

Carotid endarterectomy: general anaesthesia with remifentanyl conscious sedation vs loco-regional anaesthesia

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Aim. To retrospectively evaluate and compare the safety and efficacy of general anaesthesia with remifentanyl conscious sedation (RCS) vs local-regional anaesthesia (LA) for carotid endarterectomy (CEA).

Methods. From January 2004 to January 2008, 390 CEA performed in 325 patients (M/F 214/111, age 75 ± 7) were collected in 2 groups: RCS group included 275 consecutive CEA in 230 patients carried out under remifentanyl conscious sedation with stopping of the remifentanyl infusion at the carotid clamping time to evaluate the clinical neurological status; LA group was composed of 115 consecutive CEA in 95 patients, performed under local-regional anaesthesia. We evaluated complications, postoperative morbidity and mortality, need for shunt insertion and compared the results by means of Student's t-test and χ^2 analysis. P value <0.05 ($T=2.28$) was considered significant.

Results. The 30 days mortality was 0.35% in the RCS group and 0% for LA group ($P=NS$). The 30 days stroke rates were 0.3% and 0% respectively ($P=NS$). TIA/RIND rates were 0.3% for RCS group and 1.7% for LA group ($P=0.47$); shunt usage was 20% for RCS group and 17% for LA group ($P=0.26$). We found higher postoperative nausea/vomiting in the RCS group (3.9% vs 0.8%, $P<0.05$).

Conclusion. General anaesthesia with remifentanyl conscious sedation seems to be a safe technique, allowing monitoring of the neurological status, cerebral protection during arterial clamping, better control of the airway and a good compliance to both the surgeon and the patient. A randomized control trial is needed to prove RCS to be effective as LA.

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Key words: Remifentanyl - Carotid endarterectomy - Anaesthesia.

The role for carotid endarterectomy (CEA) in stroke prevention is well established and, despite the indications and the standardization of surgical techniques, some controversies still remain about the best anesthetic management.

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Both general anaesthesia (GA) and local anaesthesia (LA) have advantages and disadvantages and there is no evidence of a clear superiority of either anesthetic technique from randomized trials,¹ as confirmed by the summary of the findings of the GALA (general versus local anaesthesia) Trial, just reported.²

In 2001 Muchada *et al.* reported their results with a new anesthetic procedure using remifentanyl in patients who were intubated and ventilated but in which the use of the same opiate could lead to a consciousness level that permits an awake monitoring (remifentanyl conscious sedation). This procedure appears to have the advantages of both the local and general anaesthesia leading to safe neurological monitoring, better airway control, hemodynamic stability, with good early and long term surgical results.³

The aim of this study is to evaluate the effectiveness and the safety of CEA with conscious sedation under remifentanyl with orotracheal intubation. A comparative analysis with consecutive CEA performed under LA, before this series, has been carried out.

Materials and methods

From January 2004 to January 2008 390 consecutive CEA were performed in 325 patients. In the years 2004 and 2005 115 consecutive CEA were performed under local-regional anaesthesia in 95 patients (LA Group). From 2005 to 2008, 275 consecutive cases of CEA were carried out under remifentanyl consciousness sedation in 230 patients (RCS Group).

Demographic population profile has been reported in Table I. All patients underwent non-invasive

TABLE I.—*Patient's datas.*

| | RCS-CEA | LA-CEA | P |
|---------------------------------|-------------|------------|--------|
| Age (years) | | | |
| mean±SD | 75 ± 7.2 | 74 ± 5.8 | 0.45 |
| Male gender | 154 (66.9%) | 60 (63.1%) | 0.21 |
| Coronary artery disease | 132 (48%) | 49 (42.6%) | 0.33 |
| Diabetes | 90 (32.7%) | 30 (26%) | 0.33 |
| Smoking | 147 (53.4%) | 75 (65.2%) | 0.0001 |
| Hypertension | 187 (68%) | 71 (61.7%) | 0.31 |
| Symptomatic | 126 (46.1%) | 61 (53%) | 0.32 |
| Asymptomatic | 149 (53.9%) | 54 (46.9%) | 0.30 |
| Controlateral CEA | 45 (16.3%) | 20 (17.3%) | 0.21 |
| Controlateral carotid occlusion | 20 (7.2%) | 10 (8.6%) | 0.47 |
| ASA 2 | 103 (37.4%) | 43 (37.3%) | 0.84 |
| ASA 3 | 156 (56.7%) | 58 (50.4%) | 0.31 |
| ASA 4 | 16 (5.8%) | 14 (12.1%) | 0.31 |

TABLE II.—*Surgical's data.*

| | RCS-CEA | LA-CEA | P |
|---------------|-------------|------------|------|
| Direct suture | 1 (0.3%) | 3 (0.2%) | 0.84 |
| Patch | 227 (82.5%) | 91 (79.1%) | 0.64 |
| Eversion | 42 (15.2%) | 20 (17.3%) | 0.42 |
| By-pass | 5 (1.8%) | 1 (0.8%) | 0.45 |
| Shunt | 55 (20%) | 20 (17.3%) | 0.26 |

preoperative assessment of carotid artery stenosis with Duplex imaging. Forty six patients (11.7%) were submitted for angiographic study. Angio-CT scan and magnetic resonance angiography (MRA) were respectively performed in 136 (34.8%) and 128 (32.8%) patients. A cranial CT scan was carried out in 300 patients (76.9%). Surgical data have been report in Table II.

Statistical analysis

We compared RCS vs LA results by means of Student's t-test and χ^2 analysis. All analyses have been developed by software SPSS (13.0 version, SPSS Inc, Chicago, USA). A P value <0.05 has been considered significant.

Anaesthetic protocol

REMIFENTANYL GROUP

A superficial plexus block with ropivacaine (Naropin) 7.5% 10-15 mL along the posterior border of sternocleidomastoid muscle was performed. Anesthetic management was carried out by means of induction with intravenous infusion of propofol 1% 1.5-2 mg/kg with transmucosal topical appli-

cation of lidocaine 10% 10 mL during tracheal intubation. After intubation, a continuous intravenous remifentanyl infusion 0.12-0.25 $\mu\text{g}/\text{kg}/\text{min}$ (Ultiva, Glaxo-Wellcome Inc, Research Triangle Park, NC, USA) was started. The patient was mechanically ventilated in IPPV (intermittent positive pressure ventilation) modality (tidal volume 8-12 mL/kg, respiratory rate 11 ± 2 , O_2/air 40/60%). During pre-clamping, the remifentanyl was slowly reduced until the patient was awake and able to collaborate. The neurological status was tested by means of foam-rubber toy squeeze and through the open and close eyes movement. The remifentanyl was set to get a good motor evaluation avoiding pain and discomfort. After clamping, the squeeze test was repeated every 15-30 seconds for two minutes. When the clamping was tolerated the procedure was carried out. Instead, in cases of intolerance, a Pruitt F3 carotid shunt 9 Fr (LeMaitre Vascular Inc, Burlington, USA) was inserted and the patient was deepened by propofol. At the end of the procedure, remifentanyl was stopped and the endotracheal tube was removed. In all cases a carotid bulb infiltration with 2-3 mL of xylocaine 1% through a short 25 gouge needle was given to avoid bradycardia sinus reflex.

LOCAL-REGIONAL GROUP

A superficial plexus block with 15-20 mL of bupivacaine 25% along the posterior border of the sternocleidomastoid muscle was carried out. A deep cervical block was performed by 7-10 mL of bupivacaine 25% near each transverse process of C2-3-4. Surgeon could reinforce the block with lidocaine 2% by infiltration or splash into the carotid arteries. In all cases a carotid bulb infiltration with 2-3 mL of xylocaine 1% through a short 25 gouge needle was performed to avoid bradycardia sinus reflex.

Results

In the RCS group, 1 patient (0.3%) died on the 6th postoperative day because of myocardial infarction (ASA IV). Two patients (0.6%) showed a postoperative neurological deficit. In the first case, a transitory left side monoparesis with rapid regression after 2 hours occurred. In the second, a minor stroke with monoplegia of the right arm was detected with partial improvement after 3 months.

TABLE III.—*Results.*

| | RCS-CEA | LA-CEA | P |
|--------------------|--------------|----------------|-------|
| Minor stroke | 1/275 (0.3%) | — | N/S |
| Major stroke | — | — | N/S |
| Mortality | 1/275 (0.3%) | — | N/S |
| Shunt applied | 55/275 (20%) | 20/115 (17.3%) | 0.26 |
| TIA/RIND | 1/275 (0.3%) | 2/115 (1.7%) | 0.47 |
| Haematomas | 4/275 (1.4) | 1/115 (0.8%) | 0.65 |
| Nausea/vomiting | 9/275 (3.9) | 0/115 (0%) | <0.05 |
| Conversion to GA | 55/275 (20%) | 20/115 (17.3%) | 0.26 |
| Complications rate | 7/275 (2.5%) | 3/115 (2.6%) | 0.84 |

All patients underwent duplex scan examination, transcranial Doppler and angio neck and cranial CT scan to exclude ICA thrombosis, technical defects or hyperperfusion syndrome. The neurologic morbidity was 0.6% and no neurological mortality rate was reported. The incidence of shunt deployment was 20%. Postoperative hematoma presented an incidence of 1.4% (4/275).

A comparative analysis with 115 consecutive CEA in 95 patients before these series (demographic data in Table I) has been done.

In the LA group, the 30-day mortality rate was zero. Two patients (1.7%) had a transient monoparesis with rapid regression. Shunt was inserted in 17.3% of cases. The hematoma incidence was 0.8% (1/115).

There were no statistically significant differences between the two groups with respect to the incidence of major and minor neurological and cardiac complications. Similarly no differences were detected in shunt deployment and in hematoma incidence. No postoperative nausea was observed in the LA group (Table III).

Discussion

The GA and LA anesthesia present results and complications well recognized in many series and data recovered from randomized trials by the Cochrane Systematic Reviews and preliminary results of the GALA Trial do not indicate which is the best procedure, despite the non-randomised studies seem to show potential benefits by the use of LA.⁴ Indeed, the LA has slowly established itself in becoming the main choice of anesthesia in clinical practice.^{5, 6}

The widely established benefits of CEA per-

formed under LA include awake monitoring, better cerebral auto-regulation, higher cardiovascular stability, shorter post-operative recovery, but the discomfort to the patient and the surgeon seems to be a major challenge especially in cases of technically demanding intervention or intra-operative ischemia due to vessel clamping.

In our experience, we observed discomfort in cases of high bifurcation, hostile neck, time consuming operation or in cases of clamp related ischemia with problematic conversion to general anesthesia due to dramatic difficulty to achieve a rapid and safe airway control by means of oro-tracheal intubation.

The introduction of the remifentanyl conscious sedation (RCS) in CEA by Muchada *et al.*² seems to give the possibility to combine the pros and cons of GA and LA. The advantage of this technique is that the duration of anesthesia is not limited and adequate ventilation and maintenance of a safe monitoring of the neurological status are assured.

Coppi *et al.* reported their experience with 533 consecutive patients submitted to CEA under RCS anesthesia and they compared their results with 533 conventional LA CEA performed before these series showing no significant difference in the outcomes. The authors concluded that the RCS CEA is safe, effective and satisfactory, but the complications due to intubation and side effects of the remifentanyl needed randomized control trials to prove the superiority of this method compared with the LA.⁷

We applied these anesthetic procedures in 275 consecutive CEA operations with a very safe neurological monitoring of the mental and the motor function during the arterial clamping without the need for neurological monitoring instruments. A selective shunt policy was carried out in all cases with a deployment shunt incidence of 20% (55/275) without statistical difference with the LA group (17.3%).

Remifentanyl conscious sedation seems to influence a potential major number of shunt deployment in contrast with the other experiences reported in literature,^{8, 9} especially in cases of very old or non compliant patients. Although these procedures can lead to a little overestimation of false positive cases but no false negative cases were reported in our experience, showing an excellent neurological monitoring in most patients.

We did not observe major alterations of the

hemodynamic stability. Episodes of hypertension or hypotension were immediately corrected without cardiac complications and difference between RCS and LA groups.

The use of RCS leads to technically precise repair in a calm atmosphere especially in cases of a high bifurcation or lesion extending into the ICA, allowing careful hemostasis of the operating field at the end of the operation with potential benefit in reduction of postoperative hematoma, although in our experience no statistical difference in postoperative hematoma was noted.

With a good level of analgesia the orotracheal tube and the operative position are well tolerated and the airway control is guaranteed avoiding patient anxiety and stress due to the position for long time. Prophylaxis of postoperative nausea and vomiting with 10 mg of metaclopramide to reduce the incidence of these complications in 9 cases (3.2%).

Despite the many advantages, this anesthetic procedure can show important side effects due to hemodynamic instability during the induction, like bradycardia, arterial hypotension or hypertension especially in beta blocked patients or due to respiratory muscle contraction.¹⁰⁻¹⁴

In our experience, all changes occurred were quickly corrected on the basis of hemodynamic parameters, no cardiac complications in perioperative and post-operative were detected and no respiratory muscle contraction happened.

We consider that RCS has many anesthetic advantages due to safe neurological monitoring without impairment of cerebral auto-regulation, cardiovascular stability and a better airway control. From the surgical point of view this procedure can lead to a selective shunt policy, good compliance to both the patient and the surgeon, a calm environment during the endarterectomy, patching and haemostasis avoiding neck movements or patient discomfort.

Conclusions

Remifentanyl conscious sedation seems safe and effective with a very satisfactory results in term of early cardiovascular and neurological mortality and morbidity and long term outcomes comparable with those found in the literature using LA or GA. RCS may lead to an excellent monitoring of the neurological status, better airway

control and cerebral protection during arterial clamping. The possibility of hemodynamic instability during the induction still remains a controversial topic and it seems to be the Achilles heel of the procedure.

Randomized studies that compare this procedure with LA or GA are necessary to validate the techniques, but in our opinion remifentanyl conscious sedation might become an established anesthetic procedure for CEA.

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