

Combined Spinal Epidural Anaesthesia versus Spinal Anaesthesia with Clonidine for Hip Surgeries: A Randomized Comparative Study

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Abstract

Background: Surgeries for hip fracture are often time consuming. Both THR and Bipolar surgeries are usually performed under spinal anaesthesia or combined spinal epidural anaesthesia. These surgeries are often accompanied by several peri-operative morbidities like blood loss, post operative pain, nausea, vomiting, headache and post operative urinary retention. **Aim:** Aim of our study was to assess the intraoperative hemodynamic stability, blood loss, intra and postoperative analgesic requirement and intra and postoperative complications in the study groups. **Materials and Methods:** This study was conducted in tertiary care government hospital during the period of 2014-2016. In this prospective study after ethical committee approval, 60 patients being operated for elective hip surgeries were selected and randomly divided in two groups as Group A and Group B, 30 patients in each. All the patients were thoroughly examined, investigated and optimized for surgery. Group A Received combined spinal epidural anaesthesia. Spinal anaesthesia was given with Inj. Bupivacaine 0.5% (H) 3.5 cc+0.4 cc Normal Saline. Epidural top up was given to prolong duration of surgical anaesthesia with Inj. Bupivacaine 0.5% 4cc and for post operative analgesia with Inj. Bupivacaine 0.125% 8cc. Group B Received spinal anaesthesia with Inj. Bupivacaine 0.5% (H) 3.5cc+Inj. Clonidine 60µg. **Results:** In our study, Group B showed statistically significant fall in the pulse rate and blood pressure as compared to Group A ($P < 0.05$ statistically significant but clinically acceptable). The mean blood loss was found to be 586.6±58.6 ml in Group A while in Group B it was 495±49.7 ml (difference statistically significant). Group A had post-operative analgesia 185±110.9 mins and in Group B it was 399.9±103.8 mins. (statistically significant). The incidence of both intraoperative and postoperative complications in both the study groups was statistically not significant. **Conclusion:** The results of this prospective, randomized comparative study demonstrated that addition of clonidine to spinal anaesthesia provides hypotensive anaesthesia with acceptable hemodynamic parameters, with reduced blood loss, profound and prolonged postoperative pain relief. We conclude that the "spinal anaesthesia with clonidine" is a beneficial alternative for elective hip surgeries as compared to "combined spinal epidural anaesthesia".

Keywords: Regional Anaesthesia; Hip Surgery; Intrathecal Clonidine; CSE.

Introduction

Hip fractures include a majority of lower limb fractures and majority of these fractures occur in an elderly population. Hip fractures are now also increasing in middle age population more amongst males [1], due to increased incidence of road traffic accidents [2].

In the year 1990, around 1.7 million hip fractures have occurred world wide (WHO study group) [3]. Due to a combination of an increasingly elderly population and an increase in the age specific incidence, the number of hip fracture patients continues to rise. It has been predicted that global numbers of 6.26 million hip fractures will occur by the year 2050 [4]. (Melton 1993). The majority of these fractures are treated surgically, thus hip fracture surgery represents one of the most common

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Received on 10.08.2017, Accepted on 25.08.2017

emergency orthopaedic procedures. Hip fracture surgeries most commonly include THR (Total Hip Replacement) and Bipolar.

These surgeries for hip fracture are often time consuming. Both THR and Bipolar surgeries are usually performed under spinal anaesthesia or combined spinal epidural anaesthesia. These surgeries are often accompanied by several peri-operative morbidities like blood loss.

Clonidine is a mixed alpha-1 and alpha-2 adrenoceptor agonist with a predominant alpha-2 action (Liu N et al 1993) [5]. Clonidine has been used intrathecally as an adjuvant to spinal anaesthesia with the benefits of prolonged duration of action and a good post operative pain relief. Both combined spinal epidural anaesthesia and spinal anaesthesia with clonidine are effective techniques for controlling the blood loss and achieving a good post operative pain relief.

The hip surgeries like THR and Bipolar, pose a challenge to the anaesthesiologist both intraoperatively and postoperatively. The aim of this study is to compare the intra-operative and post-operative outcome after combined spinal epidural anaesthesia with that of spinal anaesthesia with clonidine in patients undergoing elective hip surgeries of THR and Bipolar.

Material and Methods

We studied 60 adult cases of ASA Grade I, II and III posted for elective hip surgeries of THR and Bipolar at our institute during the time period of year 2014 - 2016. Ethical committee approval was taken.

All the patients under the study underwent thorough pre anaesthetic evaluation including detailed case history, clinical examination and necessary investigations depending on age, sex, and disease of the patient and optimization was done.

Patients were divided randomly (by sealed envelope technique) in two groups as follows.

Group A: Elective Hip surgeries under "Combined Spinal Epidural Anaesthesia"

Group B: Elective Hip surgeries under "Spinal Anaesthesia with Clonidine".

Inclusion Criteria

Patients posted for Total Hip Replacement and Bipolar surgery, age group – 18 to 70 years, both Male and Female and ASA Grade – I, II and III

Exclusion Criteria

Patient refusal, Local infection at the site of lumbar puncture, patients with sensitivity to local anaesthetic drugs and patients with bleeding disorders.

The procedure plan was explained and written informed consent was taken from the patient and reliable accompanying relative of the patient in vernacular language. It was clearly explained to the patient that he/she will remain awake during the procedure but will not experience any pain. Surgeon was also informed about the procedure and was consulted about the approximate duration of the surgery. Xylocaine sensitivity test was done. Patients were kept nil per oral for 6 hrs before surgery. Operation theatre was kept ready with all the monitors and resuscitation measures. ECG and pulse oximeter monitor was attached to all the patients under study.

Intravenous canula 18 or 20 G was inserted and IV fluid started. Patients in both the groups were preloaded with intravenous Ringer's Lactate at the rate of 15ml/kg body weight. Pulse rate and Blood pressure was recorded in supine position.

All patients were given Inj. Ranitidine 1 mg/kg and Inj. Metoclopramide 0.2 mg/kg intravenously 20 minutes prior to anaesthesia.

Anaesthesia Technique

Group A: Combined Spinal Epidural Anaesthesia

In sitting position under all aseptic precautions using Touhy's needle (18 G), Epidural catheter was inserted in L2- L3 space by the 'Loss of Resistance' technique which was followed by sub arachnoid block. Epidural block for the purpose of prolonging the duration of surgical anaesthesia, when required, was given with Inj. Bupivacaine 0.5% 4cc and for the purpose of postoperative analgesia was given with Inj. Bupivacaine 0.125% 8cc.

In sitting position, lumbar puncture was done at L3- L4 space with 25 G spinal needle and after confirming a free, clear, continuous flow of CSF, Inj. Bupivacaine 0.5% (H) 3.5 cc + 0.4 cc Normal Saline was injected. Sterile dressing was done for the epidural catheter.

Group B: Sub Arachnoid Block with Inj. Bupivacaine 0.5% (H) + Inj. Clonidine

Under all aseptic precautions, lumbar puncture was done at L₃ - L₄ space with 25G spinal needle and after confirming a free, clear and continuous

flow of CSF, Inj. Bupivacaine 0.5% (H) + Inj. Clonidine 60 µg was injected.

Observations were recorded to compare the intraoperative haemodynamic stability by measuring pulse rate, noninvasive blood pressure, oxygen saturation. Vitals were noted before induction and considered as baseline values. Then same vitals were noted after induction at time interval of 10 mins, 20 mins, 30 min and 60 mins, 90 mins, and so on at half hourly interval for as long as the procedure lasted. Changes from baseline values calculated and compared statistically.

Intraoperative blood loss was calculated at the end of the procedure by measuring the amount of blood in the suction machine and the number of mops (1 mop = 100 ml). The values of both groups were compared statistically.

Intraoperative Pain Relief was Assessed as Follows

Group A: By assessing the need of an epidural top up during the surgery.

Group B: By assessing the need of a rescue analgesic in the form of Inj. Tramadol 2mg/kg body weight

Postoperatively all patients were shifted to the recovery room. Vital parameters like Pulse rate, Non invasive blood pressure and oxygen saturation were monitored for half hour. Duration of analgesia was observed and recorded on the Visual Analogue Scale (VAS) pain scoring system. The VAS consisted of a 10 cm horizontal paper strip given to the patient with two end labeled "No pain" and "Worst pain ever". When the patient complained of pain in the ward or recovery room, he/she was instructed to mark the strip at a point which corresponds to the level of pain intensity he/she currently felt. VAS was monitored at intervals of 15 mins. The time duration from after the completion of surgery and requirement of first epidural top up for pain relief (Group A) or the requirement of first rescue analgesic with Inj. Tramadol 2mg/kg body weight (Group B) was noted as the duration of post operative analgesia.

All the above recorded observations were analyzed statistically using Microsoft Excel and applying Unpaired 't' test, Chi square test and Z test wherever applicable and were concluded.

Complications were observed for in the intraoperative and postoperative period as follows:

Intraoperative

1. *Hypotension:* was said to be present if the systolic blood pressure dropped by 20% of the base line

value or if the MAP dropped by > 30%. If recorded, hypotension was treated with Inj. Mephentermine 6mg intravenously.

2. *Bradycardia:* Was said to be present when the pulse rate dropped below 60 beats/min. If recorded, bradycardia was treated with Inj. Atropine 0.01 mg/kg body weight.

Postoperative: Nausea, Vomiting Headache and Urinary retention

Observations and Results

Both the group A and B were statistically comparable with age, sex distribution, ASA status and type of surgeries performed.

Discussion

For hip surgeries namely THR and Bipolar, spinal anaesthesia, epidural anaesthesia and general anaesthesia are given routinely. Epidural anaesthesia provides the advantage of prolonging the duration of anaesthesia and also has the advantage of providing post operative analgesia for longer duration. However giving epidural top up is associated with sudden episodes of hypotension and keeping epidural catheter in situ can be associated with complications like local site infection, epidural abscess, etc. Also, the cost of combined spinal epidural anaesthesia is more as compared to spinal anaesthesia with clonidine. Clonidine, a partial agonist of alpha-2 adrenoceptor has been successfully used intrathecally for prolonging the duration of spinal anaesthesia while providing hypotensive anaesthesia with acceptable hemodynamic parameters and profound and prolonged postoperative analgesia.^{5,13,14}

In our institute, 60 patients posted for hip surgeries of THR and Bipolar, ASA grade I, II and III in the age group of 18 to 70 years, during the time period of year 2014 - 2016 were considered for regional anaesthesia. It was a prospective randomized controlled study. Ethical approval was taken. Patients were divided randomly into two groups, Group A and Group B.

Group A patients were given combined spinal plus epidural anaesthesia where epidural block was used only for prolongation of duration of anaesthesia. Spinal anaesthesia was given with Inj. Bupivacaine 0.5% (H) 3.5 cc + 0.4 cc Normal saline. For prolonging

the duration of surgical anaesthesia, epidural top up was given, when required, with Inj. Bupivacaine 0.5% 4cc and for post operative analgesia epidural top up was given with Inj. Bupivacaine 0.125% 8cc. Group B patients were given spinal anaesthesia with Inj. Bupivacaine 0.5% (H) 3.5cc with Inj. Clonidine 60 µg. All patients from both the groups were explained regarding the procedure. After taking written informed consent, procedures were carried out in the operation theatre under all aseptic precautions and patients were monitored intra and postoperatively.

Aim of our study was to assess the intraoperative hemodynamic stability, blood loss, intra and postoperative analgesic requirement and intra and postoperative complications in both the study groups.

In our present study, the average age group, the numbers of female and male patients, ASA grading and types of operations performed in both the groups is comparable.

Chart 1 shows pulse rate comparison in Group A and Group B. The baseline pulse rate readings of both the groups are comparable. However, after induction, Group B shows statistically significant fall in the pulse rate as compared to Group A ($P < 0.05$), within acceptable hemodynamic parameters. Also Group B patients showed statistically significant fall from their baseline values. Only 1/30 in Group A and 2/30 in Group B showed evidence bradycardia (pulse rate < 60 /min) and were treated with Inj. Atropine 0.01 mg/kg body weight.

The observations of our study are in co-relation with Dobrydnjov I, Axelsson K, Gupta A, Lundin A, Holmström B, Granath B [12] who studied if the addition of clonidine to local anaesthetic in combined spinal epidural anaesthesia in hip arthroplasty improved the analgesia. They reported that the group where clonidine was added to local anaesthetic, showed significant decrease in the pulse rate than the group in which clonidine was not added.

B.S. Sethi, Mary Samuel et al (2007) [10] studied the efficacy of Analgesic Effects of Low Dose Intrathecal Clonidine as adjuvant to Bupivacaine [10]. They observed that the decrease in mean heart rate from 45 minutes until the end of 6 hours was greater in Clonidine group than in the Control group ($P < 0.001$). In addition, the decrease from baseline value within the Clonidine group was also statistically significant at 45 minutes to end of 6 hours ($P < 0.001$).

Chart 2 shows comparison of mean arterial

pressure (MAP) between Group A and Group B, where Group B shows statistically significant fall in MAP from their baseline values as compared to that of Group A but within acceptable hemodynamic parameters ($P < 0.05$). Group A patients showed a sudden fall in the systolic as well as diastolic blood pressure after giving an epidural top up to prolong the duration of surgical anaesthesia. Also there is a significant fall in MAP in Group B patients from their baseline values as compared to that of Group A, within acceptable hemodynamic parameters ($P < 0.05$).

B.S. Sethi, Mary Samuel et al (2007) [10] studied the efficacy of Analgesic Effects of Low Dose Intrathecal Clonidine as adjuvant to Bupivacaine [34]. They observed that there was a statistically significant lower MAP in the Clonidine group compared to the Control group from 45 minutes after test drug administration until the end of 6 hours ($P < 0.001$) [10].

Joachim Klasen, Axel Junger, Bernd Hartmann, Matthias Benson, Andreas Jost, Anne Banzhaf, Myron Kwapisz and Gunter Hempelmann, studied Differing Incidences of Relevant Hypotension with Combined Spinal-Epidural Anesthesia and Spinal Anesthesia [6]. They observed that the incidence of relevant hypotension was more frequent with CSE than with SA alone (10.9% versus 5.0%; $P < 0.001$) [6]. "Improved analgesia with clonidine when added to local anesthetic during combined spinal-epidural anesthesia for hip arthroplasty: a double-blind, randomized and placebo-controlled study" was conducted by Dobrydnjov I, Axelsson K, Gupta A, Lundin A, Holmström B, Granath B [12]. They observed that the mean arterial pressure in Groups B-RC and BC-RC were significantly lower than in Group B-R after spinal injection ($P < 0.01$) [12].

Table 1 shows the comparison of blood loss during the surgery between both the study groups. The mean blood loss seen in the patients of Group A is (599.86±58.6) ml, whereas that seen in patients of Group B is (495±49.7) ml. The difference in the blood loss between the two study groups is statistically significant ($P < 0.05$). Thus intrathecal Inj. Clonidine is associated with decrease in the blood loss occurring during the surgery.

Table 2 shows the duration of analgesia in minutes in the postoperative period and the VAS score recorded at various intervals. VAS score was recorded starting from the recovery room and recorded at intervals of 15 mins till the time patient required first epidural top up for analgesia (Group A) and required first rescue analgesic with Inj. Tramadol 2mg/kg body weight (Group B). Rescue

analgesic or epidural top up was given when the patient complained of pain with a VAS score greater than 3. The time period between the recovery room and the first requirement of rescue analgesic or epidural top up (VAS > 3) was noted as the duration of postoperative analgesia. The mean duration of postoperative analgesia in Group A is (185±110.9) mins and that of Group B is (399.9±103.8) mins. The difference is statistically significant ($P < 0.05$). Also the difference in the VAS scores between both the groups is statistically significant ($P < 0.05$). Thus Inj. Clonidine used intrathecally as an adjuvant to Inj. Bupivacaine produces prolongation of duration of surgical anaesthesia as well as has a profound and prolonged postoperative analgesic effect. Use of clonidine also reduces the cost of anaesthesia as compared to the use of combined spinal plus epidural.

Malinovsky JM et al (1993) observed similar results in their study of ability of intrathecal clonidine alone to provide surgical anaesthesia [7]. They observed that large doses of clonidine, provides sedation and intense and long-lasting postoperative analgesia [7]. Klimscha W et al (1995)

studied the haemodynamic and analgesic effects of clonidine added repetitively to continuous epidural and spinal blocks [8]. They concluded that the addition of clonidine to bupivacaine yields long lasting, profound analgesia. Stephan Strel, Jürg A. Gurzeler et al (2004) used Small-Dose Intrathecal Clonidine and Isobaric Bupivacaine for Orthopedic Surgery [9]. In Dose-Response Study. They observed that the time interval between spinal anaesthesia and the first request for supplemental PCA morphine was significantly longer in all clonidine groups

B.S. Sethi, Mary Samuel et al (2007) they studied the efficacy of Analgesic Effects of Low Dose Intrathecal Clonidine as Adjuvant to Bupivacaine [10]. They observed that the pain free postoperative interval was more in the patients of the Clonidine group as compared to that of the control group ($P < 0.001$). The VAS scores on a scale of 10cm were also lower in Clonidine group as compared to the control group. They also observed that Inj. Clonidine used intrathecally in dose of $1\mu\text{g}/\text{kg}$ body weight significantly increases the duration of spinal analgesia as compared to Bupivacaine alone [10].

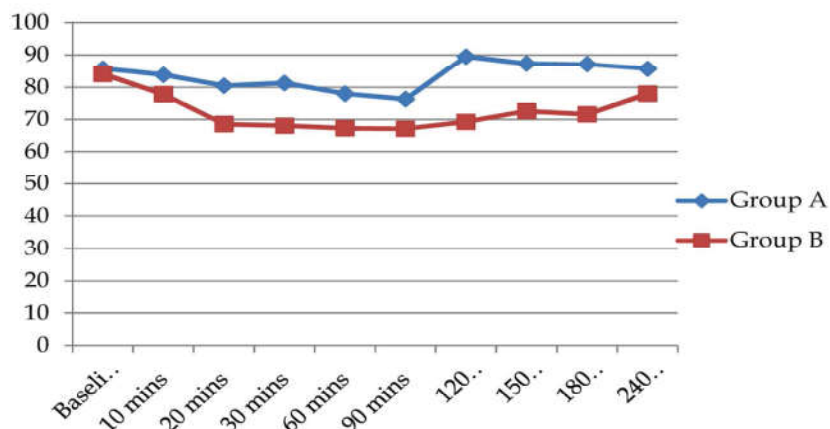


Chart 1: Shows changes in mean Pulse Rate / min at various intervals

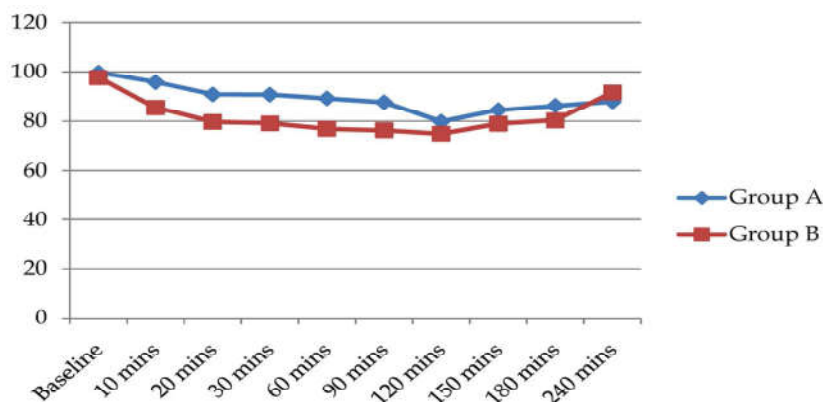


Chart 2: Variations in Mean Arterial Blood Pressure (MAP) (mm Hg) in both groups.

Table 1: Comparison of Blood Loss during the surgeries

Blood Loss ml	Group A Mean + SD	Group B Mean + SD	P value	Inference
	586.6 ± 58.6	495 ± 49.7	0.0001	Significant

Table 2: Duration of Postoperative Analgesia

Duration of Postoperative Analgesia (mins)	Group A Mean + SD	Group B Mean + SD	P value	Inference
	185 ± 110.9	399.9 ± 103.8	0.0001	Significant

Table 3: Incidence of Intra-operative and Postoperative Complications

Complications	Group A %	Group B %	P value	Inference (Z test)
Hypotension	16.6	13.3	0.35	Not Significant
Bradycardia	3.3	6.6	0.27	Not Significant
Urinary Retention	6.6	10	0.47	Not Significant

Agreta Gecaj-Gashi, Hasime Terziqi, Tune Pervorfi, Arben Kryeziu (2012) carried out a study named "Intrathecal clonidine added to small-dose bupivacaine prolongs postoperative analgesia in patients undergoing transurethral surgery [11]." They concluded that the intrathecal application of clonidine in combination with bupivacaine improves the duration and quality of spinal anesthesia; it also provides longer duration of postoperative analgesia, without significant side effects [11].

Dobrydnjov I, Axelsson K, Gupta A, Lundin A, Holmström B, Granath B [12]. Improved analgesia with clonidine when added to local anesthetic during combined spinal-epidural anesthesia for hip arthroplasty: a double-blind, randomized and placebo-controlled study". They observed that duration of anesthesia, analgesia and motor block were longer in Group BC-RC compared to Groups B-R and B-RC ($P < 0.02$). Postoperatively, both VAS score on movement and PCA-morphine consumption were higher in Group B-R than in Groups B-RC and BC-RC ($P < 0.01$). Thus intrathecal clonidine provided a better quality of anesthesia and longer-lasting analgesia.

In our present study, the intraoperative complications which we found were hypotension and bradycardia. Table 3 shows the incidence of intraoperative hypotension and bradycardia. Hypotension was seen in 5/30 (16.6%) patients in Group A whereas 4/30 (13.3%) patients in Group B showed incidence of hypotension (fall in systolic blood pressure $> 20\%$ or fall in the mean arterial pressure $> 30\%$) and were treated with Inj Mephentermine 6mg iv. The difference was statistically not significant ($P = 0.35$). Bradycardia was said to be present when the pulse rate dropped below 60/min and was treated with intravenous Inj.

Atropine 0.01 mg/kg body weight. In Group A, 1/30 (3.33%) patients showed evidence of bradycardia whereas in Group B, 2/30 (6.66%) patients showed bradycardia. The difference was statistically not significant ($P = 0.27$).

Table 3 shows the incidence of postoperative complications. The only post operative complication we observed in our study was urinary retention. 2/30 (6.66%) patients showed postoperative urinary retention as compared to 3/30 (10%) patients in Group B. The difference was statistically not significant ($P = 0.47$).

Conclusion

The results of this prospective, randomized comparative study demonstrated that addition of clonidine to spinal anaesthesia provides hypotensive anesthesia with acceptable hemodynamic parameters, with reduced blood loss, profound and prolonged postoperative pain relief, with cost effectiveness. Thus we conclude that the "spinal anaesthesia with clonidine" is a beneficial alternative for elective hip surgeries as compared to "combined spinal epidural anaesthesia".

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