between the two groups using the clock drawing (CDT) test before and after surgery (*p*-value > 0.05), no statistically significant difference was observed (Table 4).

In terms of mortality, no statistically significant differences were observed between the two groups (*p*-value > 0.05) (Table 5).

No other complication was observed in the two study groups.

8. Discussion

In this study, GA was associated with more stable readings of MAP after induction of anesthesia compared to SA. This could be explained by loss of sympathetic outflow that happens with SA with a subsequent decrease in the systemic vascular resistance, venous return, and cardiac output. In addition, loss of blood vessel wall elasticity with age could cause limitation of cardiovascular compensation [9].

Following cement implantation, a significant decrease in MAP was observed in SA group patients (mean ± SD = 69.60 ± 17.1) when compared to pre-cement implantation (mean ± SD = 79.90 ± 7.5). This could be explained by the loss of sympathetic response to histamine release following the application of cement as suggested by Messina et al. [10]. Additionally, White and Griffiths [11] assigned its cause to inhibition of adrenocortical response caused by SA, which interferes with cardiovascular compensation mechanisms in response to hypotension resulting from the histamine release.

These results agree with those of Svartling et al. [12] who documented that spinal anesthesia was linked to a drop in blood pressure with the use of methyl methacrylate in patients with femoral neck fracture. Also, Whiting et al. [13] demonstrated that SA for hip fracture surgery was associated with significant complications compared to GA. Messina et al. [1] demonstrated that MAP in the elderly was lower than baseline after induction of SA for hip fracture operations. Conversely, Khanna et al. [14] demonstrated the lack of effect of anesthesia type on the severity of BCIS. Griffiths et al. [15] in their 2020 guidelines for hip fractures management in patients above 65 years of age suggested that careful delivery of anesthesia is more important than the type of anesthesia delivered. Their opinion is supported by White et al. [16] 2016 who suggested that mortality is not related to type of anesthesia

Table 1. Comparison of groups based on demographic information.

Demographic information		(A) group (*n* = 30)	(B) group (*n* = 30)	*p*-value
Age (years)		69.77 ± 4.6	70.30 ± 3.9	0.63
ASA	I	1 (3.3%)	2 (6.7%)	0.57
	II	21 (70%)	23 (76.7%)	
	III	8 (26.7%)	5 (16.7%)	
Sex	Male	10 (33.3%)	7 (23.3%)	0.39
	Female	20 (66.7%)	23 (76.7%)	

Data expressed as mean ± SD, proportion, A= general group, B= Spinal group.

Table 2. Comparison of the MAP between groups.

Hemodynamics	A group (*n* = 30)	B group (*n* = 30)	*p*-value
MAP after induction of anesthesia (mmHg)	86.90 ± 19.6	77.70 ± 13.5	0.038*
MAP pre cement insertion (mmHg)	85.17 ± 16.4	79.90 ± 7.5	0.12
MAP post cement insertion(mmHg)	78.57 ± 16.7	69.60 ± 17.1	0.04*

Data expressed as mean ± SD, A= general group, B= Spinal group.

Table 3. Comparison of renal function data between groups.

	(A) group (*n* = 30)	(B) group (*n* = 30)	*p*-value
Uop preoperative (ml/hr)	84.00 ± 24.3	83.33 ± 24.0	0.92
Uop at 1st 24 hrs post-operatively (ml/hr)	68.00 ± 24.6	75.86 ± 25.4	0.23
Creatinine preoperative	0.98 ± 0.3	1.04 ± 0.5	0.56
Creatinine 24hrs post-operatively	1.36 ± 0.5	1.36 ± 0.8	0.96

Data expressed as mean ± SD, A= general group, B= Spinal group.

Table 4. Comparison of conscious level between groups.

	(A) group ($n = 30$)			(B) group ($n = 30$)			
	Range	Median	IQR	Range	Median	IQR	*P*-value
CDT pre-operative	0–1	1	1–1	0–1	1	1–1	0.64
CDT 24hrs post-operatively	0–1	1	1–1	0–1	1	1–1	0.44

Data expressed as median and IQR, A= general group, B= Spinal group.

Table 5. Comparison between groups as regard mortality.

	(A) group ($n = 30$)	(B) group ($n = 30$)	*p*-value
Mortality	0 (0%)	2 (6.7%)	0.15

Data expressed as, proportion, A= general group, B= Spinal group.

but increase with fall in blood pressure. Whilst Wesselink et al. [17] found that GA is commonly associated with intraoperative hypotension which affects organ perfusion in non-cardic surgeries.

The incidence of acute kidney injury (AKI) showed no statistically significant difference between groups. This goes with Başkan et al. [18] who found that there was no difference between the anesthesia method applied in hip fracture surgery and the change in renal function of patients. Conversely, Kim et al. [19] found that spinal anesthesia has favourable outcomes on kidney function when compared to general anesthesia but the mechanism is unclear yet.

The postoperative cognitive dysfunction results between both groups showed no statistically significant difference in this study, which is in agreement with Neuman et al. [20], Li et al. [21] and Choi et al. [22] found that anesthesia type did not affect postoperative delirium. On the other hand, Shi et al. [23] found a significantly higher incidence of postoperative cognitive dysfunction in old patients who had hip replacement surgery under GA.

Two patients in the SA group developed cardiac arrest following cement implantation, and both of them died following failed resuscitation attempts. This observation was statistically non-significant due to the relatively small number of cases in the study. Neuman et al. [24] showed that there was no effect of both types of anesthesia on mortality rates 30 days postoperative. A retrospective analysis by Opperer et al. [25] of 90 days mortality between 2003 and 2011 in the UK mentioned that spinal anesthesia had a better outcome and illustrated that most studies showed lower mortality rates with SA.

At times of hemodynamic crisis following cement implantation, there is a need to institute resuscitation measures. In the lateral position, it is more challenging to ventilate and intubate patients [26]. General anesthesia poses theoretical advantages over SA in cemented hip arthroplasty as airway control, end tidal CO2 monitoring, controlling depth of anesthesia and preservation of sympathetic and adrenocortical response to hemodynamic stress, which is lost with SA [10,11].

9. Study limitation

We did not use invasive blood pressure monitoring in spite of it being more sensitive than non-invasive blood pressure in detecting blood pressure fluctuations, this is because old age patients have the possibility of systemic atherosclerosis and other comorbidities which may increase the risk of complications like arterial thrombosis and spasm.

10. Study recommendations

We recommend GA as an anesthetic technique of choice in elderly patients who undergoing cemented hip arthroplasty and more studies in this topic with higher sample size should be done to support this opinion.

11. Conclusions

Patients who received GA had more stable hemodynamic parameters especially the MAP than those who received SA.

Disclosure statement

No potential conflict of interest was reported by the authors.

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