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CHILDREN VASCULAR ANOMALIES MANAGEMENT: RESULTS OF PHOTODYNAMIC THERAPY

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This study reports about the role of photodynamic therapy in management of children vascular anomalies. A 3-year (2009-2012) retrospective study on the challenges and outcome of 245 children with vascular anomalies referred for surgical management was undertaken at the Tashkent Medical Academy, Uzbekistan. After multidisciplinary discussion, all patients underwent photodynamic therapy under general anesthesia, with 5-ALA as the photosensitising agent. In a time of treatment 85 out 108 patients who presented with long-term pain reported improvement after treatment. Also, 43/46 reported significant reduction of bleeding related to their vascular anomaly. Improvement of swelling was reported by 189/199 patients; while reduction of infection episodes was evident in 61/63 patients and 176/205 reported reduction in the disfigurement caused by their pathology. Clinical assessment showed that more than half of the patients had good response to the treatment. Significant clinical response was reported by 148 (60,4%) patients, moderate result by 70 (28,6%). Radiological and ultrasound assessment comparing imaging 6-week post-PDT to the baseline showed moderate response in 78 (31,8%) patients and significant response in 122 (49,8%) patients.

Keywords: *haemangioma, congenital and infantile, malformations, children, laser, surgery.*

Introduction

Vascular anomalies are congenital anomalies of vascular development causing a variable degree of soft tissue abnormalities. These anomalies tend to occur most commonly in the head and neck and affect approximately 1 in 22 children. The most recent classification of vascular anomalies ISSVA includes two main categories: vascular tumours and vascular malformations [14,15]. Vascular tumours include infantile type and congenital type haemangiomas; the former being the most common vascular tumour as well as vascular anomaly. Other types include pyogenic granuloma, tufted angiomas and haemangioendotheliomas, angiosarcomas [3].

Vascular malformations, involve a variety of aberrations including: venous, arteriovenous, capillary and lymphatic. Slow-flow ones include capillary, venous and lymphatic; while, arteriovenous malformations are fast-flow. Vascular malformations differ, from vascular tumours, by having progressively enlarging aberrant and ecstatic vessels composed of a particular vascular architecture and do not contain hyperplastic cells [10].

Haemangiomas are more common in females and 80% occur in the head and neck. Haemangiomas, usually present as isolated, multifocal or segmental, result from endothelial cell hyperplasia. Infantile haemangioma develop shortly after birth and follow the expected course of proliferation and prolonged involution. They are one of the most vascular tumours. The rarer congenital haemangioma do not follow the same growth pattern but it does present at birth as the result of endothelial cell hyperplasia; and may rapidly involute or never involute. The cause of the aberrant and focal proliferation of endothelial cells in these lesions remains unclear [5,6].

Venous malformations are usually slow-flow vascular malformations composed of ecstatic venous channels that continue to grow throughout the patient's life. They commonly occur in the head and neck area, with a predilection for the oral cavity, airway and muscle groups. These lesions have unpredicted growth behavior when it comes to how much growth will occur or where; and many lesions expand well beyond their initial clinical boundaries and and actual invasion of surrounding tissue may be occurring [13]. These lesions are frequently symptomatic, depending on the locations involved and are usually obvious at birth. They fill with dependency and are compressible with variable color depending on the depth of involvement. Symptoms can be related to clot formation either from trauma or venous stasis and patients usually present with pain and swelling [2].

Lymphatic malformations are slow-flow congenital collections of ecstatic lymph vessels that form endothelial lined cystic spaces. They can be classified into macrocystic (containing cysts ≥2 cm) or microcystic

(<2 cm); the former carries a better prognosis. Usually diagnosed on prenatal ultrasound and may require special preparations for delivery if suspecting airway compromise. Lesions in the head and neck can be focal, multifocal, diffuse, macrocystic or microcystic; with frequent involvement of the oral cavity and airway [16]. If not identified prenatally, diagnosis is made during childhood with a slow growing lesion which may rapidly swell during infection or with hormonal changes. Clinical presentation include pain, swelling, dysphagia, odynophagia, airway and speech problems and recurrent infections. The lesions are fluid filled and are non-compressible [1].

Arteriovenous malformations are fast-flow vascular malformations consisting of abnormal capillary beds shunting blood from the arterial system directly into the venous system resulting in a high-flow vascular abnormality [10]. They grow throughout the patient's life and are associated with frequent and aggressive growth spurts. They are commonly identified in the lips, cheeks, neck, scalp, ear, tongue and mandible, extending to involve multiple cervico-facial regions. They clinically present with various symptoms, suggesting a spectrum of disease and not only one disease process [12,19].

The various therapeutic options are available for vascular anomalies as well as the recent advances in psychosocial aspects of care, interventional radiology, laser and pharmacological therapy [7,22].

Important to choose the method of treatment depending on skin types (T.B.Fitzpatrick, 1975) – see Tabl. 1. Because Asian people had brown color of skin, this skin type satisfy III-IV by Fitzpatrick classification scale. All surgical treatment access complicate with the scars, wich mostly visible in dark skin. Laser access can complicate with depigmentation or hyperpigmentation. Hyperpigmentation aspect binded with high ultraviolet insolation of Uzbekistan region. [8]

Photodynamic therapy (PDT) is a developing technology, used in the treatment of advanced tumours. The main application for PDT is to target tumours of the head and neck, gastrointestinal tract, pulmonary malignancies and skin pathologies. One advantageous feature of PDT is that it does not cause damage to nerves (cold photochemical reaction); this has lead to its use in the treatment of benign neoplasmas [4].

The effects of PDT are a result of the interaction between a photosensitiser, oxygen and light. PDT may be provided under local, regional or general anasthesia and it may be delivered by surface illumination or interstitial application, via inserted optical fibres. The photosensitiser, administered whether locally or systemically, is selectively taken up and retained by tissues with a high vascular flow rate [17,21]. Activation by light of a specific wavelength results in the production of oxygen free radicals or singlet oxygen which leads to apoptosis and/or direct cell death, as well as vascular shut down and subsequent inflammatory/immunological response [17].

Traditionally, light is delivered to the target tissue by surface illumination, whereby a optic probe is held over the target tissue (distance 5 cm). It can penetrate up to a depth of 1 cm, when used with 5-ALA due to its wavelength and not properties of the photosensitiser. Interstitial PDT followed by the insertion of thin optical fibres into the needles, to allow light maximal tissue illumination [8]. The application of interstitial PDT, in combination with preoperative imaging, including computer tomography, magnetic resonance imaging (MRI) and ultrasound (US) images has been shown to improve the accuracy of the technique [9].

Table 1

Fitzpatrick skin classification

Type	Color	Reaction to sun exposure
I	White	Always burns / never tans
II	White	Usually burns / tans with difficulty
III	White	Sometimes mildburn / average tan
IV	Moderate brown	Rarely burns / tans with ease
V	Dark brown	Very rarely burns / tans very easily
VI	Black	Never burns / tans very easily

In this study we present the outcome following the management of vascular anomalies using PDT. Patients' reports on quality of life with clinical and radiological evaluation were the main parameters used to assess the outcome.

Material and methods

In this clinical study, 245 patients were referred between 2009 and 2012 to the General and Maxillafacial Surgery Department, Tashkent Medical Academy (Uzbekistan) for treatment of vascular anomalies. Demographics of these patients are characterized by the following quantities.

Gender: male - 54 patients (22%); female – 191 (78%).

Age (years): mean – 1.2; minimum–maximum – 0.1-3.4; stand. deviation – 0.4.

Race and type of skin by Fitzpatrick scale: Central Asian - 220 patients (89.8%), among them

I type – 8 (3.6%), II – 26 (11.8%), III – 80 (36.3%), IV - 68 (30.9), V – 38 (17.2%). European – 19 patients (7.7%), among them I type – 5 (26.5%), II – 14 (73.6%). Different with VI type – 6 patients (2.4%).

Primary site position are: oral cavity - 25 patients (10.2%); upper face - 37 (15.1%); middle face - 62 (25.3%); lower face - 46 (18.8%); neck - 38 (15.5%); thorax, abdomen - 13 (5.3%); upper extremity - 18 (7.3%); lover extremity - 6 (2.4%).

Vascular tumours included: infantile haemangioma - 74 patients (30.2%); congenital haemangioma - 6 (2.4%).

Vascular malformations included: venous malformation - 46 patients (18.8%); lymphatic malformation - 57 (23.3%); arteriovenous malformation - 62 (25.3%).

Disease staging: local (localised) - 35 patients (14.3%); regional (extended) - 210 (85.7%).

Presentations: disfigurement - 205 patients (83.7%); swelling - 199 (81.2%); pain - 108 (44.1%); infection - 63 (25.7%); breathing problems – 5 (2.0%); bleeding - 46 (18.8%).

Previous management included: surgery - 78 patients (31.8%); embolisation - 8 (3.3%); sclerotherapy - 46 (18.8%); alcohol therapy - 28 (11.4%); CO_2 laser - 68 (27.7%); adjuvant chemoradiotherapy - 11 (4.5%); none - 6 (2.4%).

The patients' symptom-related disease included pain, bleeding, swelling, infection, disfigurement, breathing problems. One hundred eight patients observed with chronic/recurrent pain which was associated with local pressure of the anomaly on nearby nerves. 46 patients observed bleeding which was mostly associated with trauma to their haemangiomas and arteriovenous malformations. Swelling problems were reported in 199 patients, while disfigurement was reported in 205 patients. Recurrent infection was identified in 63 patients, mostly in patients with lymphatic malformations. Breathing difficulties was associated with pathological growth in the nasal region in 5 patients.

The anomaly volume was assessed using preoperative imaging (MRI, US).

Further conventional treatment rejected by 165 patients (67.3%); further treatment not offered to 80 (32.7%).

78 patients refused further conventional therapy (i.e. surgery) and elected to receive PDT, while 80 patients were not offered further conventional treatment and elected to receive PDT; the other 87 patients chose to undergo PDT.

All patients were discussed at a multidisciplinary meeting involving surgeons, radiation and medical oncologists, interventional clinical radiologists and allied healthcare professionals. It was agreed to offer PDT under general anesthesia, using 5-ALA (alasens) as the photosensitising agent. Photosensitizer doses were 200 mg/kg intravenous for malformation, 500 mg as 20% ointment was administered on skin surface, or 3% solution inject into vascular anomaly 6 hours (min 6, max 24) prior to light treatment. Irradiation was carried out at a energy fluence of 10–20 J/cm^2 and a standardised fluence rate (power density) of 100 mW/cm^2. This would allow the agent to accumulate in the pathological area which would increase effectivity. Patients were usually kept in a side room (with a dim light) to avoid systemic photosensitisation. Intraoperatively, an US probe was used to examine the centre and periphery of the anomaly when assessing volume, depth, invasion of large vessels, hollow organs and/or hard tissue. This was followed by insertion 18 Gauge 70 mm long spinal needles under US-guidance into the target tissue. Great care was taken to ensure that the needles are inserted parallel to each other with 7–9 mm distance in between. If the treatment was close to a major blood vessel, a safety distance of 1 cm between the needle and the vessel was implemented.

An Iso-illumination treatment plan was carefully implemented and supervised by a senior physicist to ensure adequate light delivery to all suspect areas. A 635 nm wave-length diode laser was used for illumination. Diffuser fibres were used with/out bare polished tip fibres, with a core diameter of 400 μm, to deliver light. Light energy was then delivered from the fibres to the target tissue at 20 J per site. Tissues outside the target area were shielded completely to avoid photoactivation by scattered or reflected light.

All precautions were taken to avoid direct illumination of the patient with surgical lamps in theatres. Unplanned or emergency surgical interventions within 30 days from the photosensitiser administration were undertaken only if absolutely necessary and the potential benefits outweigh the risk to the patient. Precautions were applied to avoid exposure of skin and eyes to direct sunlight or bright indoor light during the first 15 days after injection. Patients were re-introduced to normal light gradually. No drug interactions have been observed.

The number of PDT rounds was: 1 session obtained 39 patients (15.9%); 2 – 13 (5.3%); 3 – 159 (64.9%); 4 – 11 (4.5%); 5 – 23 (9.4%).

The patients were discharged from hospital care at a mean of 5 days (min 3, max 9) postoperatively. Patients were followed-up and asked to report on the outcome of their therapy if there is any improvement, no change or worsening of symptoms. Clinical assessment outcome was performed by a team of surgeons/physicians trained in PDT at approximately 6 weeks postoperatively. The clinical assessment criterion was based on reduction of lesional size and improvement of the initial clinical symptoms.

MRI imaging and US was performed 5–6 weeks postoperatively. Comparisons were then made to as-

sess radiological outcome. Our radiological assessment parameters included: no response-progressive disease (increase in pathology size), no response-stable disease (no change in pathology size), minimal response (reduced size by <25%), moderate response (reduced size by <50%) and significant response (reduced size by 50–75%). Identification of peri-lesional inflammation, assessing response to PDT, was also reported. The time between the rounds was 3–6 months, with treatment indicated when the patient becomes symptomatic. The mean follow-up for those patients was 21 months (min 5, max 45, stand. deviation – 4.3).

The results of study were performed using the SPSS 17 (Statistical Package for Social Scientists) by an independent statistician. The patients' data were entered onto proformas which were validated and checked by interval sampling. The fields included a range of clinical, operative and radiological parameters related to the outcome following photodynamic therapy. The results were cross tabulated and the Chi-squared statistic was used to test for differences in the incidence of outcome. Fisher's exact test was used for the analysis of contingency tables and therefore to measure the *P*-value.

Results

Eighty five out of 108 patients (78,7%) who presented with long-term or recurrent pain reported significant improvement of their symptoms ($P<0.001$); while the rest 23 of the group (21,2%) reported no change. Worsening was not be observed.

Also 43 of 46 patients (93.5%) with bleeding problems reported improvement ($P<0.001$), 3 patients (6.5%) remained without changes, and nobody was reported about worsening bleeding episodes.

Swelling improvement was observed in 189 of 199 patients (95,0%, $P<0.001$); no changes reported 10 patients (5,0%).

176 of 205 patients (85,9%, $P<0.001$) reported improvement of their disfigurement, and 29 (14,1%) remained without changes.

Rate of infection problems, connected with hemangioma and malformations, was reduced in 61 of 63 patients (96.8%, $P<0.001$), and only 2 (3.2%) have not improvement.

3 patients of 5 ones (60.0%, $P<0.001$) with breathing problems observed improvement; 2 (40.0%) remained without changes.

Clinical assessment showed that good responce on PDT had 148 (60.4%) patients of 245; 70 (28.6%) - moderate response, 22 (9.0%) – minimal, and only 5 (2.0%) - no response.

Radiological images assessment before and 6 week after PDT treatment showed stable pathology with no change in size in 23 (9.4%) of 245 patients; minimal response (<25% reduction) - in 37 (15.1%) patients, moderate response (<50% reduction) - in 78 (31.8%) patients, and significant response (50–75% reduction) - in 122 (49.8%) patients. 5 patient (2.0%) during the treatment showed pathology progression (lymphangioma of the mid face).

Complications of PDT: pain was reported by 12 patients (4.9%) and was mild-moderate; bleeding - 5 (2.0%); swelling - 40 (16.3%); infection - 2 (0.8%); skin burn - 6 patients (2.4%), in sequence they were observed hyperpigmentation. Skin ulceration/necrosis, sensory and motor nerve injury and hypopigmentation are not observed. (Fig 1,2,3)

Discussion

Hemangioma prognosis established that hemangioma resolve in 50% children by 7 of age. This case leads physicians to manage these patients conservative approach, but recent studies showed that patients may present with disease specific complication. This condition requires intervention and complete resolution is quite difficult to achieve. Problematic haemangiomas can cause severe functional issues including ulceration, disfigurement and affect breathing, swallowing and speech. Common locations for these problematic haemangiomas include face, ear, orbit, lower lip and airway [14].

Conventional management can include systemic or intra-lesional corticosteroids, beta blockers, chemotherapeutic agents, surgery, laser or a combination of these methods. Where lesions are large, surgery can have marked adverse effect on form and function and due to difficulty in delineating these lesions recurrences can be high. The side effects of chemotherapy are well known and radiotherapy carries the risk of inducing new tumours. Propranolol, a known non-selective beta-blocker, has been reported to induce regression in haemangiomas in newborns [11].

Conservative measures have been initially applied in the treatment of venous malformations but it had little effect. It can be usefull to control growth of large lesions.Other interventional measures were applied and found to be effective, including laser surgery, sclerotherapy and surgery. Laser ablation is the gold standard management of mucosal and skin malformations. Commonly in Asian patient should be carefully applied, to prevent laser pigment skin complication. Sclerotherapy remains a good option and several authorities recommend its application with more literatures emerging regarding different techniques and injectable substances [18].

Spontaneous resolution of lymphatic malformations is extremely rare. The lesions that have been reported to resolve without treatment were small, macrocystic and within the posterior triangle of the neck [12]. Sclerotherapy is the most common intervention in many centres around the world. Laser surgery have been reported as the most useful in the management of airway malformations and vesicular eruptions on mucosal surfaces. However, when it comes to complex lesions

surgery is always considered as the first option. Resection of all diseased tissue is advocated as failure results in regrowth. Several studies have reported the use embolisation with varying substances (i.e. glue, coils and alcohol) in the management of arterio-venous malformations. This is mainly used in small and focal arteriovenous malformations, but can be used in very large life-threatening arterio-venous malformations, followed by microvascular free flaps to reconstruct the defect.

Since PDT is a non-heat generating process, there is no bystander tissue heating, and connective tissues such as collagen and elastin are largely unaffected. As a result, many tissues heal with little scarring in comparison to thermal treatment and hollow organs such as trachea, the gastrointestinal tract and major blood vessels maintain their mechanical integrity. PDT not effect on pigmentary layer of the skin and can be applied to all types of skin [20].

The effectiveness of PDT is dependant on the dosimetric profile. Ideally one would quantify the distribution of the light, fluence rate, the optical properties, the drug concentration and tissue oxygenation for PDT. The other advantage of PDT is that it can be repeated without cumulative toxicity. The success of PDT is dependent on upon the depth of necrosis being greater than the depth of the individual malformation. Thus, interstitial PDT represents as ideal, in that it allows more effective treatment of the target tissue volume [20].

This clinical study highlights the advantage of US, in combination with PDT. It is relatively simple to perform, easily available and examinations are non-invasive. It is inexpensive, quick, and convenient and there are no known harmful effects, since it uses non-ionising radiation suited to the soft tissues and it does not cause any pain. Ultrasound can be used to guide the optical fibres to the appropriate disease volume, enabling more accurate evaluation of treatment doses.

Conclusion

The management of vascular anomalies continue to be extremely challenging. Although several modalities have been developed and the literature reports successful treatment in many, data from long term studies reports relapse in many and the need for re-treatment or another intervention. PDT is not superior to other modalities, but it is characterised by being one of the least invasive, being repeatable with no residual toxicity and with a minimal bystander effect on the overall tissue architect and integrity as well as nerves.

The growing body of evidence regarding its efficacy, the increasing use of image guided PDT, and the innate minimally invasive characteristics of PDT suggest that it should become an important addition to the various techniques used in the management of vascular anomalies.

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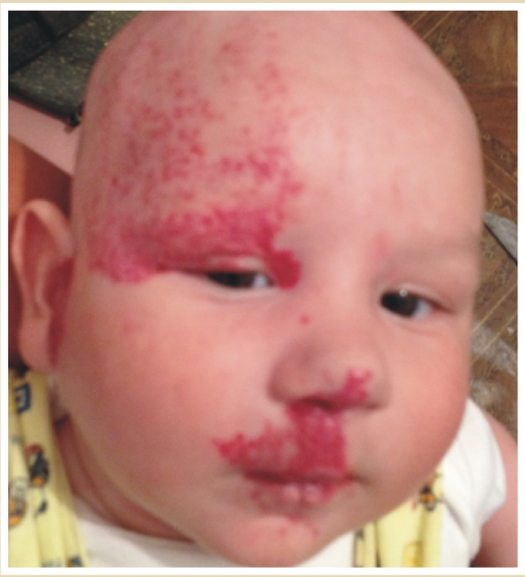
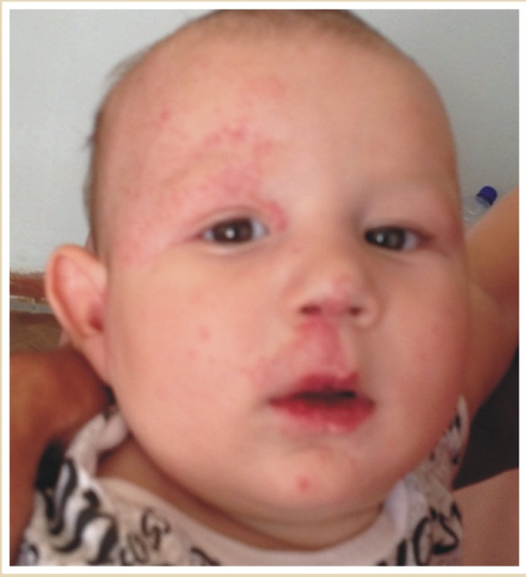
Children vascular anomalies management: results of photodynamic therapy

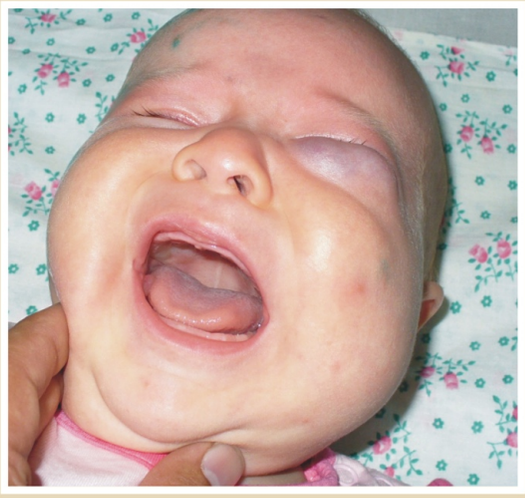


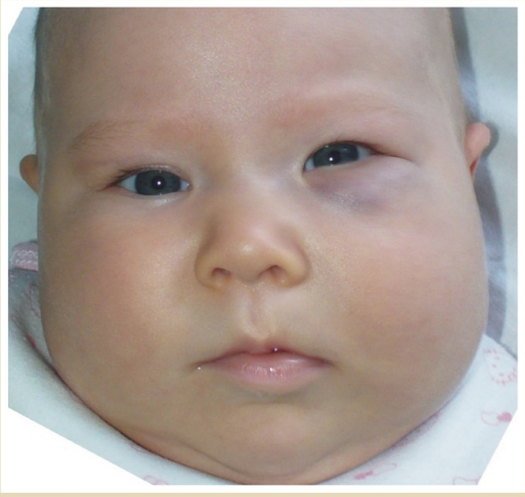
Before



After

Figure 1. Capillary malformation (upper eyebrow, lips) subjected to PDT. Clinical evaluation reported good response to the therapy. Radiological response was significant.



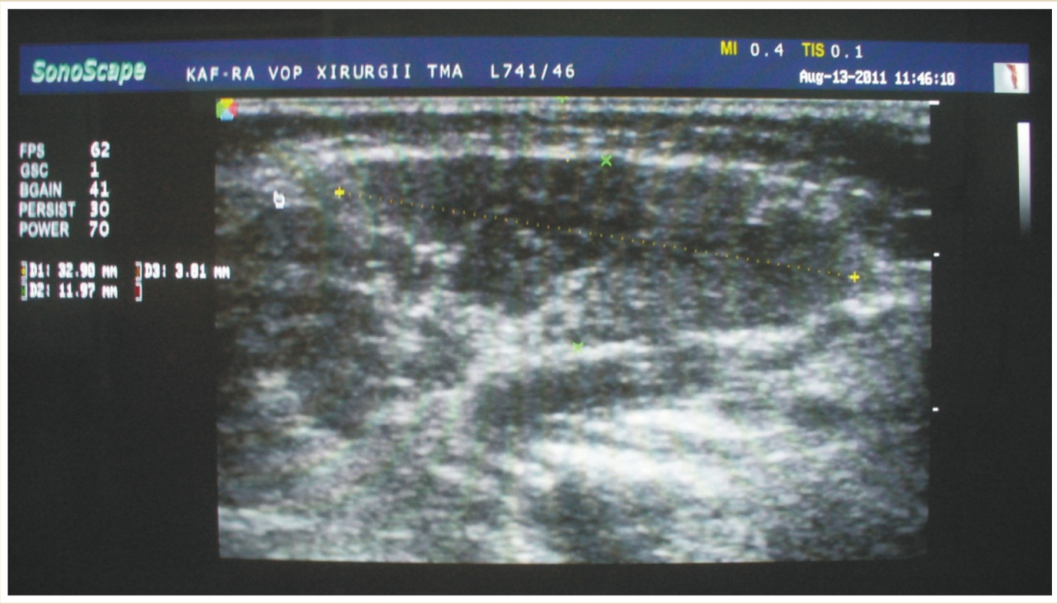


Before PDT

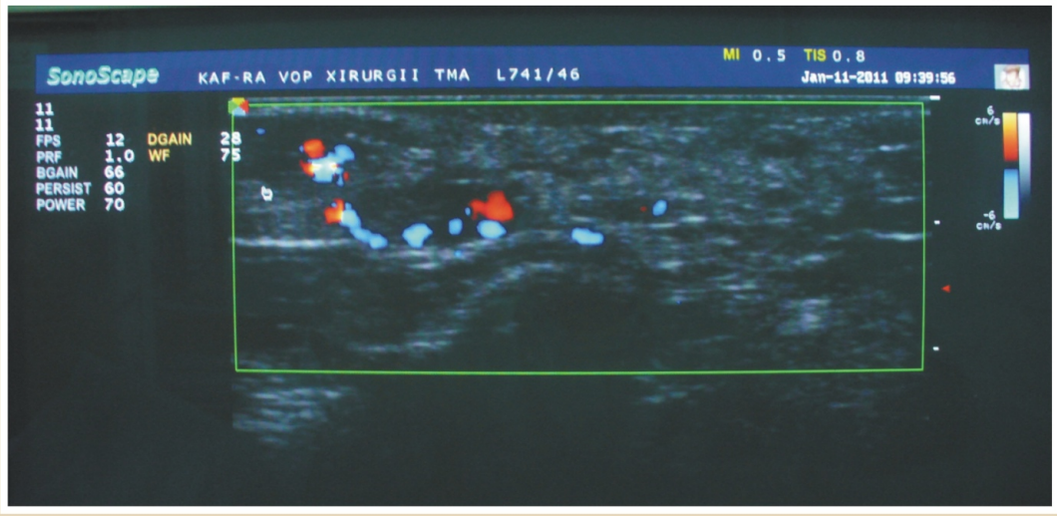
After PDT

Figure 2. Venous malformation (lower eye lid) subjected to PDT. Clinical evaluation was good response.

Children vascular anomalies management: results of photodynamic therapy



Before PDT



After PDT

Figure 3. Doppler ultraltrasound evaluation reported good response to the therapy.

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ЛЕЧЕНИЕ СОСУДИСТЫХ АНОМАЛИЙ У ДЕТЕЙ: РЕЗУЛЬТАТЫ ФОТОДИНАМИЧЕСКОЙ ТЕРАПИИ

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В работе исследована роль фотодинамической терапии в лечении сосудистых аномалий у детей. В ходе ретроспективного (за 2009-2012 гг.) исследования проанализированы результаты хирургического лечения 245 детей с сосудистыми аномалиями в Ташкентской медицинской академии, Узбекистан. После междисциплинарного обсуждения, всем пациентам проводилась фотодинамическая терапия под общим наркозом, с 5-АЛК в качестве фотосенсибилизатора. В ходе лечения 85 из 108 пациентов, жаловавшихся на длительные боли, отметили улучшение. 43 из 46 больных, страдавших кровотечениями, вызванными сосудистыми аномалиями, сообщили об их значительном уменьшении. Сокращение размеров отека наблюдали 189 из 199 пациентов, а сокращение косметических дефектов, вызванных сосудистыми аномалиями – 176 из 205 пациентов, имевших такие жалобы до лечения. В 63 из 65 случаев прекратились инфекционные проявления этих патологий. Клиническая оценка показала, что у более чем половины пациентов наблюдался хороший лечебный эффект. Значительный клинический ответ имел место у 148 (60,4%) больных, умеренный - у 70 (28,6%). Сравнение радиологических и ультразвуковых изображений через 6 недель после фотодинамической терапии с исходными показало, что у 78 (31,8%) больных имел место умеренный лечебный эффект, а у 122 (49,8%) пациентов - значительный.

Ключевые слова: *гемангиома, врожденная и детская, пороки развития, дети, фотодинамическая терапия.*

ЛІКУВАННЯ СУДИННИХ АНОМАЛІЙ У ДІТЕЙ: РЕЗУЛЬТАТИ ФОТОДИНАМІЧНОЇ ТЕРАПІЇ

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У роботі досліджено роль фотодинамічної терапії у лікуванні судинних аномалій у дітей. Під час ретроспективного (за 2009-2012 рр.) дослідження проаналізовані результати хірургічного лікування 245 дітей з судинними аномаліями у Ташкентській медичній академії, Узбекистан. Після міждисциплінарного обговорення, всім пацієнтам проводилася фотодинамічна терапія під загальним наркозом, з 5-АЛК в якості фотосенсібілізатора. Під час лікування 85 зі 108 пацієнтів, які скаржились на довгостроковий біль, відзначили покращення. 43 з 46 хворих, що страждали на кровотечі, спричінені судинними аномаліями, повідомили про їх значне зменшення. Скорочення розмірів набряку спостерігали 189 зі 199 пацієнтів, а скорочення косметичних дефектів, що спричнені судиннми аномаліями – 176 зі 205 пацієнтів, які мали такі скарги до лікування. У 63 з 65 випадків припинились інфекційні прояви цих патологій. Клінічна оцінка показала, що у більше половини пацієнтів спостерігався добрий лікувальний ефект. Значна клінічна відповідь мала місце у 148 (60,4%) хворих, помірна - у 70 (28,6%). Порівняння радіологічних та ультразвукових зображень через 6 тижнів після фотодинамічної терапії з показано, що у 78 (31,8%) хворих мав місце помірний лікувальний ефект, а у 122 (49,8%) пацієнтів - значний.

Ключові слова*: гемангіома, природжена та дитяча, вади розвитку, діти, фотодинамічна терапія.*