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November 2013

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## Recommended Citation

Qamar, F. N., Tikmani, S. S., Mir, F., Zaidi, A. K. (2013). Community-based management and outcome of omphalitis in newborns in Karachi, Pakistan. *Journal of Pakistan Medical Association*, 63(11), 1364-1369.

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## Community-based management and outcome of omphalitis in newborns in Karachi, Pakistan

Farah Naz Qamar, Shiyam Sundar Tikmani, Fatima Mir, Anita Kazmi Mehdi Zaidi

### Abstract

**Objectives:** To describe the clinical profile and outcome in newborns with omphalitis managed with home or clinic-based therapy.

**Methods:** The descriptive study was conducted from September 2004 to August 2007 in three low-income communities in Karachi, Pakistan. Newborns with omphalitis detected by community health workers through active surveillance were referred to local clinics. Those with physician-confirmed omphalitis were treated for 7 days with topical gentian violet or oral cephalixin (as monotherapy) or topical gentian violet and oral cephalixin (combination therapy) at physician discretion, or injectable therapy (procaine penicillin and gentamicin) if clinical signs of sepsis were also present and family refused hospital referral. Follow-up was at 48-72 hours and 7 days. SPSS 16 was used for statistical analysis.

**Results:** Among 1083 newborns with omphalitis, 578 (53.4%) had peri-umbilical cellulitis without purulent discharge; 365 (33.7%) had purulent discharge (with or without cellulitis); and 140 (13%) had omphalitis with sepsis. Review of outcome data at one week showed that among 943 newborns without signs of sepsis, 938 (99.5%) had improved; 2 (0.2%) died, and 2 (0.2%) were lost to follow-up. There were 5 (3.6%) therapy failures, among 140 newborns with omphalitis and sepsis managed with parenteral antibiotics at 48 hours, but 139 (99.2%) had improved by one week, while 1 (0.8%) died.

**Conclusion:** In resource-constrained environments, omphalitis can be managed in the community with minimal need for hospital referral. Further research to define optimal therapeutic regimens is needed.

**Keywords:** Omphalitis, Umbilical infection, Neonatal sepsis, Community case-management, Newborn, Pakistan. (JPMA 63: 1364; 2013)

### Introduction

Umbilical infections are an important cause of neonatal morbidity and mortality in developing countries with incidence rates as high as 55-197 per 1000 live births in community-based studies.<sup>1</sup> Home-births are a recognised risk factor, associated with a 6-fold higher incidence rate compared to hospital-born babies.<sup>2,3</sup> A number of factors contribute to the high incidence of omphalitis in developing countries: unhygienic delivery practices, unskilled birth attendants, use of non-sterile cutting instruments, and harmful traditional cord care practices.<sup>3</sup> An association between omphalitis and sepsis is suggested by the fact that as many as one-fifth of newborns admitted for sepsis also have omphalitis.<sup>3</sup> The significance of the association can be gauged by the fact that application of 4% chlorhexidine to the umbilical stump within 24 hours of birth in rural Nepal resulted in a 34% decline in all-cause neonatal mortality.<sup>4</sup>

The clinical presentation of omphalitis is variable and

depends on the severity of infection. It may range from purulent discharge, to erythema and swelling of varying degrees, warmth, tenderness, and/or foul odour from the site of the infection.<sup>5</sup> Differentiating pus from serous discharge and erythema from temporary redness due to pressure requires skilled assessment. If diagnosed early, omphalitis may successfully be diagnosed in the community with the help of pre-defined, validated sign-based algorithms.<sup>4</sup> The World Health Organisation's (WHO) current recommendation of inpatient management of omphalitis with parenteral antibiotics is likely the result of paucity of data on etiology and clinical effectiveness of oral and topical agents in community-based settings.<sup>6</sup> Adherence to this recommendation is not only unfeasible due to financial constraints, but also culturally unacceptable to many families in South Asia in the first week of life.<sup>7</sup> Management of neonatal infections with simple home or clinic-based regimens is, therefore, increasingly being studied as an alternative approach to improve patient compliance and clinical outcomes in resource-limited environments with high neonatal mortality rates.<sup>7,8</sup> Efforts to identify and implement affordable and effective community-based interventions for

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omphalitis may reduce the large burden of infection-related neonatal mortality in developing countries.

The objective of this study was to review outcome data on the clinical effectiveness of simple regimens (topical gentian violet, oral cephalixin, combination therapy with topical gentian violet and oral cephalixin) used for the treatment of omphalitis in primary care settings in three low-income communities in Karachi, Pakistan, where hospital referral was not feasible.

## Patients and Methods

The descriptive study was conducted from September 2004 to August 2007 in three low-income (one urban and two peri urban coastal) settlements of Karachi, approximately 20-30 kilometers from the city centre. Each settlement's primary healthcare needs are served by a Department of Paediatrics and Child Health-run Primary Health Centre (PHC) staffed by 2 physicians, a lady health visitor (LHV) and community health workers (CHWs). These PHCs were established for research studies on common childhood diseases, but also function as the main locus of care for families residing in the area because healthcare for children under 5 years of age is provided free of charge.

All study sites have an established neonatal surveillance system run by the Department of Paediatrics and Child Health, Aga Khan University, Karachi, in which local CHWs visit each newborn 7-8 times in the first two months of life, and refer sick newborns to the PHC. Neonatal mortality rates in the three sites are in the range of 30-45 per 1000 live births. Seventy per cent of the deliveries are conducted at home by traditional (unskilled) birth attendants (TBAs) who have no formal certification or licensure. The use of sterile delivery kits (as an indicator of effective infection control practices) in home deliveries is low (32%).<sup>9,10</sup>

The data for this study was derived from parent studies approved by the Ethical Review Committee of the University.<sup>11</sup> These studies evaluated the ability of paramedical staff to detect clinical signs of serious illness in young infants, and evaluated clinic-based injectable therapeutic options for young infants with clinical signs of possible serious bacterial infection in situations where referral failed. Neonates with omphalitis, from this 3-year cohort study, who refused injectable antibiotics, were observed with simple home-based treatment options and data as collected.

CHWs were trained in identifying serious illnesses in newborns in need of referral. Specific training regarding omphalitis was given at each field site by a

research supervisor who explained the signs and symptoms of umbilical infection and showed coloured photographs of its varying presentations. The CHWs regularly followed up the birth cohort at each of the three field sites. Using purposive sampling neonates with omphalitis identified during the field visits, were referred to the PHC, where the physician confirmed the diagnosis, as well as recorded presenting symptoms.

Omphalitis was categorised as peri-umbilical cellulitis without purulent discharge; peri-umbilical cellulitis with purulent discharge; or purulent discharge with minimal or no cellulitis. The size of peri-umbilical cellulitis, if present, was also recorded. Newborns with concurrent signs of sepsis were categorised as having omphalitis with sepsis. The diagnosis of sepsis was made on the basis of clinical signs (Annexure).

Cases of omphalitis without sepsis were diagnosed and treated with either topical gentian violet or oral cephalixin or both, depending upon physician's judgment from among the available therapies at the local PHC. Oral cephalixin was given in a dose of 50 mg/kg/day divided three times a day for 7 days, to be administered by the mother/caretaker at home. Gentian violet's first

### Annexure: Clinical Definition of Sepsis.

#### Any three of the following:

1. RR > 60/min
2. Feeding difficulty/poor suck
3. Fever > 37.5 C (ax)
4. Temperature < 36.0 C (ax) and not increasing on warming
5. Lethargic or < normal movement
6. Excessive crying or irritability
7. Weak, abnormal or absent cry
8. Persistent vomiting (last 3 feeds)
9. abdominal distension
10. Hypoglycaemia - blood glucose < 40 mg/dl
11. Presence of skin, eye, or local umbilical infection
12. For babies < 7 days old: Presence of any maternal risk factor (premature delivery, fever in the 24 hours prior to delivery, foul-smelling amniotic fluid, prolonged labor of >12 hours, prolonged rupture of membranes > 12 hours)

or

#### Presence of any one of the following:

1. Apnea/poor respiratory efforts?(in >24 hours baby present on examination)
2. Seizures in last 24 hours
3. Bulging fontanelle
4. Temp > 38.5 C (ax)
5. Temp < 35.5 C (ax)
6. Severe lethargy/floppy baby
7. Capillary refill >2 secs after adequate warming
8. severe chest indrawing in >24 hour baby
9. grunting in >24 hour baby.

application was done in the clinic and the mother was given a bottle with gentian violet solution for home application twice a day for 7 days. Those with treatment failure were given clinic-based injectable procaine penicillin and gentamicin if hospital referral was declined by the family.

Newborns with omphalitis and clinical signs of sepsis on presentation whose families refused hospital referral despite provision of free transport and cost of medications were treated with procaine penicillin and gentamicin, given once daily by intramuscular (IM) injection at the clinic as well as topical gentian violet. Injectable therapy for 7 days.

Follow up evaluations was conducted at 48-72 hours, and 7 days after enrollment in the study by physicians at the clinics. The continued presence or resolution of clinical signs or development of new clinical signs was recorded in structured case report forms of the parent studies on newborn illness. Families were advised referral if at any time signs of sepsis or therapy failure were observed. CHWs facilitated newborn visits if the family did not bring the baby to the clinic for the scheduled follow-ups.<sup>11</sup>

Main outcome measures, evaluated at 48 hours, and at 7 days after the initiation of treatment, included decreasing area of redness/cellulitis or decrease in purulent discharge, or complete resolution of clinical

signs of sepsis; no improvement at 48 hours, or development of clinical signs of sepsis (lethargy, poor feeding, fever, hypothermia etc) or increase in redness/cellulitis/discharge, or death.

Data was analysed using SPSS 16.0.

## Results

Omphalitis was diagnosed by physicians in 1,083 babies during the study period. Excluding newborns with minimal peri-umbilical cellulitis and no purulent discharge or signs of sepsis, the incidence of omphalitis was estimated to be 110 per 1000 live births (95% CI: 102.3-118).

Omphalitis without purulent discharge was observed in 578 (53.4%), omphalitis with purulent discharge in 365 (33.7%) and omphalitis with sepsis in 140 (13%) (Table-1).

After 7 days of therapy, 1078 (99.5%) newborns were successfully treated. There were 3 (0.3%) deaths and 2 (0.18%) were lost to follow-up. Of the 943 newborns with omphalitis without clinical signs of sepsis, by 48 hours, 938 (99.5%) had clinically improved; and 5 (0.5%) failed therapy, including 1 (0.1%) death.

High rates of success (>98%) with home-based therapy were observed, regardless of the severity of omphalitis or regimen used. Among newborns with omphalitis and signs of sepsis on presentation, 5/140 (3.6%) failed

Table: Clinical features, therapeutic regimens and outcomes of omphalitis.

Categories of Omphalitis	n= 1083 (%)	Treatment regimen	No. receiving regimen	Outcome n (%)	
				Day 2	Day 7
<b>Omphalitis without purulent discharge</b>	<b>578 (53.4 %)</b>				
Cellulitis <2cm	324 (56)	Gentian violet	158	Improved 155 (98.1)	Cured 158 (100.0)
				Treatment failure 3 (1.9)	
		Cephalexin	166	Improved 165 (99.4)	Cured 165 (99.4)
				Died 1 (0.6)	
Cellulitis >2cm	196 (34)	Cephalexin	Improved 196 (100)		Cured 195 (99.5) <sup>4</sup>
Swelling around umbilicus	58 (10)	Cephalexin	Improved 58 (100)		Cured 58 (100)
<b>Omphalitis with purulent discharge</b>	<b>365 (33.7%)</b>				
No cellulitis or cellulitis <2cm with purulent discharge	125 (34)	Gentian violet and cephalexin,	123 <sup>1</sup>	Improved 124 (99.2)	Cured 124 (99.2)
				Treatment failure 1 (0.8)	Died 1 (0.8)
Cellulitis of >2cm with purulent discharge	198(54)	Gentian violet and cephalexin	196 <sup>2</sup>	Improved 198 (100)	Cured 197 (99.5) <sup>4</sup>
Swelling around umbilicus with purulent discharge	42 (11.5)	Gentian violet and cephalexin	403	Improved 42 (100)	Cured 42 (100)
Omphalitis with sepsis	140 (13%)	Procaine penicillin + gentamicin	135	Improved 135 (96.4)	Cured 139 (99.3)
		daily I/M + topical gentian violet <sup>5</sup>		Treatment failure 5 (3.6)	Died 1 (0.7)

According to clinical judgment of treating physicians:

<sup>1</sup>Two newborns received oral cephalexin only and were improved.

<sup>2,3</sup>Four newborns received oral cephalexin and IM gentamicin and outcome was improved.

<sup>4</sup>One newborn in each of these groups was lost to follow up.

therapy at 48 hours and required alternative treatment or hospital admission. Among these 140, newborns families of 56 (40%) consented for a blood culture. Two (3.6%) yielded pathogens (*S. aureus* and one polymicrobial specimen *Klebsiellapneumoniae*, *E.coli*, and *Enterobacterspp*). Umbilical cultures were obtained from 54 (38%) of the 140 babies; 22 (40.74%) cultures were negative, 19 (35%) yielded pure isolates, and 13 (24%) were polymicrobial. Further details of etiological spectra and antimicrobial resistance patterns have been reported elsewhere.<sup>3</sup>

Among the 3 newborns that died, 1 (33.3%) death was observed in a male newborn with minimal cellulitis and no purulent discharge; 1 (33.3%) had purulent discharge present at diagnosis, and 1 (33.3%) was also diagnosed with sepsis at presentation. In 2 (66.6%) of the three fatal cases, the neonates had clearly failed therapy by 48 hours. Families were strongly counselled about the need for hospital care, but they chose not to accept referral or further clinic-based injectable therapy. Both these neonates were female. The third neonate who was diagnosed with mild omphalitis refused to come for followup at the clinic. Verbal audit at a later date suggested the cause of death as sepsis.

## Discussion

The high burden and lack of feasibility of delivering parenteral therapy for neonatal infections in resource-constrained settings has led to a pressing need to explore alternative, easier-to-administer therapeutic options for neonatal infections in community (home or clinic-based) settings. Recent trials of home or clinic-based antibiotic treatment for neonatal infections in areas of high neonatal mortality where hospital referral was not feasible have shown significant reduction in neonatal mortality when antibiotic therapy has been delivered at home or PHCs located close to home.<sup>12,13</sup> The antibiotics that have been successfully used for community-based treatment of neonatal infections (sepsis and pneumonia) include oral cotrimaxazole, penicillin or cephalixin, usually in combination with IM aminoglycosides.<sup>12,14</sup> Although many trials have been conducted for determining the best cord care practices for prevention of omphalitis, but there are limited data on effective management of omphalitis.<sup>4,15</sup> Some clinicians have reported treating infants with minimal symptoms with topical applications such as alcohol, bacitracin or mupirocin.<sup>16</sup> Others have treated cases of omphalitis due to community-acquired methicillin-resistant *S. aureus* with initially intravenous nafcillin followed by topical gentamicin or mupirocin. Cases of

omphalitis that occurred during a trial for triple dye vs. dry cord care, by Janssen et al in British Columbia, were treated with topical antibiotics (polysporin).<sup>17</sup> However, there are limited efficacy data on this practice or the use of oral or topical antibiotics in umbilical infections, and newborns with omphalitis almost always receive hospital care and parenteral antibiotic therapy in industrialised countries.

In developing countries, admission to hospitals and parenteral antibiotics are not possible in most cases due to social, cultural or economic reasons or in many cases due to lack of access to healthcare facilities. A system of early identification, simple home-based treatment options coupled with close monitoring may lead to improved outcomes and be cost-effective.<sup>12,18</sup>

In our study, cases of omphalitis were diagnosed and treated on an outpatient basis and an excellent cure rate was observed in all treatment groups (gentian violet, oral cephalixin, a combination of gentian violet and oral cephalixin, or injectable procaine penicillin and gentamicin).

Topical gentian violet has been reported to have good anti bacterial activity in vitro against *S. aureus* and also against selected gram negative organisms such as *Pseudomonas*.<sup>19</sup> It has long been used in artificial media to suppress growth of gram-positive organisms.<sup>20</sup>

It has been used to treat mild to moderate omphalitis in India with close follow-up by CHWs. However, outcomes have not been reported.<sup>18</sup> Some supportive evidence comes from the decrease in colonisation of the umbilical cord by gram-positive organisms with the use of triple dye (a combination of brilliant green, proflavinehemisulphate, and gentian violet) for cord care.<sup>17</sup> The preparation is also considered useful for topical use for skin infections due to *S.aureus* in primary healthcare settings. It is a low-cost, safe and stable compound, making it ideal for a public health formulary list.<sup>19</sup> As our experience has shown, topical application of gentian violet appeared to be an effective and inexpensive means of treatment of omphalitis in community setting. However, neonates with only minimal evidence of cellulitis without any purulent discharge received gentian violet alone; therefore it is difficult to comment on the efficacy of gentian violet as stand-alone therapy for more severe forms of omphalitis. The most common barrier to gentian violet use is that it stains skin and clothing. Rarely, contact sensitisation has also been reported.<sup>20</sup>



The use of oral antibiotics for neonatal infections in community settings, where referral is not possible, has been suggested by several authors in an effort to improve neonatal survival in areas with high neonatal mortality.<sup>7,9</sup> Cephalexin is a well-tolerated, inexpensive, first-generation cephalosporin with good activity against gram-positive organisms such as *Streptococcus pyogenes* and methicillin sensitive *S. aureus*. It is also active against some enteric gram-negative rods.<sup>21</sup> In addition to cephalexin, there is also some evidence of successful treatment of non-serious neonatal infections caused by *S. aureus* (pustulosis and abscess) with oral clindamycin and amoxicillin/clavulanate.<sup>22</sup> We chose cephalexin as the oral antibiotic of choice for the management of omphalitis at home, instead of a purely gram-positive agent such as cloxacillin because information from microbial cultures revealed that although *S. aureus* and *streptococci* were dominant pathogens in our setting, polymicrobial infections, including gram-negative rods, were also common,<sup>3</sup> and because of cost considerations and the ease of availability of cephalexin in Pakistan. Parenteral antibiotics followed by oral cephalexin has been used successfully for a case of omphalitis occurring during a preventive trial for cord care practices.<sup>23</sup>

The optimal duration of antibiotics for skin infections due to *S. aureus* is not known. Anti-bacterials have been given for 10 days in most clinical trials, but some suggest that a 7-day course is equally effective. We observed good results with seven days of therapy.<sup>24</sup>

Omphalitis is a potentially lethal infection and its seriousness should not be underestimated. If not treated in its early stages, it may result in serious complications, ranging from portal vein thrombosis, phlebitis, peritonitis, necrotising fasciitis, liver abscesses, and death.<sup>1</sup> Systemic infections should be considered if associated systemic signs such as lethargy, fever, irritability, and poor feeding are present.<sup>25</sup> Although this category of newborns in our setting did well with injectable clinic-based antibiotics, it was the group with the highest failure rate of 3.6%. Newborns with omphalitis without signs of sepsis on the other hand did exceedingly well with topical and/or oral antibiotics.

The major limitation of our study is that it is based on observational data, and is not a randomised controlled trial. Nevertheless, our experience demonstrates that simple home- or clinic-based management of newborn infections with close monitoring results in successful outcomes in newborns. Clinical trials are needed to define optimal therapeutic regimens and duration of therapy for

the management of omphalitis.

## Conclusion

The study corroborated prior reports of success in improving neonatal clinical outcomes through early recognition and effective community-based case management in areas with high burden of neonatal deaths. Further research is needed to define the most effective therapeutic option for omphalitis as well as duration in community settings.

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### ERRATA

In the original article "Hepatitis B vaccination coverage in medical students at a medical college of Mirpurkhas" which appeared on pages 680-682 of the July 2011 issue, the name of second author was misspelled.

His name should have appeared as **Waseem Raja**.

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In the original article "Oral Clefts: A review of the cases and our experience at a single institution" which appeared on pages 1098-1102 of the September 2013 issue, the name of the second author was misspelled.

Her name should have appeared as **Alina Ghani**.

The Journal regrets these errors.