

Review Article

# Conservative Management of Omphalocele Using Escharotic Agents Available in Resource-Constrained Settings: A Scoping Review

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## Keywords

Non-operative management  
Escharotic agent  
Exomphalos  
Omphalocele  
Resource-limited Setting

## Abbreviations

DE - disodium eosin  
GV - gentian violet  
HIC - High-income country  
LMIC - Low-middle-income country  
NA - *Acacia nilotica*  
PI - Povidone-iodine  
SSD - Silver sulfadiazine

## Abstract

**Background:** Conservative management of omphalocele is an accessible method in resource-constrained settings. This review summarizes the literature on the usage of escharotic agents in omphalocele.

**Methods:** Articles published between January 2000 and August 2023, were screened following the PRISMA guidelines.

**Results:** Twenty studies met the inclusion criteria. Five of them used disodium eosin (DE), in 249 patients, five used povidone-iodine (PI) in 70, four used silver sulfadiazine (SSD) in 38, four used honey in 55, one used gentian violet (GV) in 27, and two used *Acacia nilotica* (AN) paste in 47. The length of hospital-stay ranged from 5 to 239 days, and the time to full enteral feeding ranged from 2 days to 45 weeks. The overall complication rate ( $n=128$  patients) was 26.4% for all escharotic agents. Sac related complications occurred in 80 patients, gastrointestinal complications in 42, and drug-related toxicity (especially iodine and silver) in 4 cases. Sac infection was common with DE and SSD, but rare with GV. Mortality appears to be increased with protective dressing (e.g. DE, PI, and honey) as compared to open dressing (e.g. GV and AN paste).

**Conclusion:** Escharotic agents easily available in resource-constrained settings are valuable therapeutic aids in the non-operative management of omphalocele. However, meaningful comparison of various agents is precluded by the lack of standardized treatment and uniform reporting.

## INTRODUCTION

Omphalocele (exomphalos) is the most common congenital defect of the abdominal wall, with an incidence of 1 in 5,000 live births.<sup>(1)</sup> It occurs due to defective fusion of primitive embryonic folds between the sixth and the tenth week of gestation. During this time, several organs are in a critical phase of their formation<sup>(2)</sup> Disorders affecting the closure of the abdominal wall can also affect these organs, resulting in associated malformations in 30 to 80% of patients with omphalocele.<sup>(1)</sup>

The management of omphalocele in high-income countries (HIC) has evolved into primary surgical closure in minor omphalocele and staged repair in major omphalocele. Conservative management (delayed closure or non-operative management) as an alternative, is reserved for those cases with life-threatening associated congenital malformations.<sup>(3,4)</sup> With improvements in prenatal diagnosis, neonatal intensive care, and neonatal anesthesia, the prognosis of this condition has improved, considerably and mortality is now mainly due to associated congenital malformations, especially the cardiac anomalies.<sup>(5)</sup> On the contrary, in low- and middle-income countries (LMIC), the management of omphalocele is still a challenge.<sup>(6)</sup> This is due to the scarcity of accurate prenatal diagnosis. Many patients are born far from dedicated tertiary centers, leading to subsequent rupture of the sac during transport, infection, dehydration, hypothermia and hypoglycemia.<sup>(6)</sup> Even when the affected patients attend specialist neonatal-care facilities, operative management is still challenging due to the lack of pediatric anesthetists and pediatric surgeons, leading to an increased mortality.<sup>(7)</sup> In a Senegalese cohort, rupture of sac and primary closure were identified as the risk factors for mortality in omphalocele, no matter if it were major or minor type.<sup>(8)</sup> This led to the adaptation of conservative management as the gold standard of omphalocele management in some African centers, regardless of the size of the abdominal wall defect or associated anomalies.<sup>(9)</sup>

From the historical usage of alcohol and mercuriochrome as escharotic agents, techniques of conservative management are now more innovative and safe. Modern conservative therapies include nano-crystalline-silver applications, hydrogel dressings and negative pressure therapy.<sup>(4)</sup> However, some of the newer artifices are not easily available in LMIC. With this background, we reviewed the published evidence on the outcomes of treatment with commonly available topical agents in LMIC.

## METHODS AND MATERIALS

### Search Strategy

Two authors searched PubMed and Google Scholar for publications on the conservative management of omphalocele using the strategy detailed in the appendix-I.

### Eligibility Criteria

We considered studies on conservative management of omphalocele published between January 2000 and August 2023 that used topical agents easily available in LMIC. Chosen topical agents included *Acacia nilotica* (AN) paste, di-sodium eosin (DE), gentian violet (GV), honey, povidone-iodine (PI) and silver sulfadiazine (SSD). Excluded were theoretical articles, study using any other topical agents, reports using negative pressure, and publications that are not in English or French.

### Study Selection

Two authors independently selected articles using Rayyan® online software following the PRISMA guidelines for scoping review.<sup>(10)</sup> (Fig. 1) Duplicate publications were manually removed.

### Data Extraction and Analysis

Two authors extracted data on a Microsoft Excel sheet using Office™-2019. Extracted variables include number of patients, escharotic agent used, frequency of topical applications, use of a supportive dressing, time to full enteral feeding, length of hospital stay, discharge criteria, time to epithelia-

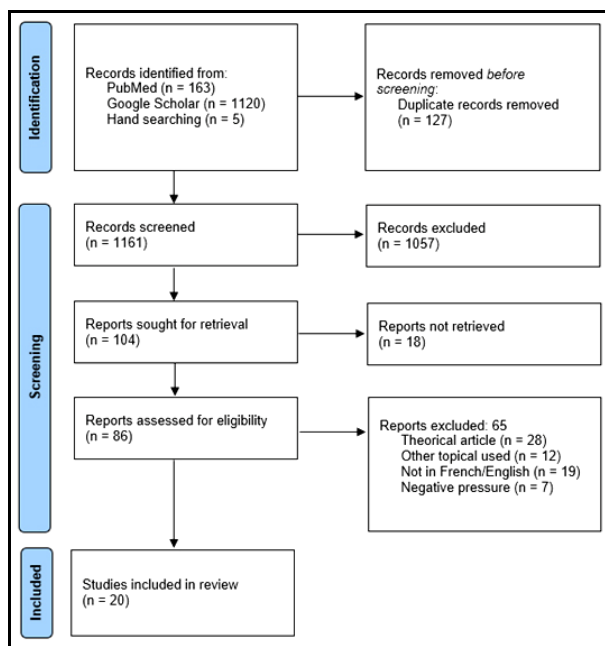


Fig 1. PRISMA flowchart

lization, toxicity of the therapeutic agents, complications, mortality and its causes. Results were grouped on the basis of escharotic agents.

## RESULTS

This review included 20 studies including 485 patients.<sup>(9,11-29)</sup> Table 1 summarizes the treatment details of various agents. Discharge criteria were not stated in 9 studies.<sup>(9,14,16,22,23,25-28)</sup> When stated, discharge criteria were based on patient stability (absence of life-threatening associated malformations or need of mechanical ventilatory assistance),<sup>(13,15,17,18,20,21,24,29)</sup> nutritional independence (full enteral feeding with weight gain),<sup>(15,17-21,24,29)</sup> and assurance of good home-care of the sac (ability of parents to do dressing or evidence of sac epithelialization).<sup>(11,12,20,21,24)</sup> Details on the time to full oral feeds was not stated in 11 publications.<sup>(9,11-14,16,22,23,26,28,29)</sup> For the remaining papers, it varied according to the presence of life-threatening comorbidities. It ranged from 2 days to 45 weeks.<sup>(15,17-21,24,25,27)</sup>

The overall complication (128 patients) rate was 26.4% for all escharotic agents.<sup>(9,11-29)</sup> Sac related

complications (bacterial colonization, infection and rupture) occurred in 80 patients, gastrointestinal complications (ileus and gastro-jejunal perforations) in 42, and drug-related toxicity (especially iodine and silver) in 4 cases.<sup>(Table 2)</sup> Mortality was reported in 114 patients (23.5%) <sup>(Table 3)</sup>

## DISCUSSION

The sac of omphalocele constituted of the outer amnion, the intermediate Wharton's jelly and the inner peritoneum. Conservative management with topical agents aims to transform the sac into a ventral hernia through progressive epithelialization of the amnion layer.<sup>(4)</sup> This procedure has evolved ever since its first description in 1899 by Ahlfeld.<sup>(30)</sup> Nowadays, several escharotic agents have been proven to be safe. However, some may not be easily available or affordable in resource-constrained areas, where omphalocele still has high mortality.<sup>(6)</sup>

Compared to surgical repairs, conservative treatment of giant omphalocele has the advantages of early full enteral feeding, lower need for ventilatory support, and shorter hospital stay.<sup>(31,32)</sup> This perfectly suits the resource-limited settings where parenteral nutrition and artificial respirators are often not available.<sup>(6)</sup> Furthermore, non-operative management has lower morbidity and mortality than surgical repairs.<sup>(31,32)</sup>

Concerning the preparation of different topical agents, there is considerable scope for improvement by standardizing their concentration. Many authors<sup>(10,12)</sup> used DE, PI and AN paste without dilution, while others<sup>(11)</sup> diluted it. Considerable variations were also noted in the frequency of application. Standardization of the concentration and frequency of application of a given topical agent would allow future multicentric studies, thus contributing to better understanding of its therapeutic role.

Table 1. Use of topical escharotic agents in omphalocele

Escharotic agent	Year	n	Preparation Strength	Application frequency	Protective Dressing of the sac	Hospital stay (days)	Time to full feeds (weeks)
<b>Disodium eosin</b>							
Ngom <sup>(9)</sup>	2004	50	2% aq.sol	BID	NR	NR	NR
Andriamanarivo <sup>(14)</sup>	2012	10	2% aq.sol	BID	GD	7 - 18	11 - 14
Kouame <sup>(12)</sup>	2014	173	2% aq.sol	BID	NR	21 ± 6	10 ± 1
Habou <sup>(13)</sup>	2017	13	2% aq.sol	QAD	GD+EB	4 - 17	6 - 11
Kasanga <sup>(11)</sup>	2021	3	2% aq.sol in 500ml NS	TID	NR	30 - 33	8 - 13
<b>Povidone-iodine</b>							
Whitehouse <sup>(15)</sup>	2010	6	1–2.5% aq.sol	OD / QAD	GD + Brace	7 - 111	12 - 24
Pandey <sup>(17)</sup>	2014	24	10% aq.sol	BID	Suspension+ Sand bags	14 ± 3	NR
Eltayeb <sup>(18)</sup>	2015	12	5% aq.sol	BID	None	19 ± 13	7 ± 6
Malhotra <sup>(16)</sup>	2016	1	5% aq.sol	OD	GD	LFU	LFU
Rattan <sup>(19)</sup>	2020	27	NR	OD / QAD	GD	18 ± 3	10 ± 2
<b>Silver sulfadiazine</b>							
Lee <sup>(24)</sup>	2006	15	1% cream	OD	GD + EB	5 - 239	NR
Lewis <sup>(26)</sup>	2010	2	1% cream	OD	GD + EB	LFU	LFU
Ein <sup>(25)</sup>	2012	20	1% cream	OD	NR	NR	20
Echendu <sup>(27)</sup>	2021	1	1% cream	OD	GD + EB	14	16
<b>Honey</b>							
Nicoara <sup>(21)</sup>	2014	5	MHG	QAD / QW	GD + EB	21 - 121	7 - 17
Ekot <sup>(23)</sup>	2017	1	Natural honey	OD	GD+ EB	14	6
Bode <sup>(20)</sup>	2018	25	Natural honey	OD	Insect net	NR	4 - 6
Lawrence <sup>(22)</sup>	2021	24	MHG	QAD / BI7D	GD + EB	7 - 66	4 - 28
<b>Gentian violet</b>							
Mitul <sup>(28)</sup>	2012	27	1% aq.sol	BID	None	21 - 28	4 - 6
<b>Acacia nilotica paste</b>							
Moustafa <sup>(29)</sup>	2005	35	25mg AN in 15ml GV	BID	None	5 - 15	6 - 8
Eltayeb <sup>(18)</sup>	2015	12	1mg AN in 1 ml GV	BID	None	16 ± 8	8 ± 5

AN - *Acacia nilotica*; aq.sol - Aqueous solution; BI7D - Bis in 7 die (twice weekly); BID - Bis in die (twice a day); EB - Elastic bandage; GD - Gauze dressing; GV - Gentian violet; LFU - Lost to follow-up; MHG - Medical grade honey gel; NR - Not reported; NS - Normal saline; OD - Omne in die (Once daily); QAD - Quaque altera die (every other day); QW - Quaque week (Once weekly); TID - Ter in die (thrice a day)

Table 2. Complications of non-operative management of omphalocele

Topical Agent	Ref.	n	Complications n (%)	Mortality n (%)
<b>Disodium eosin</b>	(9,11–14)	249	Ileus 40 (16 %) Sac infection 38 (15 %)	64 (26 %)
<b>Povidone iodine</b>	(15–19)	70	Iodine intoxication 2 (2.8%) Sac infection/sepsis 3 (4%) Sac rupture 2 (2.8%)	19 (27%)
<b>Silver sulfadiazine</b>	(24–27)	38	Blood silver elevation 2 (5%) Sac infection/sepsis 6 (16%) Sac rupture 5 (13%) Multiple* 1 (2.6%)	7 (18 %)
<b>Honey</b>	(20–23)	55	Sac bacterial colonization 15 (27%) Sac infection/sepsis 3 (5.4%) Sac rupture 1 (1.8%)	12 (22 %)
<b>Gentian violet</b>	(28)	27	Sac rupture 3 (11%)	4 (15 %)
<b>Acacia nilotica paste</b>	(18,29)	47	Sac infection 2 (4%) Sac rupture 2 (4%)	8 (17%)

\* Includes gastric necrosis, jejunal perforation, acute kidney injury and aspiration pneumonia

Table 3. Mortality of omphalocele treated with various topical agents

	DE (n=249)	PI (n=70)	SSD (n=38)	Honey (n=55)	GV (n=27)	AN paste (n=47)
Mortality (n)	64	19	7	12	4	8
<b>Causes of death</b>						
Sepsis	47 (73%)	5 (26%)	1 (14%)	2 (17%)	-	3 (38%)
Unspecified associated malformation	5 (8%)	-	-	-	-	5 (63%)
Cardiovascular failure	2 (3%)	2 (3%)	-	5 (42%)	4 (100%)	-
Respiratory failure	1 (2%)	5 (26%)	6 (86%)	2 (17%)	-	-
Unspecified complications	9 (14%)	7 (37%)	-	-	-	-
Others*	-	-	-	3 (25%)	-	-

\* Includes sac rupture, multi-organ failure and care withdrawal

AN: *Acacia nilotica*, DE: *Disodium eosin*, GV: *Gentian violet*, PI: *Povidone iodine*, SSD: *Silver sulfadiazine*

Several studies have mixed-up the therapeutic agents, making analytical interpretation difficult. For example, AN paste has been shown to be a useful escharotic agent with same efficiency as that of topical honey application.<sup>(18)</sup> However, AN

powder had been dissolved in GV, which by itself is a well-established topical agent.<sup>(28)</sup> Therefore, it would not be possible to tell if the therapeutic effect of the AN paste is due to GV, AN, or both. Independent pharmacological role of AN can be

evaluated only if it is dissolved in normal saline rather than GV. After detailed analysis of the literature, we propose a scheme of therapeutic standardization for each topical agent. If this is followed in future reporting, a meaningful meta-analysis is possible.

The application of supporting elastic bandage varied indifferent studies. Dressing with elastic bandage would prevent rupturing of the sac which is associated with poor prognosis.<sup>(8)</sup> Therefore, its application from the commencement of treatment would reduce the risks of sac rupture. This application should be soft and not attempting to reduce the omphalocele contents. Such forced bandage of may lead to either rupture of the sac or abdominal compartmental syndrome. With epithelialization, sac rupture is unlikely to occur. Therefore, the objective of the elastic bandage is to achieve partial reduction of the omphalocele content and restrain enlargement of the ventral hernia by providing counter-resistance to intra-abdominal pressure. Elastic bandage will facilitate increasing intra-abdominal capacity and will reduce the need for mesh while repairing the resultant ventral hernia.<sup>(33)</sup> We believe that application of elastic bandage should be continued until the surgical closure of the ventral hernia.

The use of escharotic agents has the potential risk of toxicity. Some of the agents are well proven to be safe. These include DE, honey, GV and AN paste. DE is non-absorbable and hence of low toxicity potential.<sup>(14,34)</sup> Although increased risks of hepatocellular carcinoma and thyroid tumors have been reported in mice fed with GV<sup>(35)</sup>, it is generally considered safe in humans. There are no reports of GV-linked cancer in human beings.<sup>(35)</sup> Transient hypothyroidism due to the Wolff-Chaikoff effect is the most feared toxicity of PI. Therefore, a regular estimation of thyroxin levels is mandatory while using PI in omphalocele. Thyroid function tests done prior to the starting of PI treatment will differentiate drug-induced thyroid deficiency from

congenital hypothyroidism. The frequency of routine thyroxin estimation suggested by different authors varies from 7 to 14 days.<sup>(15,17,18)</sup> In transient hypothyroidism, PI treatment may be continued with periodic monitoring of thyroxin.<sup>(15)</sup> Malhotra<sup>(16)</sup> reported symptomatic thyrotoxicosis after 3 days of using 10% PI in a premature newborn. Based on the study of Pandey,<sup>(17)</sup> serum thyroxin estimation once in 10 days seems to be appropriate, considering its affordability in LMIC. However, in symptomatic patients, thyroxin estimation should be done daily.<sup>(16)</sup> Extreme caution should be exercised when using PI in preterm neonates, because of immature Wolff-Chaikoff effect (auto-regulatory iodine-induced inhibition of thyroxin synthesis and release), easy absorption of iodine through the neonatal skin, immaturity of the thyroid gland and impaired renal clearance of iodine.<sup>(36)</sup> As a result of this, thyrotoxicosis may occur with PI treatment in pre-term babies.<sup>(16)</sup> The major complication of all silver-containing topical agents is due to systemic absorption of the silver. Although SSD is extensively used in the clinical practice, blood silver levels are seldom estimated. Lewis recorded elevated blood silver levels on day 21 and 22 respectively in 2 patients; however, they were clinically asymptomatic.<sup>(26)</sup> This raises a question of safety on the usage of SSD in the conservative management of omphalocele. Well designed large sample studies are required to evaluate the safety of SSD.

Sac infection was common when a dressing was used to cover the sac as it is with DE and SSD. Absolute asepsis should be observed in performing these dressings. The use of GV was not associated with infectious complications; this may be due to the dark colour of GV masking subtle infection. It is also possible that GV has excellent antibacterial property as compared to other substances. Rupture of the sac was the second most common complication. In patients with protective dressing, the rupture may be secondary to an infection that digests the epithelialized sac. In the

absence of protective dressings, rupture is often due to a mechanical injury.

Mortality appears to be increased with protective dressing (e.g. DE, PI, and honey) as compared to open dressing (e.g. GV and AN paste). It is possible that the large studies had more patients with co-existing malformations, which is a well-known cause of mortality in omphalocele.

Table 4. Suggested standardization of topical therapy of omphalocele

Topical agent	Suggested strength of preparation	Suggested frequency of application
Disodium eosin <sup>(12)</sup>	2% aq.sol	Twice daily
Povidone iodine <sup>(30)*</sup>	5% aq.sol	Twice daily
Silver sulfadiazine <sup>(14)</sup>	1% cream	Daily
Honey <sup>(16)</sup>	Natural honey	Daily
Gentian violet <sup>(22)</sup>	1% aq.sol	Twice daily
<i>Acacia nilotica</i> <sup>(24)</sup>	25g of AN in 15 ml of Gentian violet	Twice daily

\* Should be used with caution in preterm

It would be interesting to study the comparative efficacy of different escharotic agents in the management of omphalocele. To facilitate future comparison, usage of each topical agent should be standardized. Reporting should also be uniform. Crucial data are often missing from some of the published reports. To allow future comparison of different escharotics, we suggest that each report must include the following data: (a) a description of associated malformations, (b) full information of the topical agent including its nature, concentration and frequency of application, (c) the use of an elastic bandage or another supportive dressing, (d) information about enteral feeding including starting time, tolerance and time to full feeding,

(e) discharge criteria and length of hospital stay, (f) estimation of blood levels of the topical agents used (especially mandatory for PI and SSD), (g) time to epithelialization, (h) complications and their management, (i) results of swab and blood culture to diagnose infection, (j) age at mortality, (k) cause of death, and (l) timing of surgical repair of the ventral hernia.

During this review, some topical agents were not considered due to their questionable efficiency (e.g. normal saline) or due to a higher toxicity rate (e.g. ethanol). Recently, drowsiness which is a sign of alcohol intoxication has been reported in all neonates treated with topical ethanol.<sup>(37)</sup> As it may affect the brain development and pose a risk of apnea, we do not consider it safe. Animal studies have also shown abnormal brain development in mice with neonatal ethanol intoxication.<sup>(38,39)</sup>

CONCLUSION

Several escharotic agents are used in resource-constrained settings and they are valuable therapeutic arsenal in the conservative management of omphalocele. But a meaningful comparison of various agents is precluded by lack of standardized treatment and uniform reporting.

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## APPENDIX

### Search strategy for PubMed

Using MeSH and the following syntax

((Omphalocele OR Exomphalos) AND

(Conservative OR Delayed) AND Management))

### Search strategy for Google Scholar

'Advanced' option was used, with the following syntax:

- in "with all the words": Omphalocele
- in "with at least one of the words": Omphalocele, Exomphalos, Delayed; Conservative, Management
- in "where my words occur"
- in the title of the article

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