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STATISTICAL EVALUATION OF THE EFFICIENCY OF THE TWO TYPES OF PROTECTION SYSTEMS IN CAROTID ARTERY STENTING

29.1 INTRODUCTION

This article deals with a comparison of the two types of protection systems that are commonly used in carotid artery stenting (CAS). Carotid artery stenting is a treatment of carotid artery stenosis, which is a narrowing of the carotid artery (the artery that supplies the brain) caused by a plaque buildup in the artery wall (Fig. 1).

Fig. 29.1 Perioperative DSA angiography showing tight stenosis
Source: Vítkovice Hospital archive

Pieces of plaque can break off and block the blood flow in the artery, which leads to a stroke. Stroke is the third leading cause of death in industrialized countries and the major cause of functional impairment [3]. In the Czech Republic, stroke is the second leading cause of death and the leading cause of functional impairment [1].

Carotid artery stenting is an endovascular surgery where a stent (a tube-like metalic mesh, Fig. 2) is deployed within the lumen of the affected carotid artery to dilate it (Fig. 3) and prevent a stroke.

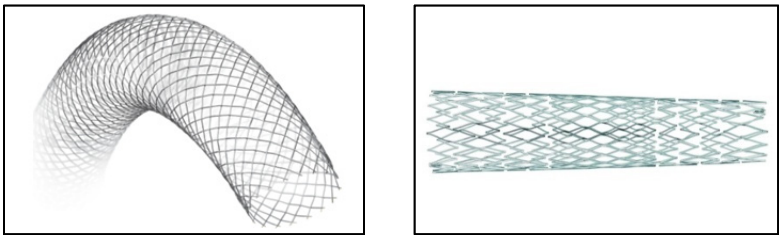

Fig. 29.2 Two types of stents

Source: Vítkovice Hospital archive

Fig. 29.3 Control DSA angiography after stent implantation

Source: Vítkovice Hospital archive

Two types of embolic protection devices are commonly used during CAS - distal protection devices (filters) and proximal protection devices.

Fig. 29.4 Two types of protection devices - filter (on the left) and proximal protection device (on the right)

Source: Vítkovice Hospital archive

29.2 METHODOLOGY

29.2.1 Aim of the study

The aim of our study was to determine whether the two types of embolic protection systems for CAS, distal protection devices - filters and proximal protection devices - Mo.Ma systems differ in the number and in the location of new ischemic lesions after surgery.

29.2.2 Study design

The study was designed as a single-center, prospective, randomized and comparative. The patients from Vítkovice Hospital, Ostrava, indicated to CAS from 2012 to 2015, were randomized in a 1:1 fashion to get either filter protection (Filter group) or proximal balloon protection (Mo.Ma group). The incidence of new microembolic lesions after CAS was detected using magnetic resonance imaging (MRI).

29.2.3 Statistical analysis

Statistical analysis was carried out with the programs SPSS (Chicago, IL, USA) and Microsoft Excel (Redmont, WA, USA). Continuous variables were presented as mean ± SD, and Mann-Whitney test was used for their comparison, categorical variables were compared using χ^2 test. χ^2 test and arcsine test were used for testing the main hypothesis. The value of $p = 0.05$ was taken as a level of significance.

29.3 STATISTICAL TESTS

29.3.1 Pearson's chi-squared test

Pearson's chi-squared test, also written as χ^2 test, is used to determine whether there is a significant difference between the expected frequencies and the observed frequencies in one or more categories. Its properties were first investigated by Karl Pearson in 1900 [5].

In our case we have two categorical variables from a single population. The χ^2 test is used to determine whether there is a significant association between the two variables. Suppose that variable X has r levels, and variable Y has s levels. Let us use the notation O_{ij} for expected frequencies and E_{ij} for empirical frequencies ($i = 1 .. r$, $j = 1 .. s$). The null hypothesis "H_0: Variables X and Y are independent", is tested using the test statistic T:

$$T = \sum_{i=1}^{r} \sum_{j=1}^{s} \frac{(O_{ij} - E_{ij})^2}{E_{ij}} \; .$$

Assuming that the null hypothesis is true, the variable T has approximately χ^2 distribution with $(r - 1).(s - 1)$ degrees of freedom.

29.3.2 Mann-Whitney test

The Mann-Whitney test [4] is the most popular of the two-independent-samples tests, which is used for ordinal or continuous data. It is a nonparametric test that, unlike the t-test, does not require the assumption of normality. It tests whether two sampled populations are equivalent in medians. The observations from both groups are combined and ranked, with the average rank assigned in the case of ties. The number of ties should be small relative to the total number of observations. If the populations are identical in medians, the ranks should be randomly mixed between the two samples.

The test statistic of the Mann-Whitney test is calculated this way: the sums of ranks for each of the groups (S_1 and S_2) are calculated and statistics U_1 and U_2 are computed:

$$U_1 = n_1 n_2 + \frac{n_1(n_1+1)}{2} - S_1,$$

$$U_2 = n_1 n_2 + \frac{n_2(n_2+1)}{2} - S_2,$$

where n_i denotes the sample size in group i (i = 1,2). The test criterion has the form:

$$T = \min(U_1, U_2).$$

The critical values of its distribution can be found in statistical tables. If the observed value of the test criterion is less than or equal to the corresponding critical value, the null hypothesis asserting that the medians of the two samples are identical is rejected.

29.3.3 Arcsine test

The arcsine test [2] is a test about parametr π of binomial distribution. It is used as an alternative of Wald test in case of files with small sample sizes. It is based on the use of the arcsine transformation, which stabilizes the variance.

Let us have a single variable X that counts the number of successes in a sequence of n Bernoulli trials (ie. X follows the binomial distribution with parameters $n \in \mathbb{N}$ and $\pi \in [0, 1]$). The null hypothesis „H_0: $\pi = p$" is tested using the following test statistics:

$$T = 2\sqrt{n}\left(\arcsin\sqrt{\frac{X}{n}} - \arcsin\sqrt{p}\right)$$

with an asymptotic standard normal distribution.

29.4 RESULTS

29.4.1 Patients characteristics

Of 77 patients who met the study criteria 21 patients were subsequently excluded for various reasons (contraindications of CAS or MRI detected after randomization, technical problems with MR, etc.). So the total amount of 56 patients entered the study, 37 in the Filter group and 19 in the Mo.Ma group. Their basic characteristics did not differ in the two groups, as showes Table 1.

Table 29.1 Baseline patients' characteristics

	Filter (n = 37)	Mo.Ma (n = 19)	p-value
Age	65.8 ± 6.1	66.5 ± 7.4	0.87
Gender (male)	75.68 %	78.95 %	0.78
Hypertension	84.00 %	89.00 %	0.57
Diabetes mellitus	24.00 %	32.00 %	0.56
Renal insufficiency	5.41 %	5.26 %	0.98
Smoking	70.00 %	63.00 %	0.59

Atrial fibrillation	3.00 %	5.00 %	0.63
Ischemic heart disease	32.00 %	21.00 %	0.37
Congestive heart failure	5.00 %	0.00 %	0.30
Peripheral arterial disease	30.00 %	37.00 %	0.59
Stroke	35.00 %	32.00 %	0.79
Transient ischemic attack	24.00 %	32.00 %	0.56
Amaurosis fugax	3.00 %	5.00 %	0.63
Carotid stenosis side (right)	62.00 %	52.63 %	0.49
Symptomatic stenosis	43.00 %	42.00 %	0.94

Source: own study

29.4.2 Hypothesis testing

New ischemic lesions on MRI after CAS were found in 32.14% (n = 18) of all patients, 32.43% (n = 12) in the Filter group and 31.58% (n = 6) in the Mo.Ma group (see Tab. 2). The difference in the proportions of new ischemic lesions in the two groups of patients was not statistically significant (χ^2 test, $p = 0.474$).

Table 29.2 New ischemic lesions after CAS

	Number of patients	New lesions
Total	n = 56	n = 18 (32.14%)
Filter	n = 37	n = 12 (32.43%)
Mo.Ma	n = 19	n = 6 (31.58%)

Source: own study

Table 3 shows the differences in the location of new ischemic lesions after surgery. Only 38.89% (n = 7) of all new ischemic lesions were located solely in the territory of the treated artery, 16.67% (n = 2) in the Filter group and 83.33% (n = 5) in the Mo.Ma group. The difference between the number of new ischemic lesions in and outside the territory of the treated artery was found statistically significant both in the Filter group (arcsine test, p = 0.006) and in the Mo.Ma group (arcsine test, p = 0.037).

Table 29.3 Vascular territories of new ischemic lesions

	Total	Filter	Mo.Ma
Treated artery	n = 7 (38.89%)	n = 2 (16.67%)	n = 5 (83.33%)
Contralateral artery	n = 3	n = 3	n = 0
Vertebrobasilar territory	n = 1	n = 1	n = 0
Several territories together	n = 7	n = 6	n = 1

Source: own study

CONCLUSION

In this randomized trial of patients undergoing CAS no difference was found in the efficacy of distal protection devices (filters) and proximal protection devices (Mo.Ma systems), as the number of new ischemic lesions in these two groups did not differ significantly. It means that there is no reason to prefer any of these protection systems in practice.

Significantly more lesions were located outside the territory of the treated artery in the Filter group and inside the territory in the Mo.Ma group. It reflects the danger of the way the protection systems are installed and removed.

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Abstract: *The article deals with the evaluation of the efficiency of the two types of protection systems in carotid artery stenting (CAS). Carotid artery stenting is a treatment of carotid artery stenosis, which is a narrowing of the carotid artery caused by a plaque buildup in the artery wall. Pieces of plaque can break off and block the blood flow in the artery, which leads to a stroke. Carotid artery stenting is an endovascular surgery where a stent is deployed within the lumen of the affected carotid artery to dilate it and prevent a stroke. Two types of embolic protection devices are commonly used during CAS - distal protection devices (filters) and proximal protection devices. The aim of this study was to determine whether the two protection systems differ in the number and in the location of new ischemic lesions after surgery. Statistical analysis was carried out with the programs SPSS and Microsoft Excel. Mann-Whitney test, χ2 test and Arcsine test were used and the value of p = 0.05 was taken as a level of significance.*

Keywords: c*arotid stenosis, embolic protection devices, statistical tests, Mann-Whitney test, χ2 test, Arcsine test*

STATISTICKÉ VYHODNOCENÍ ÚČINNOSTI DVOU TYPŮ PROTEKČNÍCH ZAŘÍZENÍ PŘI KAROTICKÉM STENTINGU

Abstract: *Tento článek pojednává o vyhodnocení účinnosti dvou protekčních systémů používaných při karotickém stentingu (CAS). Karotický stenting je léčba karotické stenózy, což je zúžení karotické tepny způsobené plakem usazeným na cévní stěně. Kousky plaku se mohou uvolnit a zablokovat průchod krve, což může způsobit mozkovou mrtvici. Karotický stenting je endovaskulární chirurgická metoda, při které se do postižené tepny zavede stent, který má tepnu roztáhnout a zabranit tak mrtvici. V průběhu CAS jsou běžně používány dva typy protekčních zařízení - distální protekční zařízení (filtry) a proximální protekční zařízení. Cílem této studie bylo zjistit, zda se tyto dva protekční systémy liší v počtu a v lokalizaci nových ischemických lézí po operaci. K statistické analýze byly použity Mannův-Whitneyův test, χ2 test a arcsinový test (s hladinou významnosti p = 0,05), výpočty byly provedeny pomocí programů SPSS a Microsoft Excel.*

Keywords: *stenóza karotidy, protekční zařízení, statistické testy, Mannův-Whitneyův test, χ2 test, arcsinový test*

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Mgr. Marcela RABASOVÁ, Ph.D.
VŠB - Technical University of Ostrava
Department of Mathematics and Descriptive Geometry
17. listopadu 15, 70833, Ostrava-Poruba, Czech Republic
tel.: +420 608 708 409, e-mail: marcela.rabasova@vsb.cz

MUDr. Ondřej PAVLÍK
Vítkovice Hospital, Ostrava-Vítkovice
Department of Neurology
Vítkovice Hospital, Zalužanského 1192/15, 703 84, Ostrava – Vítkovice, Czech Republic
tel.: +420 595 633 449, e-mail: ondrej.pavlik@vtn.agel.cz