Research Article

Single and Double Pass Pulsed Dye Laser for the Treatment of Port Wine Stain: A Randomized Controlled Trial

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Abstract

Background: Port wine stain (PWS) is a low flow vascular malformation. The gold standard treatment for PWS in childhood is pulsed dye laser (PDL).There is very little evidence in literature regarding comparison of single pass versus double pass pulsed dye laser in achieving clearance of these capillary malformations. We did a randomized controlled trial to compare outcome of single-pass versus double-pass pulsed dye laser for management of PWS.

Methodology: This randomized study trial was performed at Jinnah Burn and Reconstructive Surgery Center/AIMC Lahore, from Jan 2019 to Dec 2019. Sample size of 30 patients was divided into 2 groups (15 patients in each group). Group A was given single pass of pulsed dye laser and patients in group B were subjected to double pass of pulsed dye laser (595nm wavelength, 7mm spot size, pulse width from 2-6ms and radiant exposure of 4-12 J/cm2). Total no of 4 sessions were done with period of 3 weeks between each session and the results were analyzed after 3 months of the last session.

Results: The mean of the patient's age was 17±8 years and the mean of time since lesion appeared was 16±8 years. Nineteen participants (63%) were females. Most of the patients (83%) had PWS on face and neck. Double pass PDL was effective in 40% of patients and single pass PDL in 20% (p value <0.05).

Conclusion: Double pass is more effective in treating port wine stain as compared to single pass pulsed dye laser.

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Introduction

Port-wine stain is a congenital cutaneous vascular malformation. This capillary malformation is described as sharply demarcated pink to purple patches involving skin.[1] It is characterized by capillary ectasia in the dermis. The depth ranges from 1-5mm in the skin and over the time these lesions darken, become thicker and develop nodules.[2] Its prevalence at time of birth is 0.3-0.5% and having same ratio in both genders. Capillary malformation observed commonly in craniofacial region. PWS influence the quality of life of most patients, mainly affecting the daily activities, social interactions and feelings.[3]

The argon laser, used globally in the 1970s, had frequent side effects including scarring and pigmentation.[1] In the 1980s, these shortcomings prompted practitioners to replace the argon laser with

the flash lamp pulsed dye laser (PDL).[4] Subsequently PDL was considered as the most effective option for superficial vascular lesions.[5] Pulsed dye laser (PDL) acts by selective photothermolysis of the ectatic capillary vessels.[6]

In a study, good to excellent response of PDL was seen with single pass pulsed dye laser in 48.0% of nevus flammeus , 78.0% of telangiectasia and 54.0% of hemangioma patients.[7] To achieve near total clearance of PWS, the concept of double or multiple passes were introduced. Using double or more passes cause deeper damage to vessels which enhance the treatment efficacy of laser in port wine stain.[8]

The study by Yu et al, showed that double-pass pulsed-dye laser (PDL) resulted in good response in 20.0% patients whereas single-pass PDL was effective in 20.0% other patients. In 60.0% patients no statistical difference found between treatment options ($p > 0.05$), showing same results with single and double pass PDL.[9]

The comparative analysis reported in the international literature between efficacy of double pass and single pass pulsed dye laser in port-wine stain (PWS) is limited. Until now, such study has not been reported in our population. So, the rationale of our study was to compare the single pass pulsed dye laser (PDL) 595nm versus double pass pulsed dye laser (PDL) for the treatment of port-wine stain (PWS) and aim was to modify the treatment of such malformations and to set standard information both at national and international level.

Methods

This single blind randomized controlled trial was conducted at Jinnah Burn and Reconstructive Surgery Center, Lahore from January 2019 to December 2019, upon approval by Board of Ethics. A sample size of 30 {15 in group A (Single-pass PDL) and 15 in group B (Double-pass PDL)} was calculated with 90% confidence level, 80% power of study and expected proportion of good response in Double -pass PDL of 50% and Single -pass PDL of 30% with a difference of 20% between the two treatment options.

Patients were allocated in two groups by non-probability consecutive sampling technique. The randomization of eligible participants having age 6 to 30 years was done through a computer generated table so that the numbers of participants in each group could be approximately equalized. We excluded patients who were mentally challenged, who had sensitivity to lasers, pregnant females, patients associated with syndromes and who had hypertrophic lesions. The Ethical Review Board signed the study protocol. Patients in Group A were treated with single-pass pulsed dye laser and patients in group B were treated with double-pass pulsed dye laser. Topical anesthetic ointment was applied over the treatment area half an hour before. In the laser suite, patient wore metallic protective glasses over eyes and the operator wore special laser protective glasses. CynosureR V-Beam pulsed dye laser machine was used with the following settings for the single-pass PDL; 595nm wavelength, 7mm spot size, pulse width from 2-6ms and radiant exposure of 8-12J/cm^2. Cool air from cryogen cooling device over the lesion was given when the laser was in process. For the double-pass PDL treatment, the same settings of PDL were used as for the single-pass during first session and after completion, patient waited for 30mins. After 30mins second session of PDL was done with 595nm wavelength, 7mm spot size, pulse width 2-6ms and radiant exposure 4-6J/cm^2 (lower than the first session). Affected areas were treated with topical antibiotics and covered with gauze after each session. Patients were given 3 weeks gap in 4 sessions. For final review, pre- and post-treatment images were examined by two consultant plastic surgeons (having 3 years of post-fellowship experience at least) and a consultant dermatologist after their consent. Blinded, subjective grading of before and final follow-up images at 3 months determined treatment efficacy in terms of clinical response as follows: score 0 (no response) = 0% improvement, score 1 (poor) = 25% improvement, score 2 (fair) =26 to 50% improvement, score 3 (good) = 51 to 75% improvement and score 4 (excellent)= 76% improvement. 50% improvement from baseline (good and excellent response)was considered as effectiveness of Laser treatment.[10] All patients were followed regularly. Frequencies of side effects like blistering, crusting and post inflammatory hyperpigmentation were noted.

Statistical Analysis

The data analysis done by using SPSS version 23.0

Mean and standard deviation for numerical variables such as age, duration of lesion, size of lesion and BMI was recorded. Frequency and percentage for categorical variables such as gender, site of lesion (face/ neck/ chest/upper arm/upper back), type of skin and outcome was obtained. Chi square test was applied to compare frequencies of patients (in two groups) in whom treatment was found effective and p value ≤ 0.05 was considered as significant.

Results

There were 30 patients enrolled for trial with mean (SD) age of 17 (±8) years. The mean (SD) duration of lesion was 16 (±8) years. The mean (SD) size of lesion was 20 (±21) cm and the mean (SD) BMI were 23(±2) kg/m^2. Out of 30 patients, nineteen (63%) were females. Among 30 participants, 60% had PWS on face, 23% had on neck, 7% had on chest, 7% had on upper arm and 3% had on upper back. Double pass PDL showed effective response in 40% of the participants whereas, single pass pulsed dye laser showed effective response in only 20%. The difference in the efficacy of two treatment strategies was significant as indicated by a p value of 0.025 (i.e. <0.05). No side effects like blistering, crusting or post inflammatory hyperpigmentation were observed in any of the participants. The results in representative cases in two groups are shown in figures 1 and 2.

Figure1: *Result Obtained after 4 Sessions of Single Pass of Pulse Dye Laser.*

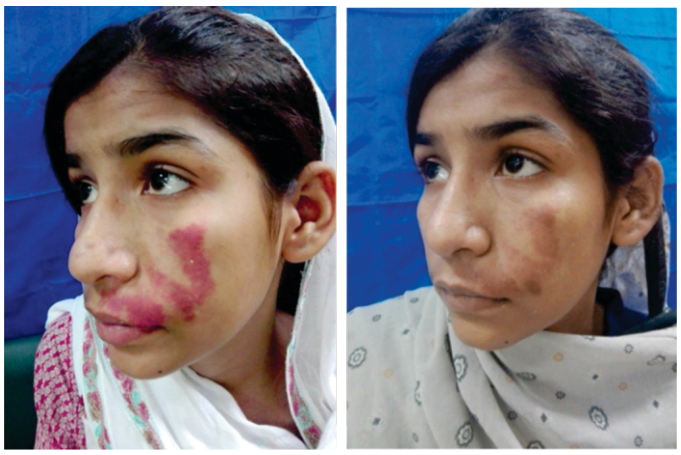

Figure 2: *Result Obtained after 4 Sessions of Double Pass Pulse Dye Laser.*

Discussion

Port wine stains are low flow vascular lesions. The effectiveness of pulsed dye laser for management of such lesions in early life is proven in the literature.[8] Evidence is inconclusive about the use of multiple-pass technique to increase the extent of vascular damage in capillary malformation. Our study showed that the double pass technique was significantly efficacious as compared to single pass technique given at 3 weeks interval with a good safety profile.

Rajaratnam et al,did a study of effect of double pass laser on 26 patients with superficial capillary lesions.[11] He treated all subjects with minimum of three sessions using double pass pulsed dye laser technique, at an interpulse interval of 20-30 minutes. The results showed that moderate or significant improvement in the port wine stain appearance was observed in almost half (n=12) of the patients. In other half (n=12) there was mild improvement. In two patients there was no change. Patients had side effects like blisters (n=5), dry scabs (n=11) and transient hyperpigmentation (n=4).[11] The results of these studies are consistent with our study which also revealed that the double pass pulsed dye laser is effective(40%) as compared to single pass pulsed dye laser (20%).

In another prospective study by Yu at el, thirty nine East Asian patients with PWS were managed.[12] None of the patient had taken any treatment before. He divided all subjects into two groups, one group treated with 3 weeks interval and second group with 6 weeks interval. In both groups total numbers of three sessions were done. After 2 months of the final session outcome was observed by visual and Chroma meter

analysis. There was no significant change in final outcome or difference in side effects observed in both groups. PDL treatment at 3- weeks' gap time proved to be safe for East Asians with PWS. Time required for effective management is shortened by reducing time between sessions.[12] In our study sessions were also done at gap of 3 weeks and consistent with the above study in reducing treatment duration. The final follow up after 3 months found that both treatments were efficacious however, double pass pulsed dye laser was significantly more efficacious than single pass pulsed dye laser and no major side effects were noted.

A prospective study was conducted by Sadeghinia et al, who evaluated the effectiveness and side effect profile of 595nm PDL in 27 Iranian children with port wine stain having mean age 5.7 years.[13] After 6 sessions of treatment with pulsed dye laser, there was 70.74% improvement which was shown after 3 months of the last session. 51.8% children showed improvement that was >75%. 33.4% had improvement of about 50 to 75%. 14.8% children showed improvement that was less than 50%. The good prognostic factors that were identified were cranial nerve V-1 involvement and improvement seen markedly in the initial five sessions of therapy. None of the factors: age, gender, type of skin and size of lesion were associated significantly with therapeutic response.[13] Our study also revealed that site of lesion had impact on outcome after PDL as face showed more improvement (37%) than other areas of the body with overall effectiveness in 60% of the participants, but double pass pulsed dye laser was significantly more effective (40% reported improvement) as compared to single pass (20% reported improvement). Our study evaluated the impact of age, gender and duration of lesion and revealed also that gender had an impact on the efficacy of pulsed dye laser as 75% females had improvement as compared to 35% of males.

In the study by Yu et al, five patients (24%) developed skin eruptions and vesicles in double-pass PDL sites, whereas 3(14%) patients complained pigmentary changes in both single-pass PDL and double-pass PDL at treated sites and recovered within 6 months.[9] Our study showed that superior efficacy of double pass 595nm pulsed dye laser over single pass pulsed dye laser and found that none of them had any significant side effects as reported by the patients, rendering pulsed dye laser therapy as safe.

Various limitations in the study can be overcome by different measures. Firstly sample size can be increased considerably by conducting multicenter trials. Secondly histopathological examination of the set of capillaries can be done to look for the factors associated with improved efficacy. Thirdly clinical improvement should not rely only on subjective assessment of the clinicians which can lead to bias and standardized objective method of evaluation can be used.

Though a lot of advances have been made recently, it is still difficult to treat and eradicate PWS completely with the current laser technologies and other light sources. The work that has been done in this field reveals that PWS has marked heterogeneity both clinically and histologically. The majority of the literature reviewed includes uncontrolled trials or case series, which results in posing constraints for making comparison of various trials and thus preventing the likelihood of conducting meta-analysis. Further trials are clearly needed, more preferably randomized trials comparing the treatment strategies, so that treatment that have superior efficacy can be looked into and further treatment response can be assessed. Future studies should also incorporate such measures that can evaluate satisfaction of the patients.

Conclusion

Our study suggests that double pass 595nm pulsed dye laser is an effective treatment as compared to single pass pulsed dye laser for port wine stains.

Ethical Approval: Given
Conflict of Interest: The authors declare no conflict of interest
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