

# Management of umbilical granuloma in infants

## *A systematic review of randomised controlled trials*

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### Background and objective

Umbilical granuloma is a common condition in infants. The aim of this study was to systematically review randomised controlled trials (RCTs) of topical treatment options for umbilical granuloma.

### Methods

PubMed, Embase, Cochrane Library, Google Scholar and grey literature were searched in September 2020.

### Results

Eleven RCTs (n = 890) that studied the use of silver nitrate, topical steroids, ethanol wipes, electrocautery, cryocautery, copper sulphate and common salt were included. Common salt achieved resolution in >90% of cases in five studies and 54–80% in two studies. Topical steroids, silver nitrate, copper sulphate and cryocautery achieved resolution in >90% and ethanol wipes in 50–65% of cases. Local side effects reported with topical steroids, silver nitrate, cryocautery and electrocautery varied in each study. Salt application did not cause side effects. The risk of bias was high in many RCTs.

### Discussion

While the majority of the interventions were effective in treating umbilical granuloma, salt application appears to be simple and effective, with minimal complications.

**UMBILICAL GRANULOMA** is a common benign condition that presents in infancy.<sup>1</sup>

It is usually noticed as a mass of red, friable granulation tissue at the base of the umbilical stump after the cord separates in the first few days after birth. While congenital conditions, such as patent urachus and persistent vitello intestinal duct, can mimic umbilical granuloma, they present with discharge of urine or faeces from the umbilicus.<sup>1</sup> The incidence of umbilical granuloma is not known, as it has not been the focus of major epidemiological studies.<sup>1</sup> Currently, there is no clear consensus on the treatment modality of umbilical granuloma. The various options that have been tried include expectant management, topical application of common salt, silver nitrate, copper sulphate, alcohol wipes, cryocautery, electrocautery and topical glucocorticoids. The researchers conducted this systematic review to summarise the current evidence from randomised controlled trials (RCTs) in the management of umbilical granuloma.

### Methods

A systematic review of RCTs was conducted using guidelines from the *Cochrane handbook for systematic review of interventions* and PRISMA (Preferred

Reporting Items for Systematic Review and Meta-Analyses) statements.<sup>2,3</sup> As only published articles were reviewed, ethics committee approval was not necessary.

### Eligibility criteria

#### Types of studies

Only RCTs and quasi-RCTs were eligible for inclusion. Case series, case control studies, cohort studies, commentaries and studies without a control population were excluded.

#### Inclusion and exclusion criteria

Studies that evaluated treatment of umbilical granuloma in infants were included. Studies that addressed the management of infants with surgical conditions that mimic umbilical granuloma, such as patent urachus or vitello-intestinal duct, were not included.

#### Intervention and comparison

Studies that compared topical agents, such as silver nitrate, common salt, electrocautery, copper sulphate, alcohol wipes and topical steroids, with each other or versus placebo/conservative management were included.

#### Outcomes

The outcomes were the resolution of umbilical granuloma and local or systemic adverse effects.

### Search strategy

PubMed (from 1966 to September 2020), Embase (from 1980 to September 2020), Cochrane Central Register of Controlled Trials (from June 1980 to September 2020) and Emcare databases (from 1980 to September 2020) were searched. Grey literature was searched using OpenGrey, Mednar and Trove. The reference lists of eligible studies and review articles were searched to identify additional studies. Both reviewers conducted the literature search independently.

### Search details

The following Mesh terms were used for searching PubMed: 'umbilicus' AND 'granuloma', with 'clinical trial' and 'RCT' applied as limits. PubMed was also searched using the keyword 'umbilical granuloma'. Embase was searched using the following terms: 'exp granuloma' and 'exp umbilicus' OR 'umbilical granuloma.mp'. No language restrictions were applied. Similar terms were used while searching other databases. The search was repeated in Google Scholar using the keyword 'umbilical granuloma'.

### Study selection

Titles and abstracts of the citations identified during the initial search were reviewed by both authors independently. Full-text articles of the selected studies were obtained and assessed for inclusion independently by the two reviewers. If multiple articles were published from the same study, care was taken to avoid duplicate data.

Methodological quality of included studies was assessed using the Cochrane risk of bias assessment tool. Grading of evidence was done using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, which comprised key information on the sample size, magnitude and precision of effect of the intervention, risk of bias, directness of evidence and consistency of results.<sup>4</sup>

## Results

The initial broad search of literature identified 878 citations, of which 11

RCTs were included in the review.<sup>5-13</sup>

The selection log is presented in Figure 1.

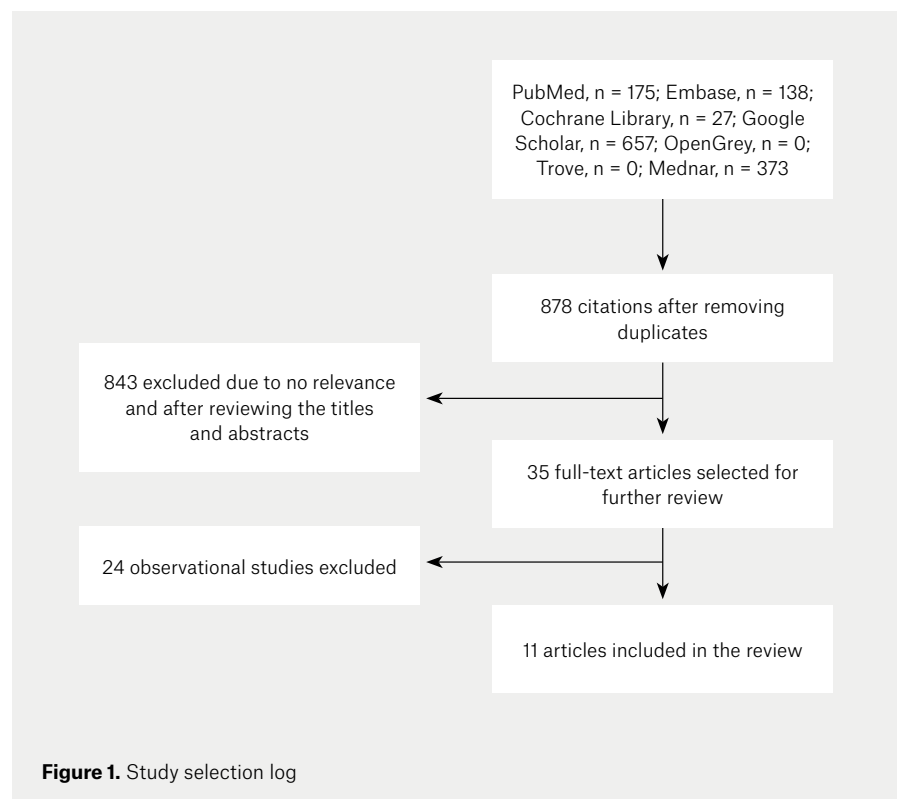
The interventions in individual studies were as follows: clobetasol propionate versus silver nitrate or ethanol wipes (n = 109),<sup>7</sup> betamethasone versus silver nitrate (n = 207),<sup>8</sup> silver nitrate versus cryocautery or electrocautery (n = 75),<sup>5</sup> silver nitrate versus ethanol (n = 40),<sup>6</sup> copper sulphate versus salt (two studies, n = 144),<sup>14,15</sup> salt versus no intervention (n = 60),<sup>9</sup> two-hour versus 24-hour application of salt (n = 40),<sup>11</sup> salt versus ethanol (n = 105),<sup>12</sup> 10-minute versus 30-minute application of salt (n = 60)<sup>10</sup> and salt versus electrocautery (n = 50).<sup>13</sup>

The study details and risk of bias assessment are presented in Appendix 1 (available online only) and Table 1.

In a UK study, Daniels et al compared silver nitrate cauterisation with conservative treatment with the use of alcohol wipes at each nappy change.<sup>6</sup> A total of 40 patients were approached to be included in the study, but the majority chose conservative management, rather than being randomised. The authors

reported that two-thirds of the granulomas resolved with alcohol wipes and did not require silver nitrate cauterisation.<sup>6</sup> The methodological evaluation of the study identified high or unclear risk of bias in all domains.

Sheth and Malpani conducted a prospective clinical trial on 75 infants in India with umbilical granuloma, comparing the efficacy of cryotherapy using nitrous oxide with electrocautery or silver nitrate application.<sup>5</sup> At one week, all granulomas had healed in the cryocautery group and no patient required second application. One patient experienced foul-smelling discharge after cryocautery. In infants who underwent electrocautery, multiple applications were needed in four patients (16%), and six (24%) experienced foul-smelling discharge. In the silver nitrate group, multiple applications were needed in five infants (20%), and 12% experienced foul-smelling discharge. The authors concluded that cryocautery yielded the best results.<sup>5</sup> The methodological assessment identified high or unclear risk of bias in all domains.



**Table 1. Risk of bias in the included studies**

Study	Random-sequence generation	Allocation concealment	Blinding of participants and personnel*	Blinding of outcome assessment*	Incomplete outcome data	Selective reporting
Daniels et al <sup>6</sup>	Unclear	Unclear	Unclear	Unclear	High	High
Sheth and Malpani <sup>5</sup>	Unclear	Unclear	Unclear	Unclear	High	High
Ogawa et al <sup>8</sup>	Low	Low	High	High	Low	Low
Brødsgaard et al <sup>7</sup>	Low	Unclear	High	High	Low	Low
Farhat and Mohammadzadeh <sup>11</sup>	Unclear	Unclear	High	High	Low	Low
Golshan et al <sup>9</sup>	Low	Unclear	High	Unclear	Low	Low
Kavthekar et al <sup>10</sup>	Unclear	Unclear	Unclear	Unclear	Low	Low
Faranoush et al <sup>12</sup>	Unclear	Unclear	Unclear	Unclear	Low	Low
Badebarin et al <sup>13</sup>	Low	Low	Unclear	Unclear	Low	Low
Annapurna and Ramu <sup>14</sup>	Unclear	Unclear	Unclear	Unclear	Low	Low
Fiaz et al <sup>15</sup>	Unclear	Unclear	Unclear	Unclear	Low	Low

\*Given the nature of the intervention, blinding could not be achieved  
RCT, randomised controlled trial; SD, standard deviation

Ogawa et al conducted a multicentre non-inferiority trial in Japan involving 207 infants, comparing the efficacy of once-a-week application of silver nitrate (n = 104) versus twice daily topical application of 0.12% betamethasone valerate (n = 103).<sup>8</sup> The non-inferiority margin for topical steroids was set to within 10% of the efficacy observed with silver nitrate. All cases were reviewed at one, two and three weeks. At the end of one week of treatment, 57 of 104 (54%) patients in the silver nitrate group and 53 of 100 (53%) patients in the steroid group had successful resolution of umbilical granuloma. After three weeks of treatment, 94 of 104 (90%) patients in the silver nitrate group and 91 of 100 (91%) patients in the steroid group had successful resolution of umbilical granuloma. Therefore, the authors concluded that topical steroid therapy is not inferior to silver nitrate application in neonates with umbilical granuloma. The authors also reported that no major adverse events occurred during treatment in either group.<sup>8</sup> The methodology assessment identified low risk of bias for the domains

of random-sequence generation, allocation concealment, incomplete outcome data and selective reporting.

In a Danish study, Brødsgaard et al conducted an RCT comparing the efficacy of 0.05% topical clobetasol propionate (n = 33) with ethanol wipes (n = 44) or topical silver nitrate (n = 32).<sup>7</sup> Clobetasol was applied twice daily at home by parents, and silver nitrate was applied twice weekly by a nurse in the clinic. Ethanol wipes were used at each nappy change at home by parents. All infants were reviewed twice per week at the clinic, with a photograph taken at each visit. The mean healing times were 12.9 (standard deviation [SD]: 7.7) days in the silver nitrate group, 17.4 (SD: 8.7) days with topical steroids and 27 (SD: 11) days with ethanol wipes ( $P < 0.0001$ ). After 30 days, 29 of 30 (96%) patients in the silver nitrate group, 27 of 30 (90%) patients in the topical steroid group and 18 of 34 (53%) patients in the ethanol wipes group showed resolution of umbilical granuloma. The difference in healing between topical steroids and silver nitrate was not statistically

significant. However, at 30 days, the rate of complete resolution was higher for the silver nitrate group compared with the other two groups. Three infants (10%) in the silver nitrate group developed mild redness and excoriation of the skin, and six infants (20%) in the topical steroid group experienced mild and self-resolving skin hypopigmentation and atrophy. No side effects were observed in the ethanol wipes group. Three infants from the topical steroid group and 11 from the ethanol group were treated with silver nitrate as a result of no clinical improvement. Two patients from the ethanol group underwent surgical ligation.<sup>7</sup> Methodological assessment identified low risk of bias for the domain of random-sequence generation, incomplete outcome data and selective reporting.

Golshan et al conducted a parallel single-blinded randomised trial in Iran to compare the application of salt powder versus no intervention in 60 infants.<sup>9</sup> Salt powder was applied for 30 minutes twice daily for five days. Complete resolution of umbilical granuloma occurred in all infants treated with salt powder, but

only in four infants in the control group ( $P = 0.00$ ). They concluded that salt application was beneficial and had no complications. Methodological assessment identified low risk of bias for the domain of random-sequence generation, incomplete outcome data and selective reporting.

Faranoush et al conducted a clinical trial in Iran comparing common salt versus alcohol in 105 infants with umbilical granuloma.<sup>12</sup> The first group received salt application for three days (once every 12 hours) and the second group was treated with 70% alcohol twice daily (0.5 mL each time). In the third group (control), the umbilicus was washed with pure water twice daily (0.5 mL each time). Umbilical granuloma healing occurred in 100% of patients in the common salt group, 34.3% of patients in the alcohol group and 14.3% of patients in the pure water group after three days of treatment ( $P = 0.0000$ ). There was no recurrence among infants treated with common salt. If there was recurrence/no resolution in infants in the other two groups, they were successfully treated with common salt. Follow up for two months in infants treated with common salt was indicative of no recurrence. No complications were observed due to the application of common salt. The risk of bias was considered to be 'unclear' for many of the domains because of the paucity of methodological details in the published study.

In an Iranian clinical trial, Farhat and Mohammadzadeh compared two-hour application ( $n = 20$ ) with 24-hour application ( $n = 20$ ) of salt in infants with umbilical granuloma.<sup>11</sup> Treatment was continued until complete healing. Successful resolution occurred in both groups, with no recurrences or complications. The number of applications was  $1.2 \pm 0.5$  for the 24-hour treatment group and  $2.1 \pm 0.4$  for the two-hour group ( $P < 0.001$ ). They concluded that 24-hour salt treatment was more effective than two-hour treatment. Methodological assessment identified high risk of bias in many domains.

In India, Kavthekar et al conducted a quasi-RCT comparing the effect of short application time (10 minutes,  $n = 30$ ) with

long application time (30 minutes,  $n = 30$ ) of common salt to infants with umbilical granuloma.<sup>10</sup> Parents were asked to apply a pinch of salt over the umbilical granuloma twice daily for seven days. Before and after the salt applications, the site was cleaned with a cotton ball soaked in cold boiled water. After salt application, the area was covered with adhesive tape for 10 minutes in group A and 30 minutes in group B. Infants were evaluated after one and three weeks. Therapeutic total response was noted in 28 (93.33%) infants from group A and 29 (96.66%) from group B. Partial response was seen in two (6.67%) infants in group A and one (3.34%) infant in group B. The authors concluded that common salt could be used for just 10 minutes twice daily for seven days for infants with umbilical granuloma. The risk of bias was considered to be 'unclear' in many domains due to the paucity of methodological details in the published study.

In an Iranian clinical trial, Badebarin et al compared 25 infants treated with sterile salt with 25 infants who underwent electrocautery under general anaesthesia.<sup>13</sup> Infants were followed for three months. The cure rate in the salt group was 96% versus 100% in the electrocautery group ( $P = 1.000$ ). No relapse or side effects were seen in both groups. Methodological assessment identified low risk of bias for the domain of random-sequence generation, incomplete outcome data and selective reporting.

Annappurna and Ramu from India compared the application of copper sulphate with common salt in 98 infants with umbilical granuloma.<sup>14</sup> Two infants were excluded because of congenital heart disease and 12 were excluded because of lack of follow up. Therefore, the study included a total of 84 infants. The infants were divided into two groups (copper sulphate,  $n = 44$ ; common salt,  $n = 40$ ). The treatment consisted of the application of common salt on the umbilical granuloma twice daily, washed 30 minutes later and repeated for three days. Parents of the common salt group were given instructions to treat their infants at home twice daily for three days, but the clinicians applied copper sulphate

on the umbilical granuloma. They reported that 42 of 44 cases had resolution after a single application of copper sulphate versus 32 of 40 in the salt group. They concluded that copper sulphate application is simple, cost-effective, curative, safe and superior to common salt.<sup>14</sup> The risk of bias was considered to be 'unclear' in many domains because of the paucity of methodological details in the published study.

Fiaz et al from Pakistan conducted a comparative experimental study of 60 infants with umbilical granuloma.<sup>15</sup> Infants were allocated to receive copper sulphate or common salt after parental consent by lottery method. Excellent response was observed in the copper sulphate group (100% versus 53.3%,  $P < 0.05$ ).<sup>15</sup> The risk of bias was considered to be 'unclear' in many domains because of the paucity of methodological details in the published study.

The overall GRADE of evidence was considered low, given the low sample size, and unclear or high risk of bias in many domains for the majority of the included studies.

## Discussion

The results of this systematic review, which included 890 infants from 11 RCTs, indicate that most of the topical interventions are effective in treating umbilical granuloma.

Common salt application was evaluated in seven RCTs and found to be effective in treating umbilical granuloma, with no side effects. In addition to the RCTs, many observational studies involving approximately 1000 infants have reported a high level of success (>90%) with the use of common salt, which is also associated with lower cost and complication rates.<sup>16-23</sup> Therefore, common salt could be used as the first option to treat infants with umbilical granuloma. Many centres in the UK recommend the use of common salt twice daily for two days as the first-line therapy of umbilical granulomas.<sup>24</sup>

While both RCTs on topical steroids reported excellent resolution of the umbilical granuloma,<sup>7,8</sup> it is important to note that clobetasol is an ultra-high

potency steroid and betamethasone is a high-potency steroid.<sup>25</sup> Application of these potent steroids for 3–4 weeks on highly vascular granulomatous tissue may result in systemic absorption and suppression of the hypothalamic–pituitary–adrenal (HPA) axis;<sup>26</sup> local side effects, such as skin hypopigmentation and atrophy; and infections. Both RCTs reported that no major adverse effects were noted with the use of steroids; however, the effects on the HPA axis were not analysed/reported. Therefore, it is prudent to avoid the use of potent steroids as first-line treatment for a benign condition, such as umbilical granuloma, when other simple and effective strategies are available.

Silver nitrate and copper sulphate were found to be efficacious in treating umbilical granuloma in the included studies, but there are case reports of burning of the surrounding skin with their application,<sup>6,27</sup> and therefore, will need to be cautiously applied by experienced clinicians. The use of petroleum jelly or liquid paraffin to protect the surrounding skin during their application may be beneficial. Their application may also need more than one visit to the clinic.

Ethanol wipes had the lowest healing rates, and therefore could be considered inferior to other options.<sup>7,12</sup>

While efficacious, cryocautery needs cryogenic nitrous oxide as a refrigerant and sophisticated equipment. Hence it is a less preferable option to treat umbilical granuloma. Electrocautery was associated with foul-smelling discharge in a significant proportion of infants in one study, which can be mistaken with local infection. Both cryocautery and electrocautery carry the potential risk of burns to the surrounding skin, and therefore, caution is needed while using them.

In Australia, the recommended treatment for umbilical granuloma is variable. The Royal Children's Hospital Melbourne recommends the application of silver nitrate three times daily, protecting the surrounding area with Vaseline and referral to a surgical clinic if no improvement is noticed in one week.<sup>28</sup> Perth Children's Hospital recommends

expectant treatment and the use of silver nitrate, if parents insist, whereas Sydney Children's Hospitals Network recommends expectant management alone.<sup>29</sup> The results of this systematic review will enable the creation of uniform evidence-based guidelines to treat umbilical granuloma.

An important strength of this review is its comprehensive nature and the inclusion of many studies that were not published in indexed journals. An important limitation was that the majority of the included studies had high or unclear risk of bias in many domains.

In conclusion, while the majority of the interventions are effective in treating umbilical granuloma, salt application appears to be a simple and effective option, with minimal complications.

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