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ORIGINAL RESEARCH

Efficacy and Safety Evaluation of 595 nm Pulsed Dye Laser Treatment in 120 Cases of Asian Infants With Port Wine Stain

Yiqun Guo, Hua Jiang, Yizhou Jiang, Xiaoyun Tan, Haibo Li, Jiejun Xia, Zhen-Yin Liu

Department of Interventional Radiology and Vascular Anomalies, Guangzhou Women and Children's Medical Center, Guangzhou, 510120, People's Republic of China

Correspondence: Haibo Li; Zhen-Yin Liu, Department of Interventional Radiology and Vascular Anomalies, Guangzhou Women and Children's Medical Center, Guangzhou, 510120, People's Republic of China, Tel +86-20-38076434, Email 448214152@qq.com; liuzhenyinch@163.com

Introduction: This study aimed to evaluate the efficacy and safety of a 595 nm pulsed dye laser (PDL) for the treatment of port wine stain (PWS) in 120 Asian infant patients.

Methods: A retrospective analysis was carried out to assess the efficacy and safety of 595 nm PDL in 120 Asian infant patients with PWS.

Results: This study identified excellent (21.67%), good (23.33%), fair (30.83%), and poor (15.83%) clearance. Multiple treatments significantly improved efficacy, with 61.56% of patients achieving good or excellent responses after more than six sessions. Younger patients showed better treatment outcomes than older patients did. The lesion location influenced the response, with leg lesions exhibiting the poorest response. The pink lesions were the most susceptible, whereas the purple lesions displayed the least response. Smaller lesions (<10 cm²) showed a size-dependent excellent rate (41.0%) and lower poor rate (5.1%).

Conclusion: The 595 nm PDL treatment displayed a favorable safety profile, with only mild, well-tolerated adverse effects. Rare adverse effects were resolved within 3–6 months. No severe adverse events were reported. The 595 nm PDL is safe and effective for Asian infant patients with PWS. The side effects were mild and well-tolerated by the patients.

Keywords: port wine stain, pulsed dye laser, 595 nm, Asian infants, safe, effective

Introduction

Port wine stain (PWS) is a congenital malformation of vasculature in the superficial dermis, occurring in approximately 0.3–0.5% of newborns.[1,2] PWS typically presents at birth and does not commonly vanish. If left untreated, it usually progresses. Without intervention, the color of the lesions gradually darkened, and epidermal hyperplasia increased with age. Pyogenic granulomas may develop in some cases, there is even the development of pyogenic granuloma.[3] In addition to medical complications, PWS experience a considerable degree of psychological morbidity.[4]

The flash lamp-pulsed dye laser (PDL) is currently the gold standard for treating PWS.[5] The efficacy of laser treatment is influenced by various factors such as lesion size, color, location, hypertrophy, and vessel architecture.[6,7] While most PWS studies have been reported in Europe and North America, little data are available on white men. Moreover, there is a scarcity of data about Asian populations, particularly infants and children.

In this study, we collected data from 120 Asian infants with PWS at the Guangzhou Women and Children's Medical Center between January 2019 and January 2020. We assessed the relative safety and efficacy of PDL in a cohort of Asian infants with PWS.

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Materials and Methods

Patients

This study was a retrospective review of patients with congenital PWS who were treated at our institution between January 2019 and January 2020. Patients aged between 1 month and 6 years with extra-facial homogenous PWS were eligible for inclusion, resulting in a total of 120 cases enrolled in this study. Patients were categorized into three groups based on age: Group A (3–12 months), Group B (13–36 months), and Group C (> 36 months). Key exclusion criteria included the presence of a nodular or hypertrophic component in the treatment area, and a history of laser treatment for PWS in the last three months. Information on age, sex, anatomical location, side effects, and adverse events was extracted from chart records, and written informed consent was obtained from the guardians of all participants before study participation. This study was approved by the Ethics Committee of our institution.

Treatment Procedure

All treatments utilized a 595-nm V-beam Pulsed Dye Laser (PDL) (Candela Corp, Wayland, MA, USA). Fluence settings ranged from 6.50J/cm² to 8.50J/cm², with a 7mm or 10mm spot size and 1.5-millisecond pulse duration, and the influence settings were adjusted based on treatment response. Dynamic cooling was applied using tetrafluoroethane spray 30 ms before each pulse, followed by a 20-millisecond post-laser pulse delay. During treatment, the infants were held by nurses with eye protection. No anesthesia was administered. The pulsed laser was delivered to the entire lesion, with an overlap of only 15%. A cool hydrogel dressing was applied immediately after treatment for a few minutes, followed by further wound care. Doctors captured photographs of lesions before treatment using digital cameras under similar lighting conditions.

Colorimetric Assessment

The colors of the treatment areas and contralateral normal skin were measured using a colorimeter (CR-300; Konica Minolta). The Commission Internationale de l'Eclairage (CIE) color measurement system was used to express colors as lightness (L), a (values from green to red (a), and b (values from blue to yellow (b). The color difference (DE) between the PWS lesion and contralateral normal skin was calculated. The blanching rate (%) was determined based on the color differences before and after treatment (at 6 months follow-up).

Photographic Evaluation

Standardized digital photographs were taken pre- and six months post-treatment and at the 6-month follow-up. The sequences of the four treatments were randomly assigned based on a list generated by the Department of Biostatistics at Guangzhou Women and Children's Medical Center. Blanching of the PWS lesion was independently assessed by three experts to evaluate the degree of color fading and/or area reduction respectively using clearance scores of 5 (excellent, >75% clearance), 4 (good, 51–75% clearance), 3 (fair, 25–50% clearance), and 2 (poor, <25% clearance).[8] Serial photography was utilized for scoring. If the three experts disagree, the same opinion of two of them shall prevail.

Statistical Analysis

The data were analyzed by using SPSS 17.0 software. Significant differences among treatment groups were assessed by Kruskal–Wallis test followed by a Mann–Whitney test with a Bonferroni correction. $P < 0.05$ was considered statistically significant.

Results

Patient Characteristics

The demographic details of the 120 enrolled patients are summarized in Table 1. The median age of the patients was 22 months (range: 1–77 months). Lesions were observed on the forehead, orbit, cheeks, wings of the nose, lips, necks, limbs, and trunks. This study included 51 male cases and 69 female cases. Patients were categorized into three groups: Group A (3–12 months), 45 cases; Group B (13–36 months), 49 cases; and Group C (36 months and older), 26 cases.

Table 1 Demographic Data of All Participants

	No. of Patients (%)
Sex	
Male	51 (42.5)
Female	69 (57.5)
Age (months)	
Range	1–77
Median	22
Fitzpatrick skin type	
II	5 (4.2)
III	5 (4.2)
IV	110 (91.6)
Location	
Face, neck	66 (55.0)
Arm	20 (16.7)
Leg	19 (15.8)
Back, chest	15 (12.5)
Size (cm^2)	
<10	39 (32.5)
10–50	55 (45.8)
>50	26 (21.7)
Color	
Purple	9 (7.5)
Red	80 (66.7)
Pink	31 (25.8)
Hypertrophy	
Yes	9 (7.5)
No	111 (92.5)

Based on lesion color, the patients were divided into pink (31 cases), red (80 cases), and purple (9 cases) groups. Regarding lesion size, 39 patients had lesions smaller than 10 cm², 55 had lesions between 10 and 50 cm², and 26 had lesions larger than 50 cm². As shown in Table 1, 51 male cases and 69 female cases. According to the Fitzpatrick skin type, there were 5 cases of type II, 5 cases of type III, and 110 cases of type IV. In terms of lesion location, 66 cases showed lesions on the face and neck, 20 on the arms, 19 on the legs, and 15 on the back and chest. Among the 120 cases, only 9 exhibited hypertrophy.

Treatment and Evaluation

At 6 months follow up, there were statistically significant differences in the percentage clearance between different locations, colors, and ages.

The clearance rates of PWS after the PDL treatment are summarized in Table 2. 26 cases (21.67%) showed excellent clearance rates. 28 cases (23.33%) showed good clearance rates. 37 cases (30.83%) showed fair clearance. Nineteen patients (15.83%) showed poor clearance rates.

Table 2 Treatment Effect of PDL for PWS

	Excellent	Good	Fair	Poor
Cases	26	28	37	19
Percentage (%)	21.67	23.33	30.83	15.83

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The effects of multiple treatments on clinical outcomes are shown in Table 3. The results indicated that the improved treatment efficacy of PDL for PWS could be achieved by applying multiple treatments. The treatment response was evaluated as good or excellent in 30.8% of patients after receiving more than six treatments, which was significantly better than those receiving five or fewer treatments (20.8%; $P < 0.05$).

Table 4 shows the relationship between patient age and the clinical outcomes. The effect of age below one-year-old was better than that more than one-year-old. This is probably because the younger the patient, the thinner is the skin.

As summarized in Table 5, treatment efficacy was related to lesion location, with lesions on the legs showing the poorest responses. It is possible that the skin of these lesions was thicker and was not sensitive to the 595 nm PDL.

Regarding the color of PWS, pink lesions (31 cases) seemed most susceptible to treatment, whereas purple lesions (9 cases) were the least susceptible (Table 6). As summarized in Table 7, lesions demonstrated a size-dependent excellent rate after treatment, with lesions smaller than 10 cm^2 demonstrating the highest excellent rate (41.0%) and the lowest poor rate (5.1%), whereas lesions larger than 50 cm^2 showed the lowest response (11.5% excellent and 34.6% poor).

Safety and Adverse Effects

Pain, edema, and purpura were the most commonly observed reactions, with incidence rates of 95.8%, 68.3%, and 35.0%, respectively, immediately after treatment. In general, the pain was mild and transient, and the edema and purpura

Table 3 Summary of Clinical Outcome With Different Treatment Repetition Time

Times	Cases	Effect (%)			
		Excellent	Good	Fair	Poor
≤ 3	28	5 (17.9)	5 (17.9)	10 (35.7)	8 (28.6)
3–5	32	8 (25.0)	7 (21.9)	8 (25.0)	9 (28.1)
6–9	39	15 (38.46)	9 (23.1)	9 (23.1)	6 (15.4)
≥ 10	21	7 (33.3)	6 (28.6)	5 (23.8)	3 (14.3)
P		0.01	0.01	0.27	0.31

Table 4 The Relationship Between Ages (Treatment Begins) and the Effect

Age (Months)	Cases	Effect (%)			
		Excellent	Good	Fair	Poor
3–12	45	16 (35.6)	12 (26.7)	10 (22.2)	7 (15.6)
13–36	49	15 (30.6)	13 (26.5)	11 (22.4)	10 (20.4)
37–107	26	4 (15.4)	2 (7.8)	11 (42.3)	9 (34.6)
P		0.01	0.01	0.38	0.45

Table 5 The Relationship Between Location and the Effect

Location	Cases	Effect (%)			
		Excellent	Good	Fair	Poor
Face&neck	66	19 (28.7)	17 (25.8)	17 (25.8)	13 (19.6)
Arm	20	7 (35.0)	4 (20.0)	6 (30.0)	3 (15.0)
Leg	19	2 (10.5)	2 (10.5)	6 (31.6)	9 (47.4)
Back&chest	15	7 (46.7)	4 (26.7)	3 (20.0)	1 (6.7)
P		0.01	0.25	0.31	0.36

Table 6 The Relationship Between Color and the Effect

Color	Cases	Effect (%)			
		Excellent	Good	Fair	Poor
Purple	9	0 (0)	1 (11.1)	1 (11.1)	7 (77.8)
Red	80	24 (30.0)	16 (20.0)	22 (27.5)	18 (22.5)
Pink	31	11 (35.5)	10 (32.3)	9 (29.0)	1 (3.2)
P		0.01	0.01	0.01	0.45

Table 7 The Relationship Between Size and the Effect

Size (cm^2)	Cases	Effect (%)			
		Excellent	Good	Fair	Poor
<10	39	16 (41.0)	11 (28.2)	10 (25.6)	2 (5.1)
10–50	55	16 (29.1)	15 (27.3)	9 (16.4)	15 (27.3)
>50	26	3 (11.5)	1 (3.8)	13 (50.0)	9 (34.6)
P		0.01	0.01	0.39	0.01

Table 8 Safety and Adverse Effects

Adverse Effects	Pain	Edema	Purpura	Atrophic Scar	Hyperpigmentation	Hypopigmentation
No. (%)	115 (95.8)	82 (68.3)	42 (35.0)	1 (0.83)	6 (5.0)	2 (1.67)

disappeared within 1–2 weeks. Other rare adverse effects, such as atrophic scars, hyperpigmentation, and hypopigmentation, were observed in one (0.83%), six (5.0%), and two cases (1.67%), respectively. All the adverse effects disappeared after 3–6 months of treatment. No severe adverse effects were observed (Table 8).

Discussion

PWS, a prevalent congenital vascular malformation, typically manifests in visible areas like the face and neck, causing psychological stress for patients.[9,10] Various treatments for PWS, including freezing, CO_2 applications, lasers, radioisotopes, and surgeries, have been explored, but outcomes have often been unsatisfactory with potential side effects.[11–13]

The concept of "selected light and heat", introduced by Leviav and Wolf, has spurred the clinical application of lasers.[14] Optimal outcomes in managing PWS hinge on selectively destroying the dermis. Laser wavelengths near the characteristic absorption peaks of oxy-hemoglobin (418, 542, and 577 nm) enhance treatment efficacy. Although oxy-hemoglobin exhibits peak absorption at 418 nm, laser penetration at this wavelength may not reach the vessels below the surface of the skin. Consequently, we opted for a V-beam pulsed-dye laser with a wavelength of 595 nm, closely aligned with the 577 nm absorption peak of oxy-hemoglobin and offering better tissue penetration up to 2 mm below the skin. The pulse duration ranged from 1.5 to 40 ms, promoting vascular concretion during the PWS treatment. Our instrument incorporates a dynamic cooling device (DCD), spraying coolant to cool the treated skin without affecting the deep vascular temperature, enhancing efficacy, and reducing side effects.[15]

PDL is widely regarded as the gold-standard treatment for PWS treatment.[16] This study reported an overall efficacy rate of 84.17% (101/120). Key factors influencing efficacy included age, lesion type (color of the lesion), lesion size, and the number of treatments. While the effectiveness was higher in the under-one-year-old group, it is important to consider the applicability of these findings to the 6–12 years age group. For children in the 6–12 years age range, the slightly lower efficacy observed could be attributed to several factors, including the thicker and more developed dermal layers as children age, which may reduce the penetration and overall effectiveness of PDL. Additionally, older lesions may exhibit

more extensive fibrosis or vascular maturation, further limiting the laser's impact. Lesions on the body have better outcomes than those on the limbs, particularly at the limb ends. Lesions at the edges of the face showed better efficacy than those in the middle, likely due to the depth of vessels beyond the 595 nm laser's reach. Darker skin correlated with poorer treatment effects, possibly due to increased melanin cells, sharing the 595 nm absorption wavelength, and reducing laser energy applied to oxy-hemoglobin.

The findings of this study align with and extend previous research on the efficacy of 595 nm pulsed dye laser (PDL) treatment for port wine stains (PWS). For instance, Shi et al reported a similar overall efficacy rate in a larger cohort of Chinese patients, although their study focused on a wider age range, including older children and adults.[11] The higher efficacy observed in our study among infants under one year old underscores the importance of early intervention, as also highlighted by Chapas et al, who demonstrated that treatment initiated in newborns resulted in significantly better outcomes.[2] Similarly, Jeon et al reported favorable results in treating PWS during infancy, which they attributed to the thinner dermis and less mature vasculature in younger patients, facilitating laser penetration.[9] These comparisons reinforce the conclusion that early treatment with 595 nm PDL is particularly advantageous and highlight the need for further studies focusing on age-related efficacy in diverse populations.

Conclusions

In conclusion, treating PWS with a 595 nm pulsed-dye laser is safe and effective in infants. Although PDL remains the leading option, its cure rate can be enhanced by combining it with other interventions, such as therapeutic agents, photodynamic therapy, and surgery.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of Guangzhou Women and Children's Medical Center. The study complies with the Declaration of Helsinki. Written informed consent was obtained from the guardians of all participants before participation in the study.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors have declared that no conflict of interest exists.

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