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CLINICAL STUDY

Is carotid endarterectomy under the cervical plexus block safe for all patients with various degree of cardiovascular risk?

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Abstract: *Background:* The result of the GALA study did not answer the question whether it is safe to perform carotid endarterectomy (CEA) under the cervical plexus block (CPB) in patients at high cardiovascular (CV) risk. The aim of the study was to compare CV stability and the frequency of cardiovascular and neurological complications in 3 groups of patients with various degree of CV risk who underwent CEA under CPB.
Methods: 60 patients operated on in CPB were divided into the 3 groups according to the degree of their CV risk (I: very high, II: medium, III: low). Statistical analysis: Chi-square, Kruskal Wallis test.
Results: No statistically significant difference was confirmed in the changes of blood pressure (MAP, BP syst, BP diast), heart rate, cardiovascular complications, the rate of the shunt insertion and neurological complications and the level of haemodynamic instability, except for hypotension (p=0.041) in the three groups. Life threatening CV complications did not occur in any of the groups. The frequency of haemodynamic changes and postoperative complications: hypertension (I – 40 %, II – 60 %, III – 60 %), hypotension (I – 35 %, II – 25 %, III – 5 %), arrhythmias (I – 30 %, II – 15 %, III – 10 %), neurological complications: 2x (TIA), the frequency of shunt insertion: 15 %.
Conclusion: CPB can be performed in all three groups of patients, even in high-risk cardiac patients. The results will have to be confirmed in a larger group of patients in future *(Tab. 3, Fig. 4, Ref. 16)*. Full Text in free PDF *www.bmj.sk.*
Key words: carotid endarterectomy, cervical plexus block, pre-operative cardiovascular risk, postoperative complications.

The impact of the choice of anaesthesia on the outcome of carotid endarterectomy (CEA) has been studied extensively. A meta-analysis of the nonrandomized studies showed that the use of local anaesthesia was associated with significant reductions in the odds of death from all causes, stroke, myocardial infarction and pulmonary embolism within 30 days of surgery. However, a meta-analysis of the randomized studies showed a reduction in the risk of local haemorrhage, but there was no evidence of a reduction in the odds of operative stroke (1). On the other hand, the randomized trials were small, so the results of the large multicentre randomized study – GALA – were impatiently awaited. The results of the GALA – general anaesthesia vs. local anaesthesia – were published in December 2008 and no difference in outcomes between general and local anaesthesia was shown (2). The two groups did not differ significantly in terms of the quality of life, the length of hospital stay, or the primary outcome in the pre-specified subgroups of age, contralateral carotid occlusion, and baseline surgical risk. The primary outcome was the proportion of patients with stroke (including retinal infarction), myocardial infarction, or death between the randomization and 30 days after surgery. At the end of this study, it was recommended that the anaesthetist and surgeon could decide which anaesthetic technique should be used on an individual basis.

Furthermore, the results of the GALA study did not answer the question whether it is safe to perform carotid endarterectomy under the local anaesthesia in the group of patients with high cardiovascular risk. In the GALA study, 50 % of patients in general anaesthesia (GA) and 51 % in local anaesthesia (LA) were at low surgical risk and only 8 % (GA) and 9 % (LA) were at high surgical risk, similarly, if ASA classification was used, 65 % of patients were ASA I-II in both groups. A post-hoc analysis was done which predicted the overall outcome better than the original GALA analysis, but it was not clear yet whether the local or general anaesthesia was better in patients at different risks (2).

The cervical plexus block is the preferred type of anaesthesia due to the effective monitoring of the neurological condition (3, 4, 5, 6). However, this advantage is counterbalanced with a more intensive perioperative stress, which can contribute to a higher frequency of cardiac complications especially in high-risk patients (7). For example, slightly more myocardial infarctions

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Tab. 1. Risk and patients demographic factors.

	GROUP I high risk	GROUP II medium risk	GROUP III low risk
Age (median)	72.5 (65-82)	73 (55-84)	72.5 (58-82)
Gender			
Male	14	17	10
Female	6	3	10
RISK FACTORS		n	
high risk CV factors			
Myocardial infarction < 6 weeks	4	0	0
Angina pectoris: III[rd] degree	8	0	0
Heart Failure	6	0	0
Serious heart valvular disease	6	0	0
medium risk CV factors			
EF < 35%	7	6	0
Myocardial infarction > 6 weeks	9	17	0
Angina pectoris: I[st] and II[nd] degree	6	4	0
Ser. arrhythmias	2	4	0
low risk CV factors			
Diabetes mellitus	9	9	8
Hypertension	20	18	18
Smoking/ COPD	4	7	4
Obesity	1	7	1
Chronic renal disease	5	7	3
Neurological SYMPTOMS		n	
asymptomatic	11	8	6
TIA/Stroke	9	12	14

occurred in patients under the local anaesthesia than under the general anaesthesia in the GALA study (2).

In the view of the facts mentioned above, the following question arises whether the cervical plexus block can be recommended and safely performed in patients at high cardiovascular risk. The aim of this study was to compare the cardiovascular stability, the frequency of cardiac and neurological complications in the 3 groups of patients with various degree of cardiovascular risk who underwent CEA under cervical plexus block.

Method and statistics

Sixty consecutive patients who underwent the elective carotid endarterectomy under the cervical plexus block were included in the present prospective, nonrandomized study. The patients were grouped according to the cardiovascular risk and Physical Status Classification (ASA) into the 3 groups:

Group I: at high cardiovascular risk (myocardial infarction < 6 weeks, unstable AP and IIIrd degree AP, chronic congestive heart failure, hemodynamic important valvular disease), ASA IV – 20 patients.

Group II: at medium cardiovascular risk (coronary artery disease, chronic heart failure, serious arrhythmias), ASA III – 20 patients.

Group III: with associated less serious diseases (hypertension, DM, chronic obstructive pulmonary disease – COPD, chronic renal insufficiency), ASA II – 20 patients.

The various cardiovascular risk factors are given in Table 1.

Tab. 2. The values of systolic, diastolic, mean arterial blood pressure and heart rate (comparison: Kruskal-Wallis test).

	GROUP I high risk	GROUP II medium risk	GROUP III low risk	Statistical significance*
MAP				
Pre-op	100.5 (83–125)	108.5 (89–107)	105.5 (84–129)	
Pre-clamp	92 (47–131)	90 (45–122)	102 (66–134)	p=0.253 ns
Post-clamp	104.5 (75–139)	108 (62–161)	106 (69–146)	p=0.644 ns
The end	99 (63–114)	101 (71–122)	99 (72–131)	p=0.445 ns
BP syst				
Pre-op	148 (120–185)	159 (130–197)	146 (113–189)	
Pre-clamp	143.5 (60–192)	133.5 (75–189)	150 (89–186)	p=0.301 ns
Post-clamp	160.5 (113–224)	174.5 (97–221)	163.5 (102–230)	p=0.761 ns
The end	157.5 (120–177)	155 (101–194)	148 (100–206)	p=0.317 ns
BP diast				
Pre-op	78.5 (57–105)	83 (55–112)	79 (58–117)	
Pre-clamp	66.5 (40–97)	63 (30–96)	69 (47–103)	p=0.216 ns
Post-clamp	73 (53–104)	74 (45–132)	77.5 (48–105)	p=0.604 ns
The end	74.5 (43–91)	72 (48–97)	65 (50–94)	p=0.323 ns
Heart rate				
Pre-op	65 (45–100)	73.5 (57–102)	74.5 (40–102)	
Pre-clamp	60 (41–103)	68 (29–100)	74 (32–101)	p=0.310 ns
Post-clamp	67 (50–122)	71.5 (54–121)	71 (53–111)	p=0.799 ns
The end	72.5 (43–101)	69 (54–118)	66 (41–106)	p=0.236 ns

Median (IQR) * Kruskal-Wallis test ns - non significant

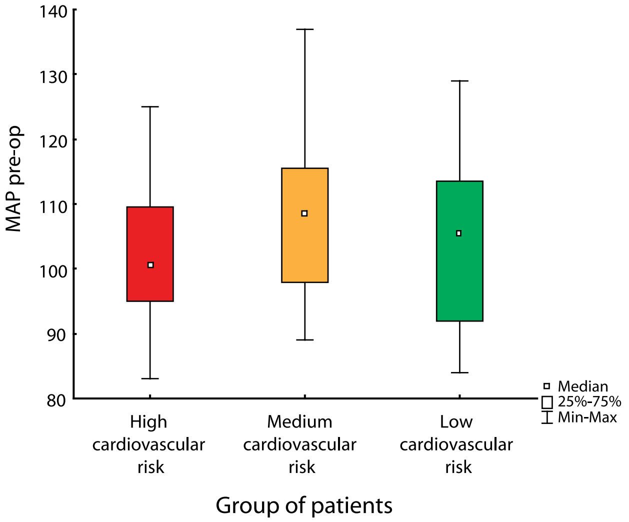

Fig. 1. MAP initial values: pre-op (group I – III).

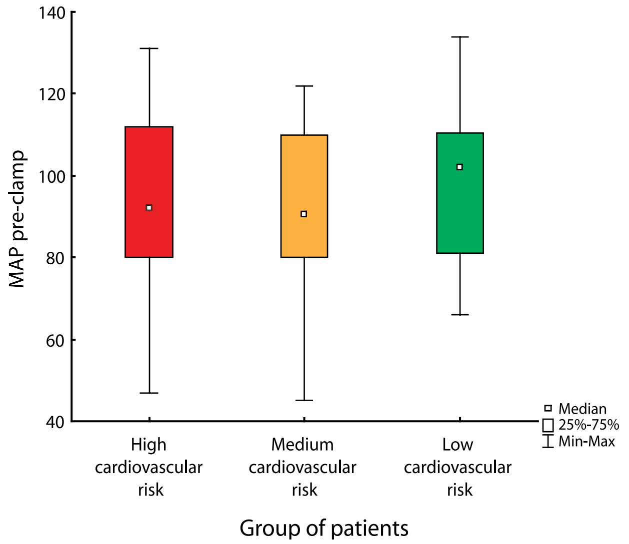

Fig. 2. MAP during preparation of carotid artery: pre-clamp (group I – III).

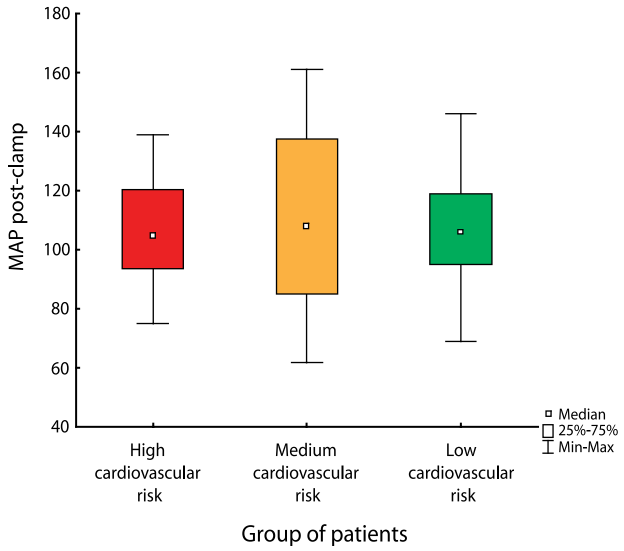

Fig. 3. MAP 1 minute after carotid cross-clamping: post-clamp (group I – III).

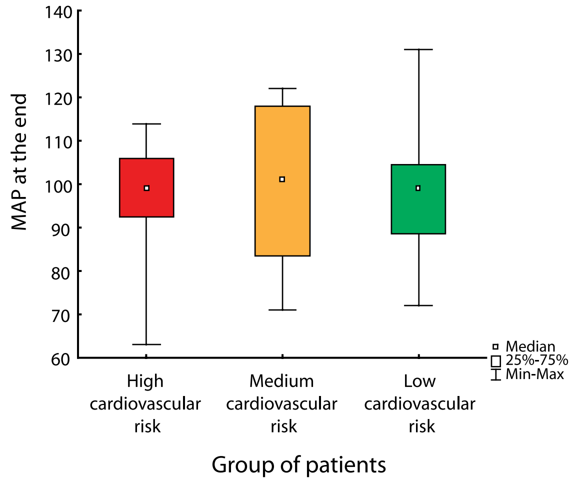

Fig. 4. MAP at the end of operation: the end (group I – III).

All the patients underwent the carotid endarterectomy under the cervical plexus block (combined with a deep part – at the level of nerve root C3). Bupivacaine + trimecaine were used as local anaesthetics.

During the operations, the following indicators were monitored: pulse oximetry, ECG, invasive arterial pressure, qualitative and quantitative state of consciousness, motor activities of the upper and lower extremities (grip strength), the function of the cranial nerves, and the quality of vision. The following data were recorded: mean, systolic and diastolic arterial blood pressure, heart rate, disorders of the heart rhythm, changes in the ST segment on the ECG of more than 1 mm, the occurrence of chest pain. Comparison was made in terms of the frequency of hypertension and hypotension, tachycardia, bradycardia, disorders of the heart rhythm, changes in the ST segment, frequency of the chest pain occurrence, and postoperative mortality. The insertion of shunt and neurological complications were recorded, too.

Hypertension was treated with i.v. infusion of vasodilators such as clonidine, isosorbide dinitrate or urapidile. Hypotension was conversely treated with intravenous application of colloids, noradrenaline or ephedrine. Tachycardia was treated with beta-blockers, bradycardia with atropine.

In the three groups of patients, the initial values (pre-op) of systolic, diastolic and mean arterial pressure and heart rate were compared to the values measured during the operation – in the course of carotid artery preparation (pre-clamp), 1 minute after the carotid cross-clamping (post-clamp) and at the end of the operation (the end). The Kruskal–Wallis test was applied to statistically analyze the changes in the values of blood pressure and heart rate during the operation compared to the initial values in the three groups of patients. A Chi-square test was used to compare the occurrence of haemodynamic changes, cardiovascular (CV) and neurological complications in the three observed groups of patients.

Results

On the basis of the calculated p-values (Kruskal–Wallis test) (Tab. 2), no statistically significant difference was proved in the changes of blood pressure (systolic, diastolic, mean arterial pressure) and heart rate in patients with various degree of cardiovascular risk. The graphic comparison of the individual variables is presented in Figures 1–4.

Hypertension (40 %), hypotension (30 %) and disorders of the heart rhythm (supraventricular and ventricular arrhythmias – 35 %) were the most frequent cardiovascular events in the group I, with high cardiovascular risk (patients with severe coronary diseases and/or chronic congestive heart failure). In the group II with medium CV risk, and III with low CV risk, the most frequent haemodynamic change was hypertension (60 % both in the group II and III), which was observed even more frequently than in the group I (high-risk patients). On the other hand, hypotension and arrhythmias were less frequent in the groups II and III than in the group I (Tab. 3).

Serious cardiovascular complications (MI, acute heart failure) did not occur in any group of patients, not even in the group I with high-risk cardiac patients. One patient in the group II with medium cardiovascular risk displayed symptoms of angina pectoris; cardiac troponin levels measured postoperatively were not increased. It was not necessary to finish surgery or to convert to general anaesthesia in any of the groups due to complications. In comparison, thr group I and III's haemodynamic instability moderately ascended with an increase in cardiac comorbidities, but no statistically significant difference in the level of haemodynamic changes among the groups I – III was confirmed (Tab. 2).

The insertion of shunt was necessary in 15 % of patients in all three groups (I – III). Neurological complications were detected twice: in one patient in the group I and in one patient in the group III. Both patients suffered from a transient ischemic attack and the symptoms disappeared in several minutes after the shunt insertion. A statistically significant difference in the occurrence of hypotension was discovered only once (Tab. 3). No statistically significant difference was found in the frequency of hypertension, tachycardia, bradycardia and postoperative complications in the groups I – III with various degree of cardiovascular risk (Chi-square test) (Tab. 3).

Surgical complications such as neck hematoma and wound infection were not detected. Short-term hoarseness was observed in 1 patient in the group II, 2 patients (1 in the group I and 1 in the group III) had temporary facial or hypoglossal nerve paralysis on the side of the block. Serious anaesthesia-related complications did not occur at all. Symptoms of systemic local anaesthetic toxicity or injection of the local anaesthetic into subarachnoid space were not observed. Severe complications such as collapse after the block placement and acute respiratory insufficiency were not noted in our patients either.

98 % of the patients were satisfied with the chosen type of anaesthesia. As sedation, we used benzodiazepines or a combination of benzodiazepines with low dose opioids.

Discussion

Surgery of carotid stenosis is one of the most frequent operations performed on elderly patients with severe concomitant illnesses. We preferred cervical plexus block in all patients even though they were cardiac limited since this type of anaesthesia allows a direct neurological monitoring. However, this advantage is counterbalanced with a more intensive perioperative stress, which can contribute to a higher frequency of cardiac complications especially in high-risk patients.

The degree of stress response during carotid endarterectomy was measured in a study by Marrocco-Trischitta and colleagues

Tab. 3. The frequency of haemodynamic changes and postoperative complications (comparison: Chi-square test).

	GROUP I high risk		GROUP II medium risk		GROUP II low risk		Statistical significance*	
Hypotension (MAP<70)	7	35%	5	25%	1	5%	0.041*	*s
Hypertension (TK>180/95, MAP>125)	8	40%	12	60%	12	60%	0.341	ns
Tachycardia (pulse>100)	3	15%	2	10%	2	10%	0.855	ns
Bradycardia (pulse<50)	2	10%	1	5%	1	5%	0.776	ns
ST- changes (depresses ST)	1	5%	0	0%	0	0%	0.328	ns
Arrhythmia	6	30%	3	15%	2	10%	0.244	ns
Chest pain (AP)	0	0%	1	5%	0	0%	0.328	ns
Frequency of the shunt insertion	3	15%	3	15%	3	15%	1	ns
Neurological complication (TIA)	1	5%	0	0%	1	5%	0.437	ns
Neck hematoma	0	0%	0	0%	0	0%	1	ns
Wound infection	0	0%	0	0%	0	0%	1	ns
Mortality	0	0%	0	0%	0	0%	1	ns

*Chi-square test: ns – non significant

(8). In this study, the patients were divided into the groups for general and local anaesthesia (the cervical plexus block). The stress response markers – ACTH, cortisol, prolactin, C-reactive protein – were monitored in both groups. The cortisol and ACTH levels during the operation were significantly higher in the cervical plexus block group. Carotid cross-clamping increased the cortisol and ACTH levels in both groups and the shunt insertion caused their further increase. Postoperatively, within 24 hours after surgery, the hormonal concentrations returned to the baseline values. Prolactin copied the tendency described in ACTH and cortisol. C-reactive protein increased postoperatively in both groups without any difference. On the basis of the measured hormones, it was proved that the intraoperative surgical stress was higher under the cervical plexus block and was escalated by carotid shunting in both groups. This difference decreases and equalizes during a short period after the operation. If the perioperative stress is higher under the cervical plexus block, we could assume that the haemodynamic instability and the frequency of serious cardiac complications would rise with an increase in cardiovascular risk. In addition, it might be necessary to convert CPB to GA or to finish surgery due to cardiac complications in the group of patients at high cardiovascular risk. In our study, we did not find any statistically significant difference in the frequency of haemodynamic instability and serious cardiac complications between the three groups of patients even if they were cardiac limited. It was not necessary to finish surgery or to convert to general anaesthesia in the group of patients at high cardiovascular risk.

Probably a good quality of sedation could help the patients tolerate the unpleasant position during the operation under cervical plexus block and contribute to a lower perioperative stress. We used benzodiazepines or their combination with opioids as sedative agents. Recently, low dose propofol or remifentanil have been the preferred type of intravenous sedation. Sedative effects and haemodynamic stability are the same for propofol and remifentanil although remifentanil has a more effective analgesic component and is associated with a higher degree of respiratory depression (a decrease in respiratory frequency, an increase in $paCO_2$) (9, 10). Both propofol and remifentanil probably could have been used in our study, but benzodiazepines or their combination with low dose opioids are safe in elderly and limited patients.

Even if CPB could be associated with a lower degree of patients' satisfaction with anaesthesia – high quality sedation can compensate this negative effect. Quigley and others did not find any statistically significant difference in the satisfaction of patients with general anaesthesia vs. local anaesthesia (11). They recommend using the type of anaesthesia, which is more suitable for the patient, the surgeon and the anaesthetist, thus coming to the same conclusion as the GALA study authors.

The second method of the local anaesthesia besides CPB is the well-described cervical epidural (CE) anaesthesia. CE anaesthesia may also provide good operating conditions and contribute to the patient's satisfaction; however, it is associated with a significant risk of major anaesthetic complications (1, 12). When both the techniques of regional anaesthesia were compared (an audit over 10 years: a study by Hakl et al), complications resulting from CE anaesthesia were significantly higher than with CPB (13). Life threatening complications occurred in 0.3 % in the CPB group and in 2.3 % in the CE anaesthesia group ($p<0.0001$). CBP was associated with a significantly lower frequency of anaesthesia-related complications. Although both methods of CPB and CE anaesthesia are acceptable for CEA surgery, in the view of the facts mentioned above, CPB was preferred in our study.

Combined CPB is commonly used in our department and due to this fact, combined CPB was chosen as the technique of cervical plexus block in our study. On the other hand, the authors of a study from 2006 addressed a new question concerning the technique of CPB (14). Young-Kug and colleagues detected that combined cervical plexus block for CEA caused changes in autonomic cardiovascular regulation. They found that systolic blood pressure and heart rate increased after combined CPB. Baroreflex sensitivity decreased and this decrease was negatively correlated to the systemic blood pressure increase. These findings suggest the alteration in autonomic cardiovascular regulation after combined CPB, which can play an important role in increasing cardiac risk especially in patients with coronary artery disease. In this case it is necessary to ask whether superficial CPB alone would be more appropriate for the high-risk patients. The comparison of superficial cervical plexus block with deep/combined CPB in the systematic review by Pandit and others could help to answer this question (15). It was found that a higher rate of serious systemic complications (odds ratio 2.13, $p=0.006$) was associated with deep/combined block when compared to the superficial block. The conversion rate to general anaesthesia was also higher with deep/combined block (odds ration 5.15, $p<0.0001$). Consequently, Pandit and colleagues concluded that superficial CPB is safer than any other method that uses deep injection. The hazard of deep CPB includes injecting into the cerebrospinal fluid, arterial injury, intra-arterial injection, and phrenic nerve paralysis resulting in respiratory distress. These anaesthetic-related complications can be dependent on an anaesthetist's practice and technique. It is apparent in our study that no serious anaesthetic-related complications were found in the groups of our patients and it was possible to use the cervical plexus block safely in all the patients. Probably, the superficial CPB will be more preferred technique in the future.

Besides carotid endarterectomy, carotid artery stenting (CAS) should be mentioned as a new safe and reasonable alternative for high risk patients. CAS has experienced tremendous growth over the last decade and could be reserved for patients with adverse local anatomic factors or prohibitive medical comorbidities (16). Patients with severe concomitant diseases, including coronary artery disease, chronic renal insufficiency, and chronic obstructive pulmonary disease should be considered as patients at increased risk for complications after carotid endarterectomy and may prove to be more safely treated by CAS. Furthermore, CAS could be a preferable choice in the subgroup of high-risk patients with contralateral occlusion and advanced age and significant cardiac medical comorbidities (16). Despite CAS has been promoted as a preferred intervention for high risk patients, the exact role of CAS in each of these individual high risk categories may still need to be defined. The long term benefit of any intervention in these patients is not well documented and due to this fact the carotid endarterectomy still remains the gold standard for carotid revascularization.

In summary, patients with high, medium and low cardiovascular risk underwent carotid endarterectomy under a combined cervical plexus block in our study. No statistically significant difference was confirmed in the occurrence of neurological complications and haemodynamic instability in the three groups of patients with various degree of cardiovascular risk. Similarly, when changes in blood pressure and heart rate during the operation were compared, no statistically significant difference was discovered in the three groups, except for hypotension (p=0.041). Conversion to general anaesthesia and life-threatening complications did not occur in any of the groups, not even in the group of high-risk cardiac patients. Haemodynamic instability (hypertension, hypotension, bradycardia, and tachycardia) was treated by common drugs in all the cases and there was no death within 30 days after surgery in the three groups of patients. Even if the size of the sample of patients is taken into account, we may conclude that the cervical block can be used in all patients, even if they are cardiac limited. Our results will have to be confirmed in a larger group of patients in future.

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