

## Diaper Dermatitis – Clinical Practice

Authors in textbooks of both dermatology and pediatrics agree that value of barrier ointments to protect the skin from irritation are important in treating diaper dermatitis. There is almost as much consistency in the opinion that corticosteroids are not routinely justified and their potency should be restricted, usually to hydrocortisone, for those cases where treatment of intense inflammation is warranted.

Antifungals are used with frequency intermediate between barriers and steroids. The decision to add an antifungal depends on the belief that *C. albicans* is contributing and authorities differ considerably in the criteria for determining the presence and role of *Candida*.

### Clinical Criteria

All authors use clinical criteria as part of their assessment. Many authors consider clinical criteria sufficient to conclude *C. albicans* are present or they will make a presumptive diagnosis that *C. albicans* are present when the eruption has lasted 3 days or more. (Krafchik,1988) (Morelli,1993) (Moschella,1992) (Oranje,1996) (Roberts,1984) (Weisse,1996) Authors frequently emphasize satellite papules and pustules as indicating *Candida* infection. However, others caution that satellite lesions are not pathognomonic for *Candida* because such lesions can also be produced by other causes, staphylococcal infection, for example. (Amdt,1983) (Cohen, 1999) (March,1995)

The clinical criteria provide only an approximate prediction of culture results. Dixon *et al* determined which patients with diaper dermatitis they did or did not expect to find *Candida*. They found 63% of cultures were positive when *Candida* was expected; in contrast to 25% were positive when *Candida* was not expected. (Leyden,1978) These results show that clinical criteria roughly correlate with results of culture, but clinical criteria were not entirely accurate for ruling *Candida* in or out.

### Laboratory Criteria

When the infant with diaper dermatitis is brought for consultation, the physician has the option to get a KOH and/or cultures to complement examination. However, only a KOH provides results in time for the initial selection of treatment.

The KOH has three possible outcomes:

- 1) Pseudohyphae are present. There is agreement that an antifungal is appropriate when pseudohyphae are present and some authors recommend anti-fungal treatment only with demonstration of pseudohyphae. (Fitzpatrick,1981) (Fitzpatrick,1996) (Paisley,1993)
- 2) Only budding yeasts are present. Some authors recommend culture and/or KOH to confirm the presence of *Candida*. (Amdt,1983) (Darmstadt,1996) (Esterly,1987) (Hoekelman,1978) (Hurwitz,1993) (Marks,1985) (Miller,1995) (Morley,1984) (Moschella,1992) (Whiting,1989) These authorities recommend antifungal treatment based simply on the presence of *Candida* without any mention of pseudohyphae. They do not present a specific recommendation when only budding yeasts are found. The practitioner is left with two choices:
  - Withholding antifungal based on a presumption that *Candida* is present but not contributory. There are three reasons we believe this option is undesirable
    - (a) The specimen could be a false negative and another site would show pseudohyphae.
    - (b) Incidental *Candida* is present and potentially able to invade this compromised skin and occluded site.
    - (c) *Candida* does not have to be invasive or even viable to produce irritation, as established in the experimental studies discussed above under Etiology.
      - Initiate antifungal treatment. We believe it is better to initiate antifungal treatment in order to reduce or eliminate the opportunity for irritation and/or for the transition to an invasive infection.
- 3) No fungal elements are detected. The trials described in this document demonstrate the advantage of PEDIASTAT™ over simple barrier ointments when cultures were positive for *Candida*, but they also show PEDIASTAT™ is effective when there was no evidence of *Candida*. In the absence of *Candida*, there is no compelling advantage of PEDIASTAT™ over a barrier ointment. The absence of *Candida* is a key point here and we will come back to it after the next section when we present the case for PEDIASTAT™.

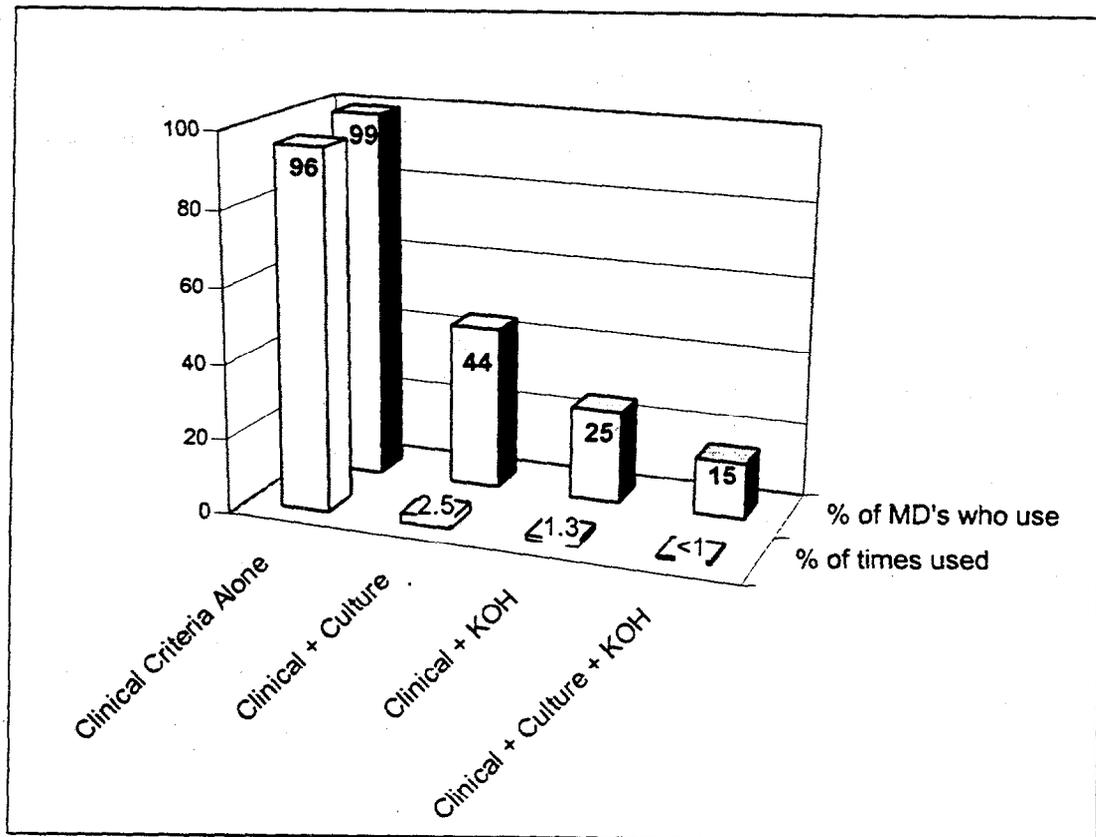
### Culture and the Choice of Treatment

Although a culture is an accurate and sensitive test for *Candida*, the results cannot be available for several days after the laboratory receives the specimen. The delay in getting information relevant to the diagnosis is unavoidable but delay in initiating treatment is undesirable when the emphasis is on rapid relief, as it invariably is. Thus the initial choice of treatment must be made without the benefit of culture results.

### Survey of Pediatricians for their Standard of Care in Diaper Dermatitis.

At this point, it is relevant to consider how physicians, in fact, approach the management of infants with diaper dermatitis. Parents may select over-the-counter treatments initially, but they consult a pediatrician most commonly when they seek the advice of a physician. For this reason, we commissioned Bruno and Ridgway Research Associates to conduct a study of diaper dermatitis in November/December 1999. <sup>(Bruno and Ridgway, 1999)</sup> A total of 157 board-certified pediatricians completed telephone interviews. Findings from these participants include (see Figure 5 below and Table 5 in Appendix A):

**FIGURE 5. CRITERIA USED BY PEDIATRICIANS TO DETERMINE TREATMENT**



- All (99%) used clinical criteria for diagnosis. For selected patients, physicians said they would supplement clinical diagnosis with the following laboratory testing: 44% sometimes used only culture, 25% occasionally used KOH alone, and 15% used both.
- While many of the physicians described using laboratory tests for selected cases, the actual proportion of cases for whom tests were done was less than 5%. Of these

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cultures were done in about 3% of cases and KOH in about 2%. Thus these doctors determined the treatment for 95% of cases based on clinical criteria alone.

- Most (96%) physicians took telephone consultations and the participants in this survey reported that they managed 37% of their diaper dermatitis patients by telephone.
- The survey did not attempt to determine all the factors that contributed to the very low rate of laboratory testing. We did ask, however, about changes in testing practice since enactment of the Clinical Laboratory Improvement Act (CLIA). Twenty-one percent (21%) of physicians reported they had decreased use of culture and KOH and less than 1% reported increased use of laboratory tests.

The survey also asked physicians how finding pseudohyphae would influence their choice of treatment. Since survey participants reported doing a KOH in only 2% of cases, this question is more hypothetical than actual practice. The selection of treatment showed many similarities between the two possible outcomes, but two differences in product usage seem noteworthy to us. The physicians said they would be three to four times more likely (10.1% vs 2.9%) to use a medicated OTC ointment if pseudohyphae were not seen and twice as likely (23.2% vs. 10.1%) to prescribe a combination of steroid and antifungal if pseudohyphae were seen (10.1% vs 2.9%). (Table 6, below)

**TABLE 6. INFLUENCE OF FINDING PSEUDOHYPHAE ON CHOICE OF TREATMENT**

Treatment choices pediatricians would make if they performed a KOH and found pseudohyphae:	Pseudohyphae	
	Present	Absent
Prescription anti-fungal product	52.2	49.3
OTC anti-fungal product	30.4	36.2
Prescription combination of steroid and antifungal	23.2	10.1
OTC hydrocortisone	4.3	5.8
Prescription steroid product	4.3	5.8
Medicated OTC Ointment (e.g. vitamin A&D ointment)	2.9	10.1
Petrolatum	1.4	4.3
Note: Percentages may add to more than 100% because more than one product was recommended.		

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**Overall, the participants in this survey reported a relatively modest influence of pseudohyphae on their prescribing decisions, except for doubling the use of products combining steroid and antifungal.**

A recent report of prescribing practices among pediatricians found only 5% of their single ingredient prescriptions being high-potency corticosteroids. However, pediatricians prescribed the high-potency betamethasone dipropionate combined with clotrimazole 389,920 times for children in the newborn to 4 year old age range for a variety of conditions, including diaper dermatitis and candidiasis. (Fleischer, 1999) This extensive off-label use of this product creates a usually warranted exposure to the risk of local atrophy from the high-potency corticosteroid. We believe such use represents a greater risk than treatment with PEDLASTAT™