A Comparison between the Clinical Results of Salt Therapy and Surgery in the Treatment of Umbilical Granuloma in Infants

Davod Badebarin[1] Saeed Aslan Abadi[1] Mohammad Mehdi Shakeri[2]*
Masoud Jamshidi[1] Farid Karkon Shayan[3]

[1]Department of Surgery, Tabriz University of Medical Sciences, Tabriz, Iran
[2] Students' Research Committee, Tabriz University of Medical Sciences, Tabriz, Iran
[3] Connective Tissue Diseases Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

*Address for Corresponder: Dr. Mohammad Mehdi Shakeri, Students' Research Committee, Tabriz University of Medical Sciences, Tabriz, Iran

(email: medicalresearchtbz@gmail.com)

How to cite this article:
Badebarin D, Aslan Abadi S, Shakeri MM, Jamshidi M, Karkon Shayan F. A Comparison between the Clinical Results of Salt Therapy and Surgery in the Treatment of Umbilical Granuloma in Infants. Iranian Journal of Pediatric Surgery 2018; 4(1):7 -13.
DOI: htt://dx.doi.org/10.22037/irjps.v3i3.20374

Abstract

Introduction: The most common umbilical disorders in infants is umbilical granuloma. To date, various therapeutic methods have been proposed to treat umbilical granuloma. This study aimed to compare the clinical results of salt therapy with surgery in the treatment of umbilical granuloma in infants.

Materials and Methods: In a clinical trial study, 50 infants with umbilical granuloma visited at the Children Educational-Medical Hospital of Tabriz University of Medical Sciences were selected and randomly allocated into two groups. In the first group, 25 patients were treated with sterile salt, and in the second group; 25 patients underwent surgery using electro cauterization. Patients were followed for three months, and the cure rate, relapse rate, and side effects of each method were evaluated.

Results: Results showed that cure rate in the salt therapy group was 96.0% but in the surgery group it was 100%. There was no statistically significant difference between the two group regarding the cure rate (p=1.000). No relapse or side effects were seen in any of the study groups.

Conclusion: Based on the findings of the present study, salt therapy is a safe and effective method in the treatment of umbilical granuloma which can be an alternative to surgical methods in this regard.

Keywords

- Umbilical Granuloma
- Salt
- Surgery
- Infants

received: 13 February 2018
accepted: 22 February 2018

ISSN 2423-5067

Introduction

Umbilical granuloma, the most common umbilical abnormality in the neonatal period affects one out of 500 newborns.[1] The umbilical cord dries and falls in the first week after birth and is covered with a thin layer of granulation tissue. This scar tissue in the second and third weeks after birth is restored and normal skin replaces it. The separation time of the umbilical cord depends on various factors such as race, geolocation, and umbilical cord care. Delay in the falling of umbilical cord may lead to infection which in turn prevents restoration and epithelialisation of the umbilical cord resulting in a granulation tissue called granuloma. Remaining granulation tissue is considered pathologic and requires treatment.[2, 3]

There is controversy regarding the best treatment of umbilical granuloma.[1] These options include: 1) silver nitrate 75% cauterisation or less commonly copper sulphate cauterisation, 2) electro cauterization, 3) cryo cautery, 4) surgical excision, 5) double ligation, and 6) use of sodium chloride salt.[3-6]

Silver nitrate, as a conventional and commonly-used treatment for umbilical granuloma, has some disadvantages such as inaccessibility, the need for specialist physician and side effects such as skin discolouration, burning and necrosis of the skin following its use.[7] Another method is electrocauterization which is routinely performed at pediatric surgery centres. There are disadvantages such as high cost of performing a surgical procedure and imposing side effects of anaesthetic drugs on the newborn.

For the first time in 1972, Smith proposed the use of sodium chloride salt for the treatment of umbilical granuloma [8] which has been shown to be very effective, inexpensive, safe, and readily accessible. In a study by Al Saleh et al., it was shown that treatment with common salt twice a day for five days completely resolves umbilical granuloma without leaving any significant side effects [9].

One of the reasons why medical reference books have not yet supported the use of common salt for the treatment of umbilicalgranuloma is the small number of studies conducted in this area. The lack of attention to this highly effective treatment, the routine use of the surgical technique in the Tabriz Children's Hospital, and the need for a relatively comprehensive study on the effect of cooking salt on the infants with umbilical granuloma compared with electrocauterization surgery confirms the necessity for such a study.

This study aimed to evaluate the success and relapse rates as well as the side effects of treatment with common salt compared with electro cauterization in umbilical granuloma in infants.

Materials and methods

In a randomised clinical trial (RCT) registered at Iranian Registry of Clinical Trials site under IRCT201604262066N3 code, 50 children with a diagnosis of umbilical granuloma referred to the Children's Hospital of Tabriz University of Medical Sciences (TUOMS), were enrolled. The duration of the study was nine months from the beginning of April 2015 to the first of February 2016.

The patients were included if their age was between 3 weeks to 4 months of infancy, had umbilical

granuloma, and parental written informed consent for the patient's participation in the study was obtained. Subjects were excluded if they were older than four months of age, had a diagnosis other than umbilical granuloma, or their parents declined to participate in the study.

Fifty children with umbilical granuloma referred to Children's Hospital of TUOMS were randomly selected using Rand list version 1.2 software, and randomly divided in to two equal groups (n=25 each) using the same software.

In the first group, after parental training, 25 infants were treated with sterile iodine-free common salt (sodium chloride). Sterilisation was performed via Hot Salt Sterilizer used in the sterilisation of dental equipment (endodontic hand files) [10]. Then, the parents were instructed to wash the area with warm water and dry it; put a small amount of salt powder on the umbilical granuloma to the extent that it was entirely covered. After about half an hour, it was washed with warm water. This procedure was repeated 12 hours later for five days. Subsequently, the infants were brought to the surgical clinic to check the course of the treatment.

In the second group, 25 infants were treated with an electrocauterization technique. Under general anesthesia, the umbilical granuloma was excised using an electric cautery device,[11] then, they were transferred to the recovery room and discharged 12 hours later. After five days, the infants were brought to the surgical clinic to check the course of the treatment. Patients of both groups were followed up after three months for evaluation of response to the treatment and possible relapse as well as side effects.

This study was approved by the Ethics Committee of TUOMS under the regional code of TBZMED. REC.1394.564. Also, written informed consent was obtained from the parents. The purpose and manner of conduction of the study, and possible benefits, as well as potential complications of each method (according to previous studies, side effects are not likely to occur), were thoroughly explained to the parents of patients and stated that all their information would be kept confidential, and their personal information would not be mentioned anywhere. No additional intervention was performed during the whole study, except for the administration of salt or conduction of electro cauterisation. Also, the cost of salt used in the study was provided by the project implementer and supported by the vice chancellor of TUOMS.

The SPSS™ software version 17 was used for all statistical analyses. The obtained data were expressed as mean ± standard deviation (SD), frequency and percentage. Chi-square test was used to compare qualitative variables. The quantitative variables between two groups were compared using independent t-test. In all cases, $p<0.05$ was considered to be statistically significant.

To determine the sample size, the primary data were collected according to the study by Farhat et al. [12]and the required sample size was calculated using the following formula:

This yielded a total of 20 patients for each group in this study. However, to consider the dropout and increase the validity of the study 25 patients were enrolled into each group.

Results

The mean age of infants in the salt therapy group was 6.64±2.73 weeks, and in the electro cauterization group was 7.76 ± 2.74 weeks. Analysis showed that the difference was not statistically significant (p=0.142).

In the salt group, 17 (72.0%) patients were male and 8 (28.0%) patients were female, and in the surgical group, 14 patients (56.0%) were male, and 11 (44.0%) patients were female. There was no significant difference regarding the gender of the patients between the two groups (p=0.561).

The mean gestational age of infants at birth was 37.91±1.51 weeks in the salt therapy group and 38.44 ± 1.00 weeks in the electrocauterization group. There was no significant difference between the two groups regarding the mean gestational age at birth (p=0.192).

The main clinical complaints of the patient in the salt therapy group were as follows: bleeding or purulent discharge (n=21 (84.0%)); lump in the umbilical region (n=2 (8.0%)); and red tissue surrounding the umbilical cord (n=2 (8.0%)). In the surgical group, 18 (72.0%) subjects were referred for bleeding or purulent discharge, and 7 (28.0%) were admitted due to a lump in the umbilical region.

Also there was no significant difference between the two groups regarding the mean size of umbilical granuloma (p=0.299). We also found no striking sonographic findings in any of the patients.

In the salt therapy group, 9 (36.0%) patients showed a relative improvement in the clinical examination five days after the treatment. These patients were treated with common salt for another five days. At the end of ten days, all patients had a complete recovery. Also, in the 5th day of the treatment with salt, one patient (4.0%) did not show any improvement and was included in the surgical group; and after the surgery, complete recovery was achieved.

The success rate of treatment of umbilical granuloma was 96.0% in the salt therapy group and 100% in the surgical (electro cauterisation) treatment group. The difference was shown to be statistically insignificant (p=1.000) **Figure 1 and 2**.

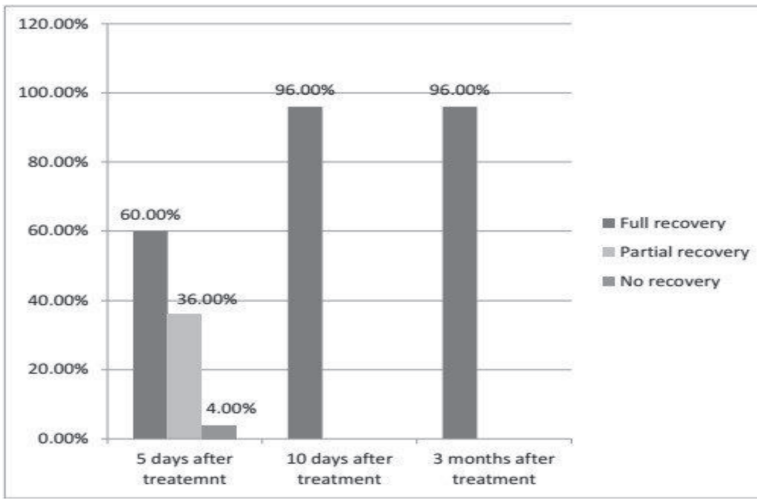

Figure 1: Therapeutic outcomes of the patients in the salt therapy group.

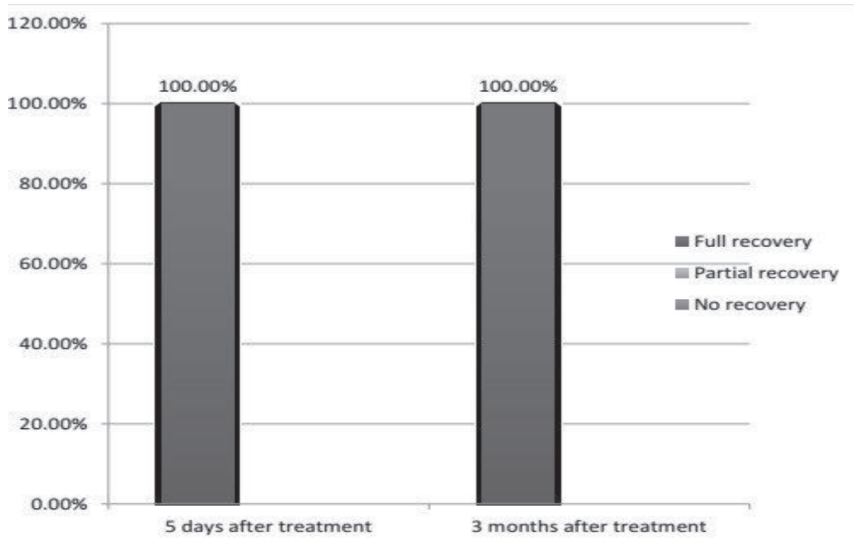

Figure 2: Therapeutic outcomes of the patients in the electro cauterisation group.

Also, in a 3-month follow-up, none of the subjects in the treatment groups experienced recurrence or complications of the treatment.

Discussion

Treatment of umbilical granuloma can vary from methods such as electro cauterisation to the use of local silver nitrate.[13] Regarding the relatively high costs of each of these methods and or their adverse effects, it is difficult to determine the best method for the treatment of umbilical granuloma.

Common salt is one of the therapeutic options in the treatment of umbilical granuloma. The high concentration of sodium ions in the granuloma region results in the removal of water from granulomatous cells, thereby causing necrosis of the granulomatous tissue without damaging normal tissue [14]. The results of the present study showed a high success rate of treatment of umbilical granuloma with common salt. It also showed no significant side effect or relapse after this treatment. The results were comparable to those of electro cauterisation.

In this regard, Marzban et al. conducted a clinical trial to evaluate the therapeutic effects of common salt and compare it with silver nitrate treatment. The results of this study showed that all patients with a diagnosis of umbilical granuloma were improved with salt therapy and no recurrence or adverse effects were observed after five days of treatment. The study concluded that salt therapy is a simple, inexpensive, non-invasive and effective method of the treatment of umbilical granuloma without a need for physicians compared to the treatment with silver nitrate [15].

Also, Farahat et al. performed a study on umbilical granuloma with an aim to investigate the effect of common salt on the recovery of this disorder. According to the results of this study, common salt is an effective method for the treatment of umbilical granuloma and 24 hours of the salt coating was more effective than two hours of salt coating[16].

In a study by Zahed Hossein et al. 28 infants aged between 3 and 12 weeks with umbilical granuloma were studied. In this study, the granuloma position was covered with salt for 30 minutes and washed off with cool water at the end. All patients were evaluated one to three weeks later. Forty-four out of 48 patients (91.7%), completely recovered after treatment with salt. No side effects were observed in this study [5].

Similarly, Faranoush et al. conducted a study on 105 infants suffering from umbilical granuloma in Semnan, Iran. The infants in this randomised clinical trial were divided into: group1 which was treated with salt for three days/twice daily, group2 which was treated with 70% alcohol twice daily, each time 0.5 ml; and group3 (control) which was treated with distilled water twice daily (0.5 ml each time). The results of the study showed that the response rate was 100% in infants treated with salt, 34.3% in subjects treated with alcohol and 14.3% in control. In 25.7% of the infants treated with alcohol and 60% of the control group, the umbilical granuloma relapsed after three days of treatment. However, no relapse was found in the group which received common salt.[17]

Conclusion

Based on the results of this study and also other studies in this area, the use of salt is an effective, safe and economically reasonable method in the treatment of umbilical granuloma, which does not result in complications arising from the use of synthetic drugs or surgery. Further studies in this field are necessary for better decision making.

Acknowledgments and financial support

We are grateful to all our patients for their contribution and patience throughout this study. This paper is based on Mohammad Mehdi Shakeri's speciality dissertation submitted to Department of Surgery, Tabriz University of Medical Sciences, Tabriz, Iran.

Conflict of interest disclosure

The authors declare that they have no conflict of interest to disclose.

References

1. Brodsgaard A, Nielsen T, Molgaard U, et al: Treating umbilical granuloma with topical clobetasol propionate cream at home is as effective as treating it with topical silver nitrate in the clinic. Acta Paediatr 2015;104:174-7.

2. Wolfe SW, Pederson WC, Hotchkiss RN, et al: Green's operative hand surgery: Elsevier Health Sciences 2010.

3. Nagar H: Umbilical granuloma: a new approach to an old problem. Pediatr Surg Int 2001;17: 513-4.

4. Lotan G, Klin B, Efrati Y: Double-ligature: a treatment for pedunculated umbilical granulomas in children. Am Fam Physician 2002;65:2067-8.

5. Hossain AZ, Hasan GZ, Islam KD: Therapeutic effect of common salt (table/cooking salt) on umbilical granuloma in infants. Bangladesh Journal of Child Health 2012;34: 99-102.

6. Sheth SS, Malpani A: The management of umbilical granulomas with cryocautery. Am J Dis Child 1990;144:146-7.

7. Majjiga VS, Kumaresan P, Glass EJ: Silver nitrate burns following umbilical granuloma treatment. Arch Dis Child 2005;90:674.

8. O'Donnell KA, Glick PL, Caty MG: Pediatric umbilical problems. Pediatr Clin North Am 1998; 45:791-9.

9. Al Saleh AS: Therapeutic effect of common salt on umbilical granuloma in infants. International Journal of Medical Science and Public Health 2016;5:911-5.

10. Hurtt CA, Rossman LE: The sterilization of endodontic hand files. Journal of endodontics 1996;22:321-2.

11. Daniels J, Craig F, Wajed R, et al: Umbilical granulomas: a randomised controlled trial. Archives of Disease in Childhood-Fetal and Neonatal Edition 2003;88:F257-F.

12. Karagüzel G, Aldemir H: Umbilical Granuloma: Modern Understanding of Etiopathogenesis, Diagnosis, and Management. Journal of Pediatrics and Neonatal Care, Edmond 2016;4:136.

13. Daniels J: Is silver nitrate the best agent for management of umbilical granulomas? Arch Dis Child 2001;85:432.

14. Faranoush M, Ghorbani R, Malek M, et al: A comparative study on therapeutic effect of sodium chloride and alcohol in infants with umbilical granulomas. 2006;10:65-8.

15. Marzban A: Curative Effect of Common Salt on Umbilical Granuloma. JOURNAL OF MEDICAL COUNCIL OF IRI 2008;26:373-7.

16. Farhat AS, Mohammadzadeh A: Comparison between two and twenty-four hours salt powder in treatment of infant umbilical granuloma. Iranian red crescent medical journal 2008;10:267-9.

17. Faranoush M, Ghorbani R, Malek M, et al: A comparative study on therapeutic effect of sodium chloride and alcohol in infants with umbilical granulomas. THE JOURNAL OF QAZVIN UNIVERSITY OF MEDICAL SCIENCES 2006;10:65-8.