

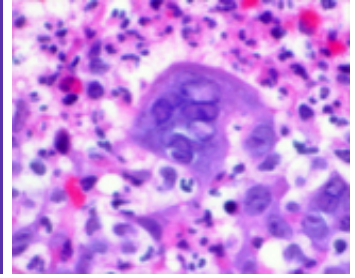


# eLITERATURE REVIEW

## eMedicalDermatology Review

Presented by  
The Johns Hopkins University  
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## October 2007: VOLUME 1, NUMBER 4

### *Ulcerated Hemangiomas of Infancy: Risk Factors and Management Strategies*

#### In this Issue...

Hemangiomas of infancy are the most common tumor of infancy, appearing in 10% of newborns by 2 months of age. Although most of these lesions are innocuous and regress without treatment, 5-10% will ulcerate during the rapid growth phase in the first 6 months of life. Ulceration is the most common reason for referral to specialists, and may be associated with pain, bleeding, infection, disfigurement, and scarring. Although there are no rigorous evidence-based studies and no FDA-approved treatments, investigators have reported their experiences with a number of therapeutic interventions.

In this issue, we review selected publications that discuss the risk factors for the development of hemangiomas, and, specifically, ulcerated hemangiomas; report on investigations into treatment options; and explore the clinical recommendations for the management of these children.

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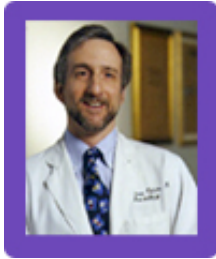
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### ***Unlabeled/Unapproved Uses***

The author has indicated that there will be references to unlabeled or unapproved uses of drugs or products in this presentation. Imiquimod, Human platelet derived growth factor, topical steroids, pulsed dye laser are not approved for treatment of ulcerated hemangiomas.

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## LEARNING OBJECTIVES

**At the conclusion of this activity, participants should be able to:**

- Discuss the risk factors associated with the development of ulcerations in hemangiomas of infancy
- Evaluate the risks and benefits of various treatment options for ulcerations in hemangiomas of infancy
- Integrate the information presented herein into current treatment paradigms for the management of children with hemangiomas of infancy

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The *eMedicalDermatology Review* podcast is a discussion between our October author, Bernard Cohen, MD and Robert Busker, *eMedicalDermatology Review's* Medical Editor. The topic is ulcerated hemangiomas: recognizing risk factors and designing a management algorithm.

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## COMMENTARY

Hemangiomas are the most common tumor of infancy, developing in 10% of children by 2 months of age. Although most hemangiomas resolve without intervention, all dermatology practitioners who treat pediatric patients can expect to be called upon to assist primary care providers and parents with the management of these lesions. Therefore, it is imperative that dermatologists diagnose these lesions early in the course, recognize hemangiomas at risk for complications, and treat complicated lesions appropriately.

Our focus is on hemangiomas with ulcerations, the most frequent complication associated with these tumors. These ulcerations, which may persist for months when untreated, are associated with pain, bleeding, infection, disfigurement, and scarring, so immediate consultation and treatment may be required.

Over the last 10 years, investigators have taught us to recognize lesions at high risk for ulceration based on location, anatomic depth, size, pattern, and growth phase. Most ulcerated hemangiomas are located in periorificial sites, particularly the diaper area and mouth. Lesions in areas of trauma such as intertriginous sites are also at risk. Hemangiomas with a prominent superficial component are at greater risk of ulceration than those that are primarily deep dermal or subcutaneous.

Although ulcerated lesions can be any size, they tend to be relatively large, and often develop in a segmental pattern (recognizable patterns, eg, dermatomal, lines of Blaschko, petaloid), while focal (single round to oval and nonpatterned) and multifocal lesions are at lowest risk. Finally, most ulcerations develop in the proliferative phase, particularly during the first 2-6 months of life, and only rarely develop after 10 months of age.

Although effective management of ulcerated hemangiomas may include multiple concurrent modalities, early conservative treatment is often effective. Topical antibiotics (eg, mupirocin, retapamulin), barrier pastes (eg, zinc oxide 20%), and gentle cleansing and debridement with tepid tap water may result in clearance of erosions, crusts, and superficial ulcerations in stable hemangiomas. Bio-occlusive dressings, absorbant nonstick dressings, alginate dressings, and petrolatum-impregnated gauze may result in immediate improvement in pain as well as potentiate debridement and healing.

Ulcerated rapidly-growing hemangiomas may require systemic therapy (eg, oral corticosteroids 2-3 mg/kg/day) to shut off the proliferative process before healing of the ulcer can be achieved. Rapid healing of ulcerations recalcitrant to conservative measures may respond quickly (within 2-4 weeks) to pulsed dye laser with minimal risk to the infant. Concurrent treatment with experimental topical therapies including imiquimod, recombinant human platelet derived growth factor, steroids, and new antiangiogenic agents may also trigger re-epithelialization. Successful management of ulcerated hemangiomas requires immediate attention to pain, which is often neglected in newborns and infants. Consistent use of oral acetaminophen or acetaminophen with codeine, as well as judicious application of topical anesthetics, may also be necessary.

The clinician must also be prepared to counsel families regarding the anticipated course of ulcerated hemangiomas and the safety and efficacy of treatment strategies to gain their confidence and ensure compliance. Ongoing communication with families by phone and online digital imaging can be used to assess progress. Communication and collaboration with the primary care provider is also critical.

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Finally, increased understanding of the biochemical and molecular aspects of angiogenesis and wound healing will undoubtedly lead to new treatment options. Although there are no rigorous evidence-based studies and no FDA-approved treatments, current efforts by the Hemangioma Investigators Group and other investigators will hopefully make these new treatments safe and consistently effective.

## CURRENT KNOWLEDGE & FUTURE DIRECTIONS

Frieden IJ, Haggstrom AN, Drolet BA, et al. **Infantile Hemangiomas: Current knowledge, future directions. Proceedings of a Research Workshop on Infantile Hemangiomas.** *Pediatr Dermatol* 2005; 22(5):383-406.

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In this workshop, sponsored by the National Institutes of Health and initiated by pediatric dermatologists in the Hemangioma Investigators Group, the latest data on infantile hemangiomas was reviewed and updated. Preliminary data collected by the investigators and based on a cohort of 1058 children, aged  $\leq 12$  years, with infantile hemangiomas enrolled from September 2002 until October 2003 was compared to the National Vital Statistics for Children born in 2002. A survey of the literature suggested an incidence of hemangiomas in 4-10% of infants, with a female predominance of 2.5-4/1. In some complex hemangioma syndromes like PHACES, the female predominance approached 9/1. Risk factors for hemangiomas also included prematurity, low birth weight, and chorionic villus sampling.

Early data analysis of the cohort group showed a statistically significant risk of developing a hemangioma to be associated with Caucasian race, delivery by caesarian section, prematurity, low birth weight, multiple gestation, older maternal age, preeclampsia, and placental abnormalities.

The most common complication and reason for referral to specialists was ulceration, which occurred in 13% of infantile hemangiomas. Problems in affected infants included pain, scarring, and disfigurement, and, less commonly, infection, bleeding, and anemia. Ulceration developed most frequently during the proliferative phase in the first 3-4 months of life and lasted weeks to months. However, ulcerations occasionally appeared in the early precursor lesions and later during involution. Moreover, ulceration also developed in some hemangiomas as a complication of treatment with oral corticosteroids, laser therapy, and topical imiquimod.

A review of ulcerated hemangiomas revealed certain risk factors when compared to uncomplicated hemangiomas--most notably lesions of large size demonstrating a segmental pattern and a significant superficial component. Only 8% of focal (usually round to oval, relatively small, and localized) hemangiomas, compared to 29% of segmental (usually large and covering a significant segment of the body) hemangiomas, developed ulcerations.

Although the cause of ulceration was unclear, investigators suggested predisposing factors including sites of trauma (eg, diaper area, intertriginous areas), infection, and tissue hypoxia. Treatment strategies included slowing proliferation (eg, corticosteroids, interferon, pulsed dye laser), alteration of the local environment (wound care), systemic antimicrobial agents, and alteration of

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the local vasculature. Pain management included oral analgesics, topical anesthetics, and occlusive dressings.

## CLINICAL CHARACTERISTICS PREDICTING COMPLICATIONS

Haggstrom AN, Drolet BA, Baselga E, et al. **Prospective Study of Infantile Hemangiomas: Clinical characteristics predicting complications and treatment.** *Pediatrics* 2006; 118(3): 882-887.

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In September 2006, the Hemangioma Study Group published a prospective study (initially presented at the NIH workshop) based on the cohort of children with infantile hemangiomas enrolled in 2002-2003. Patients recruited from the US were followed until June 2004. Investigators completed 2 training sessions to insure interrater reliability for assessment of hemangioma types, and subsequently completed standardized scannable data forms on each patient. In addition to detailed epidemiologic data, hemispherical measurements were obtained to assess hemangioma volume; treatment and complications incurred before and during the study period were also noted. Appropriate data analysis was performed in conjunction with the National Outcomes Center at the University of California San Francisco Biostatistics Department.

Data on 1,915 hemangiomas in 1,058 US children were included in the analysis. Most (68.6%) had solitary lesions, and 97% had fewer than 7. Forty-one percent were located on the face, 21% head and neck, 23.3% trunk, 18.4% extremities, and 6.1% on the perineum. Nearly 67% were localized and 13.1% were segmental, with the remainder indeterminate. Hemangiomas ranged in size from pinpoint to 1320cm<sup>2</sup>; facial lesions averaged 19.9cm<sup>2</sup>, with 22% of them segmental.

Complications occurred in about a quarter of the patients before and during the study period. During the study, the most common complications were ulceration (16%), visual compromise (5.6%), airway obstruction (1.4%), and auditory canal obstruction, cardiac compromise and hepatic lesions (<1% each).

Treatments during the study period included oral, intralesional, and topical steroids (12.3%, 4.1%, 9.8%), wound care for ulceration (13.7%), oral antibiotics (2.0%), pulsed dye laser therapy (8.0%), excisional surgery (5.7%), and, rarely, interferon and vincristine. Demographic and perinatal factors (eg, gender, ethnicity, prematurity, family history, maternal illness) did not increase the risk of treatment or complications.

Complicated hemangiomas were significantly larger than uncomplicated lesions (37.3 cm<sup>2</sup> vs 19.1 cm<sup>2</sup>), and ulcerated hemangiomas had a mean size of 40.4 cm<sup>2</sup>, over 20 cm<sup>2</sup> larger than nonulcerated hemangiomas. When controlled for size, segmental hemangiomas were 8 times more likely to receive treatment, and 11 times more likely to develop complications, than localized hemangiomas. Perineal hemangiomas had the highest rate of complications at 52% because of the high risk of ulceration. Facial hemangiomas were 3.3 times more likely to receive treatment (as compared to nonfacial lesions), and 1.7 times as likely to develop complications.

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## TREATMENT WITH RECOMBINANT HUMAN PLATELET-DERIVED GROWTH FACTOR

Metz BJ, Rubenstein MC, Levy ML, et al. **Response of Ulcerated Perineal Hemangiomas of Infancy to Becaplermin Gel, a Recombinant Human Platelet-Derived Growth Factor.** *Arch Dermatol* 2004; 140:867-870.

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The authors conducted a retrospective chart review of 8 infants with ulcerated perineal hemangiomas treated between January and June 2003 with a recombinant human platelet-derived growth factor-BB gel (0.01% becaplermin gel). All of the lesions were either superficial or mixed superficial and deep hemangiomas, and all were stable or regressing at the time that treatment was instituted. Five of the 8 patients had failed to improve with prior aggressive topical wound care and other therapies for at least 2 months, and 3 patients were treated primarily with becaplermin gel. Barrier paste was continued during the trial period in all cases.

Rapid healing occurred in all patients within 3 to 21 days (average 10.25 days), and no infants experienced significant adverse effects. When the total costs of hospitalization, local wound care, and other treatment modalities are considered, topical becaplermin appears to be cost-effective, despite the high up-front cost of the medication.

Clinicians should note that while this small series found becaplermin safe and effective in the treatment of ulcerated infantile hemangiomas in the diaper area, a randomized controlled trial of becaplermin for this indication has not yet been completed.

## TREATMENT WITH TOPICAL IMIQUIMOD

Ho NT, Lansang P, Pope E. **Topical imiquimod in the treatment of infantile hemangiomas: a retrospective study.** *J Am Acad Dermatol* 2007; 56(1):63-8.

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Imiquimod—an immune response modifier with antiangiogenesis properties—has been touted as a safe and effective treatment for hemangiomas, especially for superficial lesions during the proliferative phase. Although there are no prospective studies on the subject, the report by these Canadian pediatric dermatologists provides some insight into use of this agent.

The investigators performed a retrospective chart review of 18 children between 4 and 256 weeks (median 18 weeks) with a total of 22 hemangiomas. The majority of lesions were on the head, while the others were scattered on the trunk, genitalia, and extremities. Imiquimod 5% cream was applied 3 times a week in 10 patients, and 5 times a week in 8 patients, for a mean duration of 17 weeks (range 7-46 weeks).

All superficial hemangiomas improved, with clearing in 4 subjects. The mixed (superficial and deep) and deep hemangiomas did not improve. One case of an ulcerated hemangioma showed a rapid reduction in the size of the lesion and

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healing of the ulcer. No systemic adverse effects were noted, but local reactions included self-limited irritation and crusting.

## TREATMENT WITH THE PULSED TUNABLE DYE LASER

Morelli JG, Tan OT, Weston WL. **Treatment of ulcerated hemangiomas with the pulsed tunable dye laser.** *Am J Dis Child* 1991; 145(9):1062-1064.

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Lacour M, Syed S, Linward J, Harper JI. **Role of the pulsed dye laser in the management of ulcerated capillary haemangiomas.** *Arch Dis Child* 1996; 74(2):161-163.

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Yellow flash lamp-pumped pulsed tunable dye laser (PDL) was approved for treatment of port wine stains in the early 1980s and has become the standard of care for vascular lesions of all sorts. However, the use of PDL was contraindicated for ulcerated lesions until Morelli's 1991 study showed that laser therapy was not only safe but also rapidly effective for ulcerated hemangiomas. In this initial study, the investigators demonstrated healing of 6 of 9 ulcerated hemangiomas with one treatment, 1 of 6 with 2 treatments, and 2 of 6 with 3 treatments within a month. Moreover, pain decreased subjectively in all patients within 2-3 days of treatment.

Lacour et al confirmed these results when they published their experience with 8 recalcitrant ulcerated hemangiomas in periorificial locations (perioral, diaper area). All lesions had previously failed treatment with conservative wound care; with PDL, ulcers healed within 1-4 weeks, and normal feeding, micturition, and defecation was restored without complications.

## CLINICAL CHARACTERISTICS & RESPONSE TO THERAPY

Kim HJ, Colombo M, Frieden IJ. **Ulcerated hemangiomas: clinical characteristics and response to therapy.** *J Am Acad Dermatol* 2001; 44(6):962-972.

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Although this paper was published in the *Journal of the American Academy of Dermatology* 6 years ago, it is still the most comprehensive review of the management of ulcerated hemangiomas in the literature. The investigators performed a chart review of 60 patients with ulcerated hemangiomas seen in a pediatric dermatology clinic by the senior author. Although these children may reflect a tertiary care referral pattern, the demographic data of this cohort is similar to that recently reported by the Hemangioma Investigators Group and includes data on multiple treatment strategies.

Fifty of the 60 hemangiomas seen were plaque type, 7 had both a large dermal

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and large subcutaneous component, and 3 had a large dermal and small subcutaneous component. The majority (31) were located on the head and neck, with 12 of these on the lip; 20 were located on the perineum.

Although ulcerations occurred as late as the 13th month of life, most occurred during the rapidly proliferative phase, with the mean age of onset of 93 days. Only 3 occurred after 10 months. Some ulcerations were noted before the appearance of an identifiable hemangioma. Although some of the lesions were small, most were relatively large, with only 13 of the hemangiomas smaller than 6 cm<sup>2</sup>. Ulcerations varied in size from a few mm to 16 cm<sup>2</sup> (mean, 3.5 cm) and lasted from 1 week to 12 months, requiring an average of 4.2 visits until clearing (range 1-25 visits).

No single therapeutic modality was uniformly effective, and many patients required multiple and concurrent therapies, including local wound care, systemic therapy to control growth of the hemangioma, pulsed dye laser therapy, and surgical excision. Pain management and family consultation were also integral parts of the treatment regimen.

Many small ulcerations healed with conservative wound care management such as gentle compressing with saline, Burow's solution, application of topical antibiotics (most commonly metronidazole gel and mupirocin ointment), barrier ointments, and bio-occlusive dressings. Absorbent nonstick, foam, and alginate dressings, and petrolatum-impregnated gauze, were also used. Culture-proven infections were uncommon, and were treated with systemic antibiotics.

When proliferation of the hemangiomas was a problem, treatments including systemic corticosteroids and intralesional steroids (usually for relatively small lesions) were initiated. Interferon alfa-2a, and -2b were used in 4 patients with life-threatening hemangiomas on the head and neck without neurologic complications.

In the 22 patients with ulcerated hemangiomas who received pulsed dye laser therapy, 11 improved or healed completely with a mean of 2 treatments. Only 4 patients showed no response, and 1 worsened.

Rarely, surgical excision is the treatment of choice when infants with life-threatening lesions cannot tolerate medical management, when the lesions are small and/or pedunculated, or when other options have been exhausted. Only 2 patients in this series were treated with surgery, one with a bleeding pedunculated hemangioma of the back, and another with a large nasal hemangioma which was compromising vision.

Adequate pain control was achieved with a combination of oral acetaminophen, oral acetaminophen with codeine, and judicious use of topical lidocaine.

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At the conclusion of this activity, participants should be able to:

- Discuss the risk factors associated with the development of ulcerations in hemangiomas of infancy
- Evaluate the risks and benefits of various treatment options for ulcerations in hemangiomas of infancy
- Integrate the information presented herein into current treatment paradigms for the management of children with hemangiomas of infancy

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- **Susan Matra Rabizadeh, MD, MBA** has disclosed no relationships with commercial supporters.
- **Mark Lebwohl, MD** has disclosed that he has received grants for clinical research and educational activities from, has served as an advisor, consultant and speaker to, and has served as an investigator for Abbott, Amgen, Astellas, Centocor, Genentech and Novartis.
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