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Randomized, controlled clinical trial comparison of SDM laser versus argon ion laser in diabetic macular edema

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阈下微脉冲激光与氩离子激光治疗糖尿病性黄斑水肿的临床随机对照研究

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摘要

目的:比较阈下微脉冲激光(波长 810nm)同氩离子激光(波长 514nm)治疗糖尿病性黄斑水肿的疗效。

方法:采用临床随机对照研究的方法对 84 例 99 眼进行分组,并分别行 810nm 激光与 514nm 激光,治疗后随访 6mo,行最佳矫正视力、FFA、OCT 检查,评估疗效。

结果:50 眼及 49 眼分别完成了 810nm 激光及 514nm 激光治疗,治疗后随访结果显示:无论 810nm 还是 514nm 激光均能稳定及提高视力,二组间差异无统计学意义($P>0.05$);治疗前后视网膜厚度及黄斑水肿均有所改善,且自身治疗前后差异有统计学意义($P<0.05$),二组间差异无统计学意义($P>0.05$)。

结论:无论 810nm 激光还是 514nm 激光均可以一定程度的稳定及提高视力,且对糖尿病性黄斑水肿治疗有效,二者间的差异无统计学意义。

关键词:阈下微脉冲激光;氩离子激光;糖尿病性黄斑水肿

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Abstract

• AIM: To compare the efficacy of subthreshold micropulse diode (SDM) laser treatment and argon ion laser treatment for diabetic macular edema (DME).

• METHODS: A prospective, randomized controlled trial was carried out in 84 patients (99 eyes), in which, 49 eyes received argon ion laser treatment and 50 eyes received SDM laser treatment. The changes in best corrected visual acuity (BCVA), baseline fluorescein angiography and optic coherence tomography measurements were evaluated in both groups. Follow-up visit was over 6 months from baseline.

• RESULTS: Ninety-nine eyes (84 patients) complete the study. Six months after treatment, the BCVA improved 22.4% and 20.0% eyes in argon ion laser group and SDM laser group respectively. 55.1% and 58.0% eyes received steady BCVA. Edema partial regression was accounted for 49% in argon ion laser group, while that was 56% in SDM laser group. No statistically significant changes were found in each group.

• CONCLUSION: No matter argon ion laser or SDM laser is effective to keep or improve the VA in DME. After 6-month follow-up, there is no statistically significant difference between them.

• KEYWORDS: argon ion laser; SDM laser; diabetic macular edema
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INTRODUCTION

With the prevalence of diabetes increased, the blindness populations due to diabetes are constantly expanding; while diabetic macular edema (DME) is the most common cause of visual loss among diabetic patients; acording statistics[1], 28% of the population in patients with type 2 diabetes more than 20 years will occur diabetic macular edema. Currently, macular photocoagulation is the established mode of treatment for clinically significant macular edema as defined by early treatment diabetic retinopathy study group[1]. However, laser effects on the retina vary from different wavelengths. This study aimed to evaluate the effect between the subthreshold micropulse diode laser (SDM, 810nm) and argon ion laser (514nm) in the treatment of DME.

SUBJECTSAND METHODS

Subjects Ninety-nine eyes from 84 diabetic individuals were included in this study from July 2010 to July 2012.

Inclusion criteria 1) The endocrinologist diagnosed with type 2 or type 1 diabetes; 2) diagnosis of the DME by ophthalmologist combined FFA, OCT; 3) no significant refractive media turbidity; 4) no other ocular disease history include: glaucoma or anti-glaucoma surgery history, congenital retinal disease history or acquired retinal surgery, retinal laser treatment history.

Randomization methods Ninety-nine eyes of 84 patients with DME were randomized to either SDM or the argon ion laser group. The sequence generated by the Statistics Department in our hospital, who put the generated random allocation sequence into the coding sequence, sealed, opaque envelopes, nobody know the patients would accept what kind of laser until the doctor who never join the statistical analysis open the envelope. The subjects allocated to the appropriate groups and accept corresponding laser treatment. After the laser treatment, the laser energy and the points are recorded in the envelope. The envelop can be open until 6-month follow-up finished.

Methods of the laser treatments Argon ion laser group: ETDRS treatment procedures, Laser 156 to 329 points. SDM laser group: the FFA to determine the therapeutic range were carefully studied, *i. e.*, according to FFA showed retinal vascular leakage in all areas. IRIDEX Oculight SLx 810 semiconductor laser was used to fusion laser treatment, the use of full-field microscopy confirmed the location in need of treatment, and then a micro-pulse mode is set to the alignment of the semiconductor laser in which the energy is adjusted to an area sufficient to cause a visible burning reaction, and then half the energy to the leakage area treated. Spot diameter is 125μm, the exposure time is 0.3s, 70mv, with 5% duty cycle laser treatment ,Laser points is 120-319. Macular laser treatment should be priority to PRP, because of the ophthalmoscope cannot directly detect the Photocoagulation spots Immediately, follow-up 1 month if the edema declined not ideal, re-laser treatment with SDM should be done.

Outcome measures All patients underwent a complete ocular examination, including assessment of best corrected visual acuity (BCVA), applanation tonometry, slit lamp examination, dilated fundus examination, fundus fluorescein angiography, Central macular thickness was ultomatically measured by OCT.

Responses after treatment were evaluated with respect to BCVA and examination, and measurement of intraocular pressure were conducted at each follow-up visit. OCT and FFA was performed six months after the initial treatment.

Visual acuity in the initial treatment of the baseline, after laser treatment, visual acuity improved in 2 lines or more is "better", vision fluctuations up and down a monk at baseline is "maintain", vision loss compared to baseline by 2 lines or more is "Deterioration" FFA: macular leakage disappeared completely for "edema disappeared completely.", Leakage from the previous decline but there were some leakage as "partial edema subsided," no significant change compared with the previous leaks and even aggravated by "not edema subsided.

OCT: to evaluate the thickness of foveal retinal.

Statistical Analysis Statistical analysis was performed with SPSS program (version 17.0). Data were expressed in frequency, percentage, mean and standard deviation as applicable. Analysis of variance (ANOVA) was used to compare between groups and Paired t-test was used to compare in each group. The criterion for statistical significance was taken as $P \leqslant 0.05$.

Table 1 Basic characteristics of patients

Variable	Argon ion laser group	SDM laser group
Age (a)	56.0±5.9	58.0±9.3
Sex		
Male	26 (53.1%)	36 (72.0%)
Female	23 (46.9%)	14 (28.0%)
Ethnic		
Han	33 (67.3%)	25 (50.0%)
Uighur	14 (28.6%)	22 (44.0%)
Hui	2 (4.1%)	3 (6.0%)
Diabetes duration (a)	8.9±4.2	10.1±5.0
Glycemic control (mmol/L)	8.9±1.0	9.2±1.1
VF before treatment	0.21±0.18	0.23±0.18
Retinal thickness before treatment(μm)	339.4±143.2	338.0±136.0

Table 2 Vision changes and edema regression before and after treatment with two kinds of laser treatments *n*(%)

Variable	Argon ion laser group	SDM laser group
VF		
Improve	11 (22.4)	10(20.0)
Steady	27 (55.1)	29 (58.0)
Decline	11 (22.4)	11 (22.0)
Edema changes		
Edema subsided completely	14 (28.6)	11 (22.0)
Edema partial regression	24 (49.0)	28 (56.0)
Edema aggravation	11 (22.4)	11 (22.0)

Statistical: VF: $H=0.03$, $P=0.99$; Edema changes: $H=0.23$, $P=0.89$.

RESULTS

Ninety-nine eyes of 84 patients were enrolled in the study. Table 1 describes the basic characteristics of patients. Compared with the corresponding test methods the characteristics of the two groups of patients, the test results show there has not statistically significant differences between the two groups ($P>0.05$), in other words, two groups of patients with good comparability.

Table 2 shows, BCVA stabilized in more than half of the patients, and more than one fifth eyes VA improved. DME decreased after laser treatment in both group. But there has no significant difference between two groups ($P>0.05$).

The OCT revealed that no matter which group through the laser treatment can decrease the foveal thickness to some extent (Table 3).

Table 3 Retinal thickness before and after treatment with two kinds of laser treatments

Parameters	Argon ion laser group	SDM laser groups
Before treatment	339. 4±143. 2	338. 0±136. 0
After treatment	315. 7±145. 0	301. 2±132. 7
Difference	23. 7±37. 1	36. 7±35. 1
t	4. 48	7. 41
P	0. 0001	0. 0001

Statistical: $F=0.17$, $P=0.85$.

DISCUSSION

Now more commonly used in the treatment of DME laser with an argon ion laser (514nm or 488-514nm) and krypton ion laser (647nm). Argon laser photocoagulation for DME has made reliable and safe treatment. According to the American Diabetic Retinopathy Study Group Report , argon ion laser with full photocoagulation can decrease the risk more than 50% within two years of serious visual impairment, but due to the spectral composition of the argon ion laser is more complex, big spot area, cause the large damage in the retinal[2]. Argon laser can be visible, with a short-term temperature effects, can photocoagulation local temperature rise within the 0. 5-1. 0s to 60 degrees, to produce a laser spot on the retina[3], with the progress of time, so that two spot will gradually expand adjacent spots may merge, resulting in loss of function of the retina between them[4]. In addition, the thermal effect of argon laser non-selective, in addition to acting on the RPE, but also cause nerve epithelium damage to form atrophy spots and the corresponding visual field defects, for macular lesions caused permanent vision decreased[5]. Therefore, argon laser photocoagulation treatment causes RPE acceptable axial and longitudinal heat transfer to the retina, causing neurosensory micro- structural damage.

The foveal cone cells is dense place, so, the scholars are concerned to choose a laser with treatment effect but without inner retina injury. In order to achieve the optimal effect of laser treatment, people in the laser wavelength, waveform, pulse frequency, *etc*. made many attempts, SDM is a new resultant laser photocoagulation, which is a subliminal method can selectively act on the RPE, the heat diffusion to the surrounding structures to a minimum, to minimize the damage to the inner retina. Clinical studies have been[6-9] show micro-pulse laser is effective to treat the DME. This study is hoped that through randomized clinical comparative study to make clearly which laser treatment is more better in improve the VA and make the patients feel more comfortable in the treatment process.

The survey results show that 58. 0% of patients on a stable visual acuity with SDM laser in the treatment of DME, 20. 0% of patients improved visual acuity; While in argon ion group, 55. 1% patients obtain steady VF, 22. 4 % of the patients vision improved; The vision can be maintain and enhance between the two kinds of laser treatment, meanwhile, there was no statistically significant difference among them. However, in the process of follow-up, several patients with argon ion laser group had mild decline in visual acuity, but in the end of follow-up to six months there were no differences in two groups in visual acuity.

From the FFA and the OCT measuring retinal thickness and macular edema, 80% of patients in both groups have varying degrees of macular edema reduction, but some patient with mitigated macular edema not achieve improved VA, and the principle still in discuss.

In sum, the study show whether SDM laser or argon ion laser for treatment of the DME were effective, all of them can stablized the VA and decrease the foveal thickness, but there has no statistically significant difference between the two kinds of laser treatment. While, in the process of the treatment, there still exist some difference as follow: 1) argon ion laser make the patients pain than SDM treatment. argon ion laser treatment cause macular edema aggravated in a short term, so it resulting in some patient poor follow-up. 2) SDM laser in the treatment without pain and obvious photocoagulation ports, but due to the spot not visible after treatment immediately, once the edema decline unsatisfactory, it is necessary to re-treatment, fluorescein angiography is necessary in order to prevent the spot overlap, according to the Literature shows that the spot of the SDM laser will not blend situation, because of our survey in a limited time, now it was hard to understand whether fuse or not, so the investigation team will continue to follow-up, expect to abstain more long-term clinical follow-up information to helps us to choose the laser treatment.

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