Flash-lamp pulsed-dye laser treatment of port-wine stains in childhood. A case of technology assessment

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Diffusion of FPDL in the Netherlands

Abstract

Background – In the early nineties the flash-lamp pulsed-dye laser (FPDL) has been introduced as the treatment of choice for port-wine stains (PWS) in childhood. This article describes the adoption and diffusion in the Netherlands between 1994 and 1999 of laser treatment of vascular lesions, in particular PWS treatment in childhood.

Methods - A prospective survey of 11 centres that had gained experience with the treatment of PWS and the use of laser equipment was conducted. Semi-structured interviews were recorded for 12 weeks in 1994. An evaluative telephone survey was performed for 12 weeks in 1999.

Results – FPDL has become the treatment of choice for PWS in childhood. Academic hospitals and teaching hospitals were fast adopters of this new treatment modality. Within the study period the technical refinement of laser therapy dominated all evolution. Inappropriate and unskilled use is at present one of the greatest problems with laser applications. Treatment procedures are still not standardized. Treatment capacity has not increased within the study period, nor did the number of treatments necessary to receive optimal patient outcome change. The number of referrals of patients with a PWS shows a large variation between centers, remaining stable over time.

Conclusions – Between 1994 and 1999 laser treatment characteristics and procedures have been established by consensus, rather than by adequate explicit guidelines.
Introduction

Medical lasers have advanced so rapidly over the past 10 years that specific information concerning the diffusion into medical practice was often not available. New laser systems were introduced and older systems have been improved. Furthermore, the laser industry itself is very unstable, with small companies being founded and some of them disappearing as quickly as they emerged.

The development of pulse lasers has made it possible to control treatment duration. This has changed dramatically the very nature of the laser - tissue interaction. Pulse lasers are capable of affecting a specific target tissue without a high risk of scarring and pigmentary changes. In recent years, pulsed lasers have become an indispensable part of dermatotherapy. Port-wine stains (PWS), haemangioma, telangiectasias as well as other vascular malformations and neoplasms represent the most significant indications for laser therapy.

The flash-lamp pumped pulsed-dye laser (FPDL) has been introduced as a safe and effective treatment modality for PWS in childhood. In itself, such a bold declaration does not guarantee quick adoption of the procedure and becomes a standard practice. The dissemination and implementation of new technology into everyday medical practice is an iterative and long-term process, influenced by patient demand, scientific proof of effectiveness, (societal) cost-effectiveness, as well as reimbursement systems. Physicians considering new management options must be prepared to change their own routine practice. In all cases, they must be able to apply these new techniques appropriately in order to do more good than harm.

Many feel that all promising new technologies should carefully be analysed before they are introduced into clinical practice. Examples abound of technologies that undergo multiple incremental innovations after their initial acceptance. As a consequence, technologies can be assessed at different stages of evolution and diffusion. In general the diffusion of a technology can be described in terms of the following stages: conceptual (future technology), experimental, investigational (initial clinical try out), established (standard approach and diffused into general use) and obsolete (superseded or proven to be ineffective). These stages are often difficult to delineate. A new technology does not need to mature in such a linear fashion.
To learn more about the way the FPDL has been introduced and used in the Netherlands, we contacted 11 medical centres twice. We investigated the diffusion of laser-technology in these centres, as well as the actual use of these lasers within the departments of dermatology and plastic surgery. We also studied the evolution of treatment of PWS during childhood between 1994 and 1999.

Through a technology-oriented assessment we tried to address the range of problems in which lasers are used and how appropriate the use of the laser technology is for different types of PWS in different settings. Within a period of five years we looked at the introduction of the FPDL within developed treatment procedures, within treatment, and tried to locate its the current position of the treatment of PWS in medical practice, especially in childhood.

Methods

Centers

The study was carried out in two time frames: the first period was November 1994 through February 1995, the second March 1999 through May 1999. The period between these two intervals was considered sufficiently large to allow for changes in practice following the publication in 1998 of a prospective clinical study, investigating the effectiveness of PWS treatment in relation to age.

In each time frame we contacted 11 centres. These included two private centres, four general hospitals and five academic hospitals. All had gained experience with the treatment of PWS in childhood and the use of laser equipment in the early nineties. The performing specialties were Dermatology and Plastic Surgery.

In the first period, November 1994 – February 1995, information was obtained through semi-structured interviews with medical specialists, their assistants, and hospital technicians. Each interview took from two to four hours. We examined the treatment setting using a self-developed checklist.

Between March 1999 and May 1999 we approached the same centres and informants a second time, to update our data. The second interview was conducted over the telephone. The structure and items of the second interview was largely identical to the first one. The telephone interviews took approximately 30 minutes.
In addition we gathered data from various sources on appropriate use of laser. In general these concluded technical properties, clinical safety, and standardisation of treatment procedures.

**Questionnaire**

The questionnaire used in the interviews had two sections. The first section contained 10 items concerning centre characteristics, hospital type, laser types, number of lasers used, replacement of lasers, local investment plans, teaching status, patient mix, and type of treatments. Within the second section we investigated specific issues concerning technical properties as well as the use of lasers in the treatment of PWS. This second part contained 22 items related to the intensity of use, treatment capacity, mobile and shared use of laser equipment, current treatment procedures, ease of use, treated number of patients with PWS, appraisal of the laser treatment of PWS and the clinical assessment of experienced outcome.

**Analysis**

The results were summarised for each time period: 1994 and 1999. Within as well as between centres comparisons were made. The academic centre that had been investigating the effectiveness of the FPDL treatment in relation to age was excluded from the main analysis.

**Results**

**Center characteristics**

In 1994 four different types of lasers were reported to be in use for the treatment of PWS: the flash-lamp pumped pulsed-dye laser, the argon-dye laser, the copper vapour laser, and the KTP-laser. These lasers were also applied in the treatment of other vascular malformations, such as telangiectasias, couperose, and tattoos. Within the investigated centres, lasers were shared between specialties. The multidisciplinary use of lasers developed itself further within the study period. Only one (private) centre considered mobile use.

In 1994 two centres, one general and one academic hospital, treated PWS with the FPDL. In contrast, four centres used the FPDL in 1999. Two academic hospitals had added the FPDL to their treatment options, in order to be able to treat PWS in children.
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Ninety percent of the lasers were introduced in the early nineties. In 1999 most centres were using the same laser equipment. Some had purchased new accessories, such as scanning devices, to refine the treatment process. The use of such devices increased speed and accuracy, while minimising the risk of scarring that can result from uneven scanning. Some centres had started to treat patients with a larger spot size (7mm versus 5 mm).

It appeared that the investment decision of buying a new laser in both periods was largely supported by new industrial and technical developments. The individual clinician or hospital had been searching for an appropriate laser system, concentrating on techniques best suiting the needs of the centre.

During the first interview sessions it was generally agreed that the skills of the user of the laser were important for treatment outcome. Participants expressed a wide spectrum of opinions concerning the specific training of physicians to qualify for laser treatment. At both points in time treatment was not necessarily performed by plastic surgeons or dermatologists. In one general hospital x-ray technicians were treating patients, under the supervision of a dermatologist. In 1999 there was no general agreement as to whether the laser should be used only by laser specialists or could also be used by generalists. Most centres concluded that there was need for teaching a basic knowledge of the function and tissue-interaction of lasers.

In contrast to 1994, two clinical groups had started to produce some kind of clinical guidelines for laser use. Such a guideline identifies the type of laser considered to be appropriate for a given condition, as well as exposure time and power. This issue proved to be controversial, with some laser experts expressing serious reservations about the utility of such guidelines.

The frequency of using lasers into routine medical care varied from at least once a day to once a month. About 30% of the laser equipment was used weekly. Treatment capacity in the centres had not changed significantly over time. In 1999 all academic centres stated that, in order to gain experience, lasers should be frequently used.

Port-wine stain treatment

The number of referrals for PWS treatment varied between the centres. In 1994 the number of new patients with a PWS varied from 2 to 200 a year. Relative differences in the number of new and treated patients between centres remained stable within time. Compared to 1994 each centre was treating more patients in 1999. This was caused by an increased number of
referrals of new patients and the fact that a substantial part of earlier patients had not yet finished treatment within the 5 years. In 1993 two centres had introduced a waiting list for the laser treatment of PWS. They maintained the waiting list within the investigated period. In both centres treatment capacity could not be expanded.

The size of the lesions varied from a few square centimetres to over 10% of the body surface area (approximately 2000 square centimetres). All centres reported purpura, a darkening akin to bruising, as the most common side effect of treatment of PWS. The observed incidence of undesirable side effects such as scarring, changes in skin texture, and pigmentation varied between 1 and 10%. No changes were reported using other devices in 1999.

In 1994 four centres were treating children under the age of 4 on a regular basis. All other centres expressed reservations on treating children under the age of 10. In 1999 six centres, 4 academic hospitals and 2 general (teaching) hospitals, were treating young children. Of these, three academic and one general hospital treated PWS in childhood with the FPDL (4/6).

It was already apparent in 1994 that multiple treatments were necessary to treat PWS, even in childhood. Treatment of the same area of the PWS was repeated at intervals varying from six to twelve weeks. Three clinicians, two in a general hospital and one in an academic centre, determined before onset of treatment the maximum number of treatments necessary as well as the locations of the PWS to be treated. They felt that treatment for years should be avoided. The average time per visit per patient varied between 15 and 45 minutes, depending on the size of the PWS. These observations were confirmed in 1999. Comprehensive written instructions or explicit guidelines to treatment procedures were not used.

In 1994 treatment of PWS at any age had been variably carried out using conventional pain control like icepacks and local anesthetics (lidocaine and EMLA®). In 1999 three participants had introduced the use of general anaesthetics to treat PWS in childhood.

Categories of 'excellent', 'good' and 'fair' were used to describe the degrees of clearance. The assessment of treatment was mostly based on a direct comparison with the original lesion made by the treating physician. Patient dissatisfaction was seldom a reason to discontinue treatment. Assessment did not change in time. In 1994 only one centre was satisfied with the result of PWS treatment in children. This centre was also the centre that had gained
most experience with treatment at early ages. In 1999 clinicians treating children concluded that the results of treatment were favourable. Some of them were increasingly concerned about the practical implications of differences in efficacy and effectiveness of treating PWS in childhood. During the second interview clinicians expressed the view that the subjective nature of disfigurement makes an objective assessment of need difficult.

**Discussion**

Although the selection of the best treatment parameters still requires further refinement, laser surgery has evolved to a position where it is the treatment of choice in PWS and other vascular lesions in 1999. The observed progress in laser treatment has resulted from the refinement of lasers and techniques. The comparative advantage of lasers for treatment has been established by consensus, not by evidence-based, explicit guidelines.

The use of the FPDL in treating PWS at all ages was first reported in the early nineties. Nowadays FPDL has become the treatment of choice for children with classic PWS. This treatment option is available in most large medical centres. It offers significant advantages over any other modality for the PWS treatment of children. Nevertheless, careful screening, referral and parental/patient consultation remain important issues to achieve optimal results and minimal risks.

The first data for this survey were obtained in 1994. We contacted 11 centres that had gained experience with laser treatment of vascular lesions and PWS in children. We studied the diffusion of the FPDL and its use in the treatment of PWS during childhood over a period of 5 years. In 1999 we approached the same centres. It is possible that within the study period hospitals that were not included had started to treat these vascular lesions with lasers. Therefore the rate of diffusion might be higher as reported.

All participating academic hospitals and two general teaching hospitals have adopted FPDL treatment of PWS in children. The literature on the diffusion of medical innovations states that large hospitals as well as teaching hospitals are early adopters. This was shown to be true in our survey. Such a development might be supported by the necessity of using general anaesthetics in treating (young) children.

The rate of adoption could have been influenced by the length and timing of the study period. Earlier studies, examining the diffusion of new medical
technologies, showed that the time taken to reach at least 75% adoption into routine medical care varies. From the literature it appeared that the level of 75% adoption of electronic fetal monitoring or ultrasound imaging took 8 and 11 years, respectively.\textsuperscript{11}

Because most (young) patients applying for laser therapy were self-referrals the reported numbers of submissions could have been influenced by the awareness of the existence and the strength of the demand for access to this treatment.

There have been few attempts to standardise the criteria by which results of PWS treatment should be assessed. The descriptive categories used, such as ‘excellent’, ‘good’ and ‘fair’, prove to be inadequate when used subjectively by different clinicians.

It is important to keep in mind that the proliferation of laser technology has made many systems available to a wide variety of medical specialists, many of who may not be specifically trained or experienced in treating either children or vascular lesions. A technology may be established for certain patient applications and investigational for others.

Rapid adoption of a new health care technology is not undesirable per se. However, there is a risk that such a technology is broadly adopted without sufficient consideration of its potential benefits and harms. Questions regarding the safety of the procedure, cost implications, influence on existing treatment protocols, and appropriate training may be ignored. The diffusion of the FPDL described illustrates the difficulties of evaluating a procedure in a sufficiently comprehensive manner before a technology finds widespread use.
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References