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Title: Perioperative outcome of carotid endarterectomy under regional anesthesia - a two decade experience from the Caribbean

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Abstract: Study Objective
To evaluate the perioperative outcome of carotid endarterectomy during regional anesthesia
Design
A retrospective chart review of consecutive patients who underwent carotid endarterectomy under regional anesthesia for a period of twenty-three years
Setting
Operating rooms in a developing country
Interventions
Deep cervical plexus block
Measurements
Demographic data, perioperative clinical data, post-operative morbidity and unplanned admissions were recorded.
Main results
A total of 183 carotid endarterectomy procedures were performed. In 172 cases, it was done exclusively under deep cervical plexus block and local infiltration, while in 11 (6%), there was a

need for conversion to general anesthesia intraoperatively. Clamping of the internal carotid artery for a period of 3 minutes was the method implemented to monitor the development of neurological impairment. Perioperative complications included intraoperative seizures in one patient, intraoperative transient hemiparesis in 3 patients, postoperative transient hemiparesis in 2 patients and intraoperative hemiplegia in one patient. One hundred and fifty three patients (83.6%) were discharged home within 24 hours and 29 (15.8%) stayed for 48 hours. The patient who had the hemiplegia had a hospital stay of 12 days. There was no perioperative mortality.

Conclusions

Regional anesthesia is a safe method for carotid endarterectomy in a limited-resources setting since it facilitates intraoperative clinical assessment of the effects of internal carotid artery clamping.

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To 28th April 2009
Robert R Gaiser MD
Editor-in-Chief
Journal of Clinical Anesthesia

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Dear Sir,

Re: Submission of the revision of manuscript entitled ***"Perioperative outcome of carotid endarterectomy under regional anesthesia – a two decade experience from the Caribbean"***

Many thanks for accepting the manuscript. We have modified the article according to the type-script suggestions. We herewith submit the revised version for your kind review and consideration of publication in the Journal of Clinical Anesthesia. The paper has been formatted in accordance with the instructions and meets the requirements of your journal.

We request you kindly review the article and consider its publication.

Looking forward to hearing from you,

Thanking You,

Yours truly,

Seetharaman Hariharan

*** Response to Reviewers**

Title page: Titles of authors have been provided in parentheses
Throughout manuscript, "loco-regional" has been changed to "regional"

Abstract
Line 2: "under" has been changed to "during"
Line 7: "with limited resources for advanced intraoperative monitoring" has been deleted
Line 10: "none for the study per se" has been changed to "Deep cervical plexus block"
Line 21: "in" has been inserted before "2 patients"
Line 23: "only" has been deleted

Introduction
Line 4: "increase and in the developed countries, the" to has been changed to "increase. In developed countries, the"
Line 8: "in the long term" has been deleted
Line 13: "Not only these are" has been changed to "These are not only"
Line 14: "they are" has been changed to "but"
Line 14: "and many studies have questioned the reliability of such monitoring" has been deleted
Line 22: parentheses have been inserted around "including carotid endarterectomy"
Lines 25-27: "To the authors' . . . regional anesthesia" has been deleted
Line 29: "we report" has been deleted
Line 30: "under loco-" has been changed to "with"
Line 31: "is presented" has been inserted after "facilities"

Methods
Line 8: "in patients" has been deleted
Line 13: "and" has been inserted before "biochemical"
Line 13: "and a radiology suite" has been deleted
Line 17: "Under" has been changed to "using"
Line 17: "important" has been deleted

Results
Line 2: "males" has been changed to "men"
Line 2: "age" has been changed to "ages"
Line 3: "belonged" has been changed to "were"
Line 12: "under loco-" has been changed to "during"
Lines 15-17: "In 10 patients, although most of the dissection was performed under loco-regional anesthesia, they" to has been changed "Ten patients"
Line 33: "normalcy" has been changed to "function"
Line 42: "under loco-" has been changed to "during"
Line 44: "under" has been changed to "during"
Line 57: "only" has been deleted
Line 59-61: "After the surgery, . . . symptoms and signs" has been deleted

Discussion
Line 2: "under loco-" has been changed to "during"
Line 13: "under" has been changed to "during"
Line 26: "under" has been changed to "with"
Line 30: "under loco-" has been changed to "during"
Line 49: "patient and reports" has been changed to "patient. Reports"
Line 59: "however reverted to normalcy" has been changed to "that resolved"
Line 67: "loco-" has been deleted
Line 70: "under" has been changed to "during"
Line 76: "under loco-" has been changed to "during"

Perioperative outcome of carotid endarterectomy under regional anesthesia – a two decade experience from the Caribbean

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SHORT TITLE: Carotid endarterectomy under regional anesthesia.

KEYWORDS: Carotid endarterectomy, regional anesthesia, developing country

Abstract

Study Objective

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Design

A retrospective chart review of consecutive patients who underwent carotid endarterectomy under regional anesthesia for a period of twenty-three years

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Demographic data, perioperative clinical data, post-operative morbidity and unplanned admissions were recorded.

Main results

A total of 183 carotid endarterectomy procedures were performed. In 172 cases, it was done exclusively under deep cervical plexus block and local infiltration, while in 11 (6%), there was a need for conversion to general anesthesia intraoperatively. Clamping of the internal carotid artery for a period of 3 minutes was the method implemented to monitor the development of neurological impairment. Perioperative complications included intraoperative seizures in one patient, intraoperative transient hemiparesis in 3 patients, postoperative transient hemiparesis in 2 patients and intraoperative hemiplegia in one patient. One hundred and fifty three patients (83.6%) were discharged home within

24 hours and 29 (15.8%) stayed for 48 hours. The patient who had the hemiplegia had a hospital stay of 12 days. There was no perioperative mortality.

Conclusions

Regional anesthesia is a safe method for carotid endarterectomy in a limited-resources setting since it facilitates intraoperative clinical assessment of the effects of internal carotid artery clamping.

Introduction

Carotid endarterectomy is one of the few surgeries which have undergone immense scrutiny by randomized controlled trials with respect to its indications, surgical and anesthetic techniques, overall outcome and cost effectiveness [1]. As the world population becomes increasingly aged, the need for this surgery is likely to increase. In the developed countries, the outcome and cost-benefit of this surgery has been extensively investigated by large studies [2, 3].

While the main purpose of performing a carotid endarterectomy is to prevent stroke, preventing perioperative stroke remains the most formidable challenge to the surgeons performing this procedure. Perioperative monitoring of cerebral perfusion may be done using electroencephalography (EEG), transcranial doppler (TCD), carotid stump pressure (CSP), somatosensory evoked potentials (SSEP) or a combination of these (4). However, most of these monitoring techniques require special equipment, technicians and specialists for interpreting the results. These are not only prohibitively expensive in third-world countries, but also time-consuming [5, 6]. The benefits of local/regional anesthesia for carotid endarterectomy have been widely reported although most of these reports originate from developed countries [7, 8]. One of the clear advantages of having an awake patient during carotid endarterectomy is the avoidance of the necessity of the aforementioned monitoring modalities, since clinical neurological assessment can be done before, during and after clamping the internal carotid artery [9].

A recent article in the Lancet has proposed the view that most developing countries lack the various facilities (including carotid endarterectomy) to prevent stroke in their population (10). There are very few reports from the developing world regarding

the experience of carotid endarterectomy; there is one from India and a brief report from Bangladesh [11, 12]. There is one report from Puerto Rico; however, this region is under the administration of United States of America [13].

With this background, a case series of carotid endarterectomy done over the past two decades with regional anesthesia in a third-world Caribbean island setting, with limited equipment and simple facilities is presented.

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Materials and Methods

A retrospective chart review of all the patients who had carotid endarterectomy performed during the period from January 1984 through June 2007 was done after approval from the hospital authorities. All the surgical procedures were performed by a single surgeon.

Setting

Our operating rooms have basic monitoring equipment consisting of pulse oximeter, non-invasive blood pressure, electrocardiogram and capnograph. Although there are provisions for invasive monitoring, these are rarely used. There are no neurological monitors available in the operating rooms. Junior doctors (not qualified as specialists) provide perioperative care to the patients under the supervision of a senior anesthesiologist. Consultant surgeons, neurologists, internists, provide care to inpatients along with in-house junior medical officers around the clock. The hospitals also have modern laboratories facilitating most hematological and biochemical investigations.

Method

All patients received regional anesthesia in the form of a deep cervical plexus block and supplementation with local infiltration in the surgical site. 25 mL of a mixture of bupivacaine and lidocaine was prepared to provide a final concentration of 0.25% and 1% of each drug respectively. Of this amount, 10-12 mL was used for the deep cervical plexus block and the remaining was used for local infiltration. All patients received midazolam 2 mg intravenously just before the block.

Using aseptic precautions, the anatomical landmarks such as the posterior border of the sternocleidomastoid, the mastoid process and the transverse process of the sixth

cervical vertebra (Chassaignac's tubercle) were marked and 3 – 4 mL of the local anesthetic mixture was injected at each level of the transverse processes of the 2nd, 3rd and 4th cervical vertebrae. The remaining amount of the local anesthetic mixture was used by the surgeon to supplement local anesthesia at the surgical site. It is a routine practice of the surgeon to infiltrate 1 mL of 1% lidocaine in the region of carotid sinus before dissection of the carotid bifurcation.

Basic demographic data collected included age and gender of the patient. Clinical data recorded included preoperative physical status of the patient, co-morbidities, indications for surgery, type of anesthesia performed, reasons for conversion to general anesthesia from regional technique, surgical procedure including details of the clamping of internal carotid artery, the utilization of shunts, intraoperative and postoperative complications, ICU admissions if any, hospital length of stay and 30-day postoperative outcome for neurological status, myocardial infarction and death.

Results

During the study period, 183 carotid endarterectomy procedures were performed in 180 patients. 102 (56 %) of the patients were men. The ages ranged from 53 to 88 years and the median age was 67. All patients were American Society of Anesthesiologists (ASA) Grade II physical status.

The most common comorbidities were essential hypertension (21%), non-insulin dependent diabetes mellitus (NIDDM) (28%) and ischemic heart disease (33%). Indications for the carotid endartertecomy surgery were transient ischemic attacks (TIA) in 172 cases (94%), 'stroke in evolution' in 7 (4%) and as a preoperative prophylactic procedure before coronary artery bypass grafting in 4 (2%). The diagnosis was confirmed by Duplex scan in all cases and in 18 cases, further assessment was done using Magnetic Resonance Angiography (MRA) to exclude other lesions.

A total of 172 cases had the surgery exclusively during regional anesthesia and in 11 (6%) there was a need for conversion to general anesthesia (GA). One of the patients had a tonic-clonic seizure due to intravascular injection during the deep cervical plexus block and GA was immediately instituted; a shunt was used in this case. Ten patients were quite uncomfortable due to the surgical retraction in the region of the mandible, despite repeated local anesthetic infiltration. In these patients, before inducing GA, a 3-minute trial of carotid clamping was done to establish the safety when the patient was awake and then GA was instituted; none of these patients needed shunt placement nor suffered any neurological sequelae. GA was induced with thiopental 5 mg/kg, endotracheal intubation was facilitated by succinyl choline 1mg /kg and GA was maintained with halothane/isoflurane in nitrous oxide and oxygen. In this case series,

none of the patients who had conversion to GA required vasoactive drugs to manage the blood pressure perioperatively.

All other patients who had regional anesthesia also had a 3-minute clamping of the internal carotid artery and were clinically observed for any neurological impairment. Three patients developed altered consciousness and hemiparesis immediately following the carotid clamping; however they returned to their normal preoperative status once an intraluminal shunt was inserted. Thus the shunt utilization rate of the present series is 2%. Two other patients developed mild weakness of their contralateral upper and lower limbs during the actual endarterectomy; however they regained function on completion of the procedure. One patient developed hemiplegia during the surgery, which continued into the postoperative period. Although the patient showed some neurological improvement over several months, there was significant permanent hemiplegia. A Magnetic Resonance Angiography (MRA) done on this patient, showed a patent extracranial carotid system with an occluded middle cerebral artery and corresponding cerebral infarction.

Twelve patients experienced significant discomfort while dissecting the distal internal carotid artery. These patients required an additional 5-7 mL of 1% lidocaine infiltration intraoperatively.

One patient had uneventful surgery during regional anesthesia but developed sudden aphasia and hemiplegia two hours postoperatively. This patient was taken for immediate re-exploration under GA, which revealed acute thrombosis with complete occlusion at the surgical site. This patient had a thrombectomy with a patch closure of the carotid; no shunt was used and she recovered completely without any neurological deficit, within 3 hours of re-exploration.

Although 90% of the patients had contralateral disease, only 6 had > 60% stenosis. All these patients were asymptomatic. None of these patients needed shunting. Three had later contralateral endarterectomy and 3 are being followed up in the neurology clinic

Postoperatively, all patients were routinely monitored with pulse oximetry, half-hourly blood pressure readings, hourly assessment for level of consciousness and neurologic status. EKG and cardiac enzymes were not done routinely as there was no clinical indication for these investigations in any patient in this case series.

Within 24 hours, 153 cases (83.6%) were discharged home; 29 (15.8%) stayed for 48 hours. The patient who had hemiplegia had a hospital stay of 12 days. No patient required intensive care unit (ICU) or high dependency unit (HDU) admission.

Within the 30-days following the surgery, there was no death, nor myocardial infarction by clinical criteria in any patient. No patient developed stroke following hospital discharge other than the one mentioned earlier who had hemiplegia intraoperatively.

Discussion

The major finding of this case series is the good perioperative outcome for carotid endarterectomy during regional anesthesia in a setting with limited resources for intraoperative neurological monitoring.

Utilization of shunts during carotid endarterectomy is a commonly practiced procedure. Some authors recommend routine shunting in all patients undergoing carotid endarterectomy, although this practice remains controversial (14). Shunt utilization may be associated with air or thrombus embolization, local vessel trauma, clotting within the shunt, poor visualization of the end point and increased technical difficulty of the procedure [14]. Therefore, it seems desirable that one uses shunts only for those patients who are likely to develop neurological deficit. Selective shunting seems to be a prudent practice, which requires the assistance of intraoperative neurological monitoring.

Although one large series in the 1980s has documented the safety of doing carotid endarterectomy during GA without utilizing shunts or advanced monitoring modalities such as EEG and CSP, this has not been a widely accepted practice [15]. For the selective use of shunting during carotid endarterectomy, intraoperative monitoring such as EEG, CSP, jugular venous oxygen saturation and TCD are often recommended; despite the fact these monitors are not perfectly reliable indicators of the neurological state of the patient [9]. A previous report prospectively correlated the neurological state of the awake patient with the CSP and EEG and found that neither monitoring technique identified all the patients who developed clinical neurological deficit [16]. Some patients with either EEG changes or low CSP did not develop any neurological deficit. Since both the sensitivity and specificity are not nearly ideal for these monitoring techniques,

utilization of shunts during carotid endarterectomy is more prone to errors such as overuse or underuse.

The recent multicenter GALA trial reported 14% shunt utilization for patients with local anesthesia and 43% if GA was employed [17]. In the present series, shunt utilization was very low and comparable to another large series, which has shown that monitoring the neurological state of the awake patient can decrease the need for shunting to 3.8 – 9.7% [18]. In our series, the requirement of shunt was further reduced to 2%, probably because the safety of carotid clamping was demonstrated during regional anesthesia in most patients, even when GA was eventually instituted. This decrease in the use of shunts can minimize potential shunt complications, operating time, technical problems and decrease the associated costs. Utilization of shunts is likely to increase patient morbidity and decrease the cost-effectiveness of the surgery. This is particularly important in a developing country setting such as ours. Because clinical neurological monitoring is the most reliable method of assessing cerebral function during surgery, an awake patient may be ideal for carotid endarterectomy [9].

There has been considerable debate whether general or regional anesthesia is preferable for carotid endarterectomy [19]. GA has its own obvious attendant risks. Hemodynamic instability necessitating the use of vasoactive drugs is a major disadvantage of GA [20]. There have been conflicting reports regarding the increased incidence of post operative ICU admission, increased hospital stay and costs when general and regional anesthesia are compared [21, 22]. However, more evidence is in favor of regional anesthesia with respect to perioperative outcome and costs.

Although the recent GALA trial reported no statistically significant difference in the perioperative adverse outcomes comparing general and regional anesthesia for this surgery, there is opinion that this may be due to lack of statistical power [23]. The most important advantage of regional anesthesia for carotid endarterectomy is the ability to clinically monitor the neurological status of the patient. Reports have clearly indicated that the use of regional anesthesia lowers the risk of stroke and death in the perioperative period [24]. Thus, the lower incidence of morbidity and zero mortality in our case series may be attributable to the use of the regional anesthetic technique. The effects of brief period (3 minutes) of carotid artery clamping and clinical testing for neurological impairment had been suggested as early as 1970s [25]. We suggest that this might have been the cornerstone of the better perioperative outcome in the present series.

However, the important caveat here is that even if the patient may be normal during the period of 3 minutes clamping, ischemia may happen at a later stage and hence the patient should be carefully and continuously monitored to avert hypotension. In fact, 2 of our cases developed hemiparesis towards the end of the procedure; however that resolved immediately on declamping without the need for shunting.

Although the value of ‘deep cervical plexus block’ for carotid endarterectomy has been disputed by a recent study [26], we had started with this as the preferred technique 25 years ago. Only recently (time-period not covered by the study) we adopted ‘superficial cervical plexus’ block in some patients. However in our experience, there is an increased requirement of supplementation of local anesthetic infiltration, especially when dissecting the distal portion of the internal carotid artery.

Other disadvantages of regional anesthesia may include intravascular injection of the local anesthetic, inadequate anesthesia and patient anxiety. Furthermore, some reports have found a higher incidence of perioperative myocardial ischemia, when carotid endarterectomy was done during regional anesthesia [27]. None of our patients developed myocardial ischemia during the perioperative period. The present case series has comparable results to the reports from private institutions in India and the United States of America [11, 28]. Our conversion rate to GA, however, was a little higher (6%) than an earlier report (1.1%) [18], but well within the range of the overall literature (0.1-11.6%) [19].

In conclusion, carotid endarterectomy during regional anesthesia is associated with a low rate of morbidity and mortality and can be recommended as the preferred method of anesthesia for performing this surgery in developing country settings with limited resources. If conversion to GA is required during the procedure, whenever feasible, carotid clamping for 3 minutes should be done in the awake patient to clinically assess the neurological function.

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