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ORIGINAL ARTICLE

Effect of Common Salt in the Management of Umbilical Granuloma in Infants Compared to Copper Sulphate

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Abstract

Background: *Umbilical granuloma (UG) is the most frequent umbilical abnormality in infants with a prevalence of 1 in 500. It is a benign overgrowth of granulation tissue due to continued inflammation after the cord separation. Persistent UG causes infection, oozing, discharge and irritation if not treated on time. Chemical cauterization with copper sulphate is commonly used that causes periumbilical burn and irritation leads to find out an alternative method.*

Objectives: *To observe the outcome of topical application of common salt in comparison with application of copper sulphate in the treatment of UG.*

Methods: *This randomized controlled trial was conducted in the Faculty of Pediatric Surgery, Bangladesh Shishu Hospital and Institute from June 2020 to July 2022. A total of 150 patients clinically diagnosed as UG attending outpatient department during the study period (June 2020 to July 2022) were enrolled and randomly selected into two groups. In Group A (n=75) patients were treated with common salt and Group B (n=75) patients were treated with copper sulphate.*

Results: *The mean age was 9.88±9.37 weeks in Group A and 10.49±9.31 weeks in Group B. Maximum patients 57.7% and 53.3% were 2-8 weeks of age in Group A and Group B respectively. At the end of 28 days follow up 70 (93.3%) patients had complete resolution in Group A and 73 (97.3%) in Group B. The difference was not statistically significant ($p>0.05$). The side effects such as local irritation was found 3(4%) in Group A and 11(14.7%) in Group B. This difference was statistically significant between two groups ($p<0.05$).*

Conclusion: *Application of common salt is simple, effective and can be applied at home safely by parents and more convenient than application of copper sulphate in the treatment of UG.*

Keywords: *Common salt, copper sulphate, umbilical granuloma.*

Introduction

Umbilical granuloma (UG) is the most frequent umbilical abnormality in neonate, with a prevalence of 1 in 500.[1] It is a moist, fleshy, friable and pink granulation tissue at the center of umbilicus. UG becomes apparent after the umbilical cord dried and sheds off. It is a benign condition represents continuing inflammation of granulation tissue that has not yet epithelialized.[2]

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The exact cause of UG is unknown.[3] The umbilical cord usually dries and separates within 7-10 days after birth and is covered with a thin layer of granulation tissue. Granulation tissue formation is a normal stage in wound healing process. This normal granulation tissue of the resolving umbilical stamp of a newborn epithelialized within 2nd or 3rd week of life.[4] Failure of epithelialization of this left over granulation tissue leads to formation of UG.[5]

The granuloma frequently secretes small amounts of fibrinous exudates causing peri –umbilical skin irritation but as it contains no nerves there is no sensation of pain unless complicated by infection.[6] However, presence of a mass in place of umbilical cord causes psychological distress in the parents and may result in infection, oozing, discharge and irritation if not treated in time. As there is no record of spontaneous resolution of UG in the literature, therapeutic intervention must be needed.[5]

At present the therapeutic options for UG are chemical cauterization with silver nitrate and copper sulphate, common salt application, topical steroid ointment, albuthyl, electric cauterization, cryocauterization, surgical excision and double ligature technique. When we consider the merits and demerits of the treatment options like electrocauterization and cryotherapy needs experienced health care provider at well-equipped health care centers, costly and skin discoloration may be seen. Surgical excision is costly and need to administer general anesthesia to the patient. Local steroid therapy is not recommended for routine use due to their local and systemic side effects. Double ligature which can be applied to only pedunculated UG.[7]

The conventional method is to do chemical cauterization with silver nitrate stick or solution and copper sulphate. These are not safe and when applied liberally can cause minor burn and irritation in periumbilical healthy skin.[3]

Whereas common salt application is not associated with the above said complications, easy to apply and cheap. For the first time in 1972, Schmitt described the role of common salt on UG. Its desiccant effect and other biological properties, high concentration of sodium ion in the area draws water out of cells thus results in shrinkage and necrosis of the wet granulation tissue without damaging normal tissue.[8] On the other hand, $CuSO_4$ has astringent/caustic effects. These effects are responsible for its therapeutic role, but adjacent healthy tissues may be damaged if copper sulphate is contacted.[9]

Considering safe and effective treatment of umbilical granuloma more recently common salt is gaining popularity than conventional method of chemical cauterization with copper sulphate. So it is necessary to compare the efficacy and safety of these two treatment options.

Materials and Methods

This was a randomized controlled trial took place in the Faculty of Paediatric Surgery, Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh. Study period was two years (July 2020 to June 2022). Patients with clinically evident umbilical granuloma who sought treatment in the Surgical Outpatient Department, Bangladesh Shishu Hospital and Institute during study period.

All patients with umbilical granuloma fulfilling the selection criteria (age between 2 weeks to 48 weeks with clinically diagnosed as UG) during the study period were included. We excluded omphalitis or umbilical sepsis. Informed and written consent was obtained from the parents or guardians of children. Then we divided these patient into two groups.

In group A we applying a small amount of common salt over the UG and covering the area with adhesive tapes for 30 min and cleaning the area with normal saline and repeated twice a day for 3 consecutive days (Fig.-1).

In group B copper sulphate applied once over the UG for 5-10 minutes. All infants were Follow up after 3 days (Fig.-2), 7 days and 28 days following the last application. During each follow up visit, complete resolution, recurrence and side effects such as wound infection and local irritation were noted.

The statistical analysis was conducted using SPSS (statistical package for social science) version 26 statistical software. The student's t-test was used to compare continuous variables. Pearson's Chi-square test was used to compare categorical variables. A P-value of <0.05 was considered significant.

Results

The mean age 9.88±9.7 weeks of Group A and 10.49±9.31 weeks of Group B. Maximum patients 57.7% and 53.3% age 2 weeks – 8 weeks in Group A and Group B respectively. No significant difference of age between two groups ($p>0.05$) (Table I). In Group A, 57.3% (43) patients were male and 42.7% (39) were female. In Group B 52.0% (32) patients were male and 48.0% (36) were female. Male: Female ratio in Group A, 1:3.1 and Group B,1.1:1. Chi-square test was done, No significant difference of gender distribution between two groups ($p>0.05$).

Table I
Comparison of age at presentation of the participants between two groups (n=150)

Age	Group A (n=75) No. (%)	Group B (n=75) No. (%)	p value
2 weeks - 8 weeks	44 (57.7%)	40 (53.3%)	
>8-16 weeks	23 (30.7%)	25 (33.3%)	0.688
>16-48 weeks	8 (10.7%)	10 (13.3%)	
Mean±SD (weeks)	9.88±9.37	10.49±9.31	

Table II
Comparison of complete resolution between two groups at the end of 3, 7 and 28 days (n=150)

	End of 3 days		End of 7 days		End of 28 days	
	Yes	No	Yes	No	Yes	No
Group A (n=75)	59	16	64	11	70	5
No. (%)	(78.7%)	(21.3%)	(85.3%)	(14.7%)	(93.3%)	(6.7%)
Group B (n=75)	67	8	70	5	73	2
No. (%)	(89.3%)	(10.7%)	(93.3%)	(6.7%)	(97.3%)	(2.7%)

Table-II showed comparison the number and percentage of complete regression at the end of 3rd day, 7th day and 28th day between two groups. Chi-square test was done and there was no significant difference of complete resolution between Group A and Group B. At the end of 28 days follow up, Local irritation 3(4.07%) was found in Group A and 11(14.7%) in Group B. Chi-square test was done and fond local irritation was significantly (0.025) lower in Group A compare to Group B (p=0.025).

There was no recurrence found in both groups at the end of 28 days follow up.

Fig.-1 *Common salt, umbilical granuloma, application and follow up after 3 days*

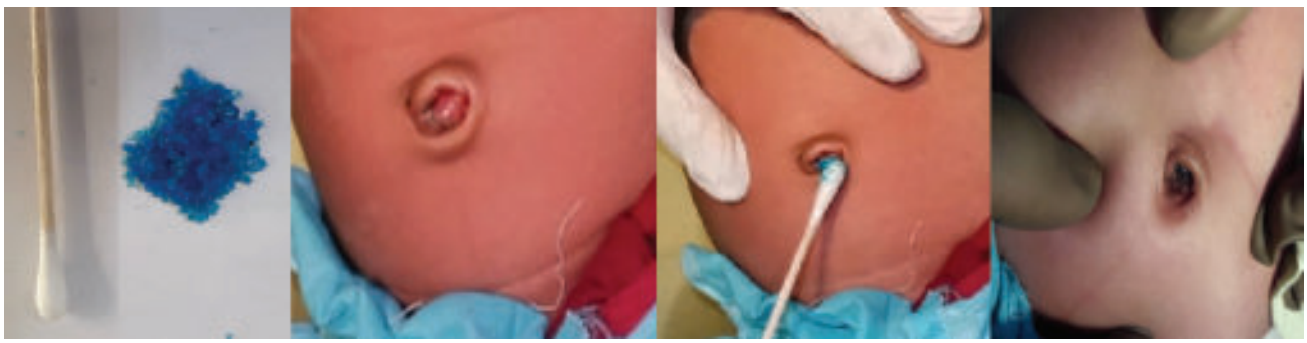

Fig.-2 *Copper sulphate, umbilical granuloma, application and follow up after 3 days*

Discussion

In pediatric practice, umbilical swelling and secretions are prevalent and can provide a diagnostic challenge. The most prevalent umbilical issue in babies is umbilical granuloma.[10] Chemical cauterization, electrocauterization, cryocauterization, and surgical excision are some of the treatment options for UG. Cauterization with silver nitrate and copper sulphate may result in a minor burn of the peri-umbilical skin area, which is painful; cryo-cautery is costly and complicated; foul discharge and failure rates were higher with electro-cautery; and surgical removal requires general anesthesia and is indicated in large size granuloma and recurrent/ intractable granulomas.

In this study total population was divided into two groups by block randomization, infants treated with common salt (Group A) and infants treated with copper sulphate (Group B). The mean age of Group A was 9.88±9.37 weeks and Group B was 10.49±9.31 weeks. Most of the patients age ranged from 2-8 weeks such as in Group A 44 (57.7%) and Group B 40 (53.3%) respectively. No significant difference of age between two groups (p=0.688). The studies from the subcontinent such as Annapurna and Ramu[3], Hossain, Hasan and Islam[8] showed that the age of study population ranged from 2 weeks to 16 weeks. Among them most of the patients age were below 2 months. Assi et al[6] from Iran showed that out of 125 study participants, 86 participants age were less than 2 months. Similarly, our study showed that the majority of patient with UG were under the age of 8 weeks. Children under the age of 2 months suffer more from UG than older children as UG is related to the umbilical cord separation which occurs few days after birth. So presence of UG, if detected immediately after that necessary corrective steps should be taken to treat it.

In group A, 43 (57.3%) patients were male and 32 (42.7%) were female. In group B, 39 (52.0%) patients were male and 36 (48.0%) were female (p=0.512). Slight male preponderance (M: F=1.21:1) was found in this study. This finding is consistent with the study of Annapurna and Ramu[3] and Chung et al[11]. But Saleh[5] and Halder et al[12] reported a higher prevalence of UG in female gender. In literature the incidence of umbilical granuloma is same in both male and female.[13]

There was no statistically significant difference noted of complete resolution between two groups. At the end of 3rd day 59 (78.7%) patients had complete resolution in common salt group and 67 (89.3%) in copper sulphate group (p=0.075). At the end of 7th day, complete resolution in common salt treated group was 64 (85.3%) as compared to copper sulphate group 70 (93.3%) (p=0.113) and at the end of 28 days 70 (93.3%) patients had complete resolution in common salt group and 73 (97.3%) patients in copper sulphate group (p=0.246). Similarly, Annapurna and Ramu[3] reported an excellent response with copper sulphate group 95.5% and slightly better response to the common salt group 55% at the end of 1st week and 80% at the end of 3rd week. Gupta and Mujalde[13] reported a high response rate 100% without recurrence in copper sulphate treatment. But Chung et al[11] reported complete resolution was higher in the table salt vs copper sulphate group [28/31 (90%) vs 23/33 (70%)]. On the other hand, while working on therapeutic effects of common salt in the treatment of UG, Hossain, Hasan and Islam[8] noted 91.67% excellent response rate in 3 days' course of treatment with table salt. In our study, after 3 days of common salt application, at 28 days follow up 70 (93.3%) patients had complete resolution and 5 (6.7%) patients had no response. We applied second cycle of common salt for 3 days in rest 5 infants and found complete resolution at the end of 1 week. This finding is consistent with the study of Singh et al[14], showed best result was obtained after 3 cycle treatment with common salt (96% cure rate). So, our study results suggested that as the duration of treatment with common salt is prolonged, the rate of recovery is improved. On the other hand, Hossain, Hasan and Islam[8] and some other studies were found a higher response to treatment with salt, while our present study, as well as Annapurna and Ramu[3] and some other studies found a relatively lower response to the treatment. It is possible that some conditions that appear to be UG might have been misdiagnosed. As Hossain, Hasan and Islam[8] suggested that diagnostic errors occur and this may delay the initiation of the proper treatment. However, as far as our study is concerned, no specific factors accounting for the low therapeutic effect of common salt are apparent at the time of the study, but suggest the need for further studies to evaluate why the use of common salt has been reported with different treatment efficacies in different studies. In case of

copper sulphate group, we tried a second application of copper sulphate in rest 2 infants who do not respond to first application and found complete resolution after 1 week. Similarly, Annapurna and Ramu[3] reported that 2 infants required a second application of copper sulphate for complete resolution in their study. Chung et al[11] also showed the similar response in one case.

In this study, local irritation was found 3 (4.0%) patients in Group A and 11 (14.7%) patients in Group B. This difference was statistically significant between two groups ($p<0.05$). This finding is consistent with the study of Chung et al.[11] who demonstrated that 3 patients suffered from superficial burns over the periumbilical skin in copper sulphate treated group but no complication was found in common salt group. Local irritation like skin excoriation in common salt group may be due to application of excess salt without proper cleaning the area and prolonged contact time. It was mild and resolved spontaneously within 2-3 days. Bagadia et al[15] also showed transient micro-vesiculation at the edges of the umbilicus at 24 h following salt application. Dhungel, Pokhrel and Acharya[16] also mentioned mild bluish discoloration of umbilicus after salt therapy. But in this study, find these type of side effects was not found. In Group B, patients had local irritation like redness and itching which resolved after applying antibiotic ointment over the site of injury. As $CuSO_4$ is a caustic agent it causes irritation to the normal tissue. But Annpurna and Ramu , Gupta and Mujalde[3,13] and some other studies did not find such type of side effects in $CuSO_4$ application. No wound infection was found in both groups in this study which is also consistent with other studies. It may be due to both common salt and copper sulphate has its own antibacterial and/or antiseptic properties.

At the end of 28 days follow up no recurrence was found between two groups and it is also consistent with the other studies, e.g., Annapurna and Ramu, Chung et al.[3,11]

Conclusion

Application of copper sulphate to the UG is simple, effective without any recurrence but having some side effects and need physician control application. Whereas, common salt needs multiple application, longer duration of treatment but very few side effects and can be applied by guardians at home. So common salt may be an effective alternative in the treatment of UG.

Recommendations

Common salt is a feasible treatment for UG. However, further multicentric, large number of patients with longer follow up period comparative study is recommended to prove the therapeutic effect of common salt in the management of UG.

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