



Nickel Gluconate–Mercurius Heel–Potentised Swine Organ Preparations: a new therapeutical approach for the primary treatment of pediatric ranula and intraoral mucocele

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Received 26 July 2006; received in revised form 6 October 2006; accepted 7 October 2006

KEYWORDS

Ranula;
Mucocele;
Nickel Gluconate–
Mercurius Heel–
Potentised Swine Organ
Preparations D10/D30/
D200;
Homotoxicology

Summary

Objective: Many authors consider surgical therapy of pediatric ranula and intraoral mucocele as the election treatment. Recently, an intracystic sclerosing injection with OK-432 has been proposed as a ranula primary treatment. This preliminary study evaluates the effectiveness of the use of Nickel Gluconate–Mercurius Heel–Potentised Swine Organ Preparations as the primary treatment of pediatric ranula and intraoral mucocele.

Methods: Eighteen children (9 ranulas, 9 labial mucoceles, 2 lingual mucoceles) were treated with oral administration of Nickel Gluconate–Mercurius Heel–Potentised Swine Organ Preparations D10/D30/D200.

Results: Eighty-nine percent ranulas (8 out of 9), 67% labial mucoceles (6 out of 9) completely responded to the therapy. One ranula, that interrupted therapy after only 4 weeks, was subjected to marsupialization in another hospital. A double mucocele case partially responded (one of the two was extinguished), another case incompletely responded, decreasing the size beyond 50%, and just one case, changing volume, resisted the therapy. Lingual mucocele healed at once. Blandin–Nuhn polypoid

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congenital mucocele responded to the treatment with gradual reabsorption, permitting surgical excision of the atrophic polypoid remnant, without removing glands of origin. No solved case showed recurrence (follow up range: 4–32 months).

Conclusion: Homotoxicological therapy with Nickel Gluconate–Mercurius Heel–Potentised Swine Organ Preparations D10/D30/D200 is an effective primary treatment of pediatric ranula and intraoral mucocele.

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1. Introduction

Mucocele represents a mucous cavity that originates from major or accessory salivary glands. Ranula is the mucocele of the sublingual gland within the floor of the mouth. The Blandin–Nuhn mucocele occurs exclusively on the anterior ventral surface of the tongue near the midline. Labial mucocele is of minor salivary glands' origin. Salivary gland excretory duct trauma or obstruction, with consequent salivary hypertension and acinar structure rupture, can be the cause of extravasation of mucus from the gland into the surrounding soft tissue. Saliva extravasation causes granulomatous reaction that is associated with a devoid of epithelium pseudocyst [1]. The saliva flow disruption, due to sialolith or mucus plug, induces progressive duct dilatation that is associated with an epithelium cyst.

In extravasated mucus there are increased levels of matrix metalloproteins, tumor necrosis factor- α [2], type IV collagenase, plasminogen activators and proteolytic enzymes [3] that are responsible for the invasive character of extravasated mucus. The pseudocyst composed of granulation tissue with fibroblasts, proliferating small-caliber vessel and mostly foamy histiocytes with mucus phagocytized. Atrophic and focal ulceration areas can be in the pseudocyst mucosa.

The clinical features associated with mucocele include a dome-shaped enlargement, bluish to translucent hue in depth, normal mucosa coloration on the surface, mobile, normally not painful with variable dimensions.

Many authors consider surgical therapy of pediatric ranula and intraoral mucocele as the election treatment. Surgical therapy includes marsupialization, ranula excision with or without adjacent associated sublingual gland [4]. Lingual mucocele is treated with surgical excision of pseudocyst and the Blandin–Nuhn glands associated [5]. Even labial mucocele is treated with surgical excision of the mucocele and adjacent labial glands.

Various surgical treatments have recurrence rates and also risk of complication as bleeding and lingual peripheral nerve damage, injury to the Wharton duct leading to stenosis, obstructive sialadenitis and leakage of saliva, injury to the

lingual nerve and to the marginal mandibular nerve with paresthesia.

Recently intracystic injection of the streptococcal preparation, OK-432, has been used to treat oral ranulas [6,7].

OK-432 is a sclerosing agent, widely known to treat cystic lymphangiomas. The authors propose a new, non invasive, without significant side effect treatment of pediatric intraoral ranula and mucocele, based on the use of homotoxicological drugs as Nickel Gluconate–Mercurius Heel–Potentised Swine Organ Preparations (PSOP) D10/D30/D200.

2. Materials and methods

A total of 18 children between September 2003 and March 2006 were treated with homotoxicological therapy: 8 patients with 9 sublingual ranulas (4 right sided, 3 left sided, 1 bilateral), 8 patients with 9 mucoceles of the lower lip (5 left sided, 2 right sided, 1 case with double midline mucocele) and 2 patients with mucoceles of the anterior lingual salivary glands (glands of Blandin–Nuhn, 1 with polypoid congenital variation). Of the 18 patients, 9 were male and 9 female (range 1 month to 15 years), as indicated in Table 1.

Nickel Gluconate–Mercurius Heel–PSOP D10/D30/D200 was orally administered for a minimum of 6 weeks and a maximum of 6 months. The homotoxicological therapy was started immediately after clinical diagnosis; only in a case, twice marsupialized in another hospital, a magnetic resonance imaging (MRI) was performed before treatment to evaluate ranula's extension. Doses were corrected according to children's age: Nickel Gluconate 0.5 mg on alternate days (for unweaned 1/3 dosage, for from 1 to 6 year children 1/2 dosage), Mercurius Heel (Table 2) 1 tablet three times a day (for unweaned 1/3 dosage, for early childhood 1/2 dosage), PSOP D10/D30/D200 (Glandula Submandibularis Suis Injeel for ranula, Lingua Suis Injeel for lingual mucocele, Salivary Glands Suis for labial mucocele, Table 2) 0.1 ng twice a week for 4–6 weeks, decreasing once a week (for unweaned and for from 1 to 6 year children 0.1 ng a week for 4–6 weeks, decreasing 0.1 ng every 10 days.

Table 1 Patient summary

Case no.	Patient name	Sex/age	Mass onset	Previous surgery	Side	Length of the homotoxicological therapy	Side effects	Surgery after homotoxicological treatment	Outcome	Follow-up (months)
Ranula										
1	P.P.	F/12 years	32 weeks	—	Right	10 weeks	>Volume and tension for 24 h	—	Resolution after 8 weeks	32
2	M.G.	F/5 months	6 weeks	—	Right	8 weeks	—	—	Resolution after 4 weeks	21
3	B.L.	M/2 months	3 weeks after birth	—	Bilateral	10 weeks	—	—	Resolution after 10 weeks	14
4	G.A.	M/5 years	8 weeks	—	Left	12 weeks	—	—	Resolution after 7 weeks	14
5	M.N.	M/3 months	4 weeks	—	Left	6 weeks	—	—	Resolution after 4 weeks	10
6	C.M.	M/7 years	6 weeks	—	Left	15 weeks	—	—	Resolution after 12 weeks	7
7	A.M.	F/13 years	4 weeks	—	Right	4 weeks (incomplete therapy)	—	Marsupialization	—	Lost
8	F.F.	F/8 years	28 weeks	Two marsupializations	Right	24 weeks	— Asthenia — >Volume and tension for 48 h	—	Resolution after 22 weeks	4
Lingual mucocele										
1	A.F.	M/15 years	2 weeks	—	Right	8 weeks	—	—	Resolution after 3 weeks	25
2	R.S.	F/1 months	At birth	—	Right polypoid	16 weeks	—	Excision of the fibrous atrophic remnant	Resolution	13
Labial mucocele										
1	N.F.	M/8 months	2 weeks	—	Left	8 weeks	—	—	Resolution after 6 weeks	25
2	T.M.	F/6 years	12 weeks	—	Right	10 weeks	—	—	Resolution after 8 weeks	13
3	M.G.	F/17 months	8 weeks	—	Double Midline	20 weeks	—	Excision of the one residual labial mucocele	Partial Resolution after 8 weeks	7
4	E.M.	M/7 years	4 weeks	—	Left	16 weeks	—	—	Resolution after 14 weeks	4
5	C.D.	M/18 months	5 weeks	—	Left	24 weeks	—	Excision	No Response	—
6	C.V.	F/6 months	4 weeks	—	Right	24 weeks	—	Excision of the residual mucocele	Nearly complete	—
7	M.D.	M/8 years	6 weeks	—	Left	16 weeks	—	—	Resolution after 14 weeks	4
8	B.A.	F/10 years	8 weeks	—	Left	12 weeks	—	—	Resolution after 10 weeks	4



Fig. 1 Case no. 1: lingual mucocele.

Table 3 shows the list of the drugs' dosage (amount and time frame) for each patient.

3. Results

Seven ranulas recovered after 4 to 12 weeks of therapy, without surgical treatment. One ranula relapsed after 2 marsupializations; it cleared up after 22 weeks of treatment. Just one case, arbitrarily interrupted therapy after 4 weeks, had marsupialization in another hospital. Of the 9 labial mucoceles treated, 5 recovered after 6 to 14 weeks of therapy, in the double mucocele just one recovered, another case decreased volume >50%, just one patient, changing volume of the mucocele, did not completely respond to the therapy.

Eighty-nine percent ranulas (8 out of 9) excellently responded to the therapy; the ranula case surgically treated effected incomplete therapy (4 weeks). Sixty-seven percent mucoceles of the lower



Fig. 2 Case no. 1: lingual mucocele after 15 days of treatment.

Table 2 Composition and concentration of the active ingredients in Mercurius Heel and PSOP

Mercurius Heel

Labelling and composition according to UE rules for homeopathic medicines

1 tablet contains: Mercurius solubilis Hahnemanni D10, 90 mg; Hepar sulfuris D8, Lachesis D12, Phytolacca D4, Ailanthus glandulosa D3, Echinacea angustifolia D3, each 30 mg; Belladonna D4, 60 mg

Concentration of the active ingredients

For 1 tablet: Mercury II nitrate 10^{-3} ng (nanogram); Hyoscyamine 5 ng; Sulfur 0.1 μ g (microgram); Lachesis Tincture 1 ng; Phytolacca Tincture 0.03 mg; Ailanthus glandulosa Tincture 0.3 mg; Echinacea angustifolia Tincture 0.3 mg

Potentised Swine Organ Preparations

Glandula Submandibularis Suis Injeel

UE rules: 1 ampoule of 1 ml contains: Glandula Submandibularis Suis D10, D30, D200

Concentration of the active ingredient: Tincture of porcine submandibularis gland 0.1 ng (nanogram)

Lingua Suis Injeel

UE rules: 1 ampoule of 1 ml contains: Lingua Suis D10, D30, D200

Concentration of the active ingredient: Tincture of porcine tongue 0.1 ng (nanogram)

Salivary Glands Suis D10/D30/D200 (OTI)

UE rules: 1 ampoule of 2 ml contains: Salivary Glands Suis D10, D30, D200

Concentration of the active ingredient: Tincture of porcine salivary glands 0.2 ng (nanogram)

lip (6 out of 9) completely recovered, in the double mucocele just one recovered, another case incompletely responded and just one patient did not respond to the therapy.



Fig. 3 Case no. 1: lingual mucocele after 3 weeks of treatment.



Fig. 4 Case no. 1: lingual mucocele after 25 months.

Lingual mucocele was completely reabsorbed after 3 weeks. Blandin–Nuhn polypoid congenital mucocele therapy allowed the excision of the atrophic remnant, without Blandin–Nuhn glands' excision (Figs. 1–14).

Asthenia of one patient (ranula section: case no. 8) and transitional increasing volume with local tension for about 24–48 h in the first week of treatment in two children (ranula section: case nos. 1–8) were registered as side effects (Table 1). During treatment and in the follow up range (4–32 months) no allergic symptoms and complications have been reported in any case.

4. Discussion

Nickel is considered an essential element [8]. The human body normally contains 10 mg nickel. It accumulates in pancreas, bones, arteries but it is found even in sweat, saliva and serum. Oysters, herrings,



Fig. 5 Case no. 8: right relapsed ranula with left ematoma after two marsupializations.



Fig. 6 Case no. 8 right ranula after 22 weeks of treatment.

lamb, unrefined cereal, peanuts, spinach, tomatoes, peas, rosemary, taraxacum, pears, hazelnuts, tea and cocoa are all foods rich in nickel. Only 10% nickel taken with diet is absorbed and the digestive barrier overcoming occurs according to duodenal transport system of iron. Ninety percent of swallowed part is found in stool. Of nickel absorbed, 24% is found in serum, 13% in red blood cells and 63% in platelets. In serum it is bonded to cysteine, histidine, aspartic acid and albumin or bonded to metal–protein nickel–plasmin that occurs in organic transport of nickel ions. A big part is excreted from plasma to urine. The average serum concentration is 5 µg/l and daily requirements are 0.035 mg. The lack of nickel or non-bioavailability causes gluco-genesis failure and anaemia for Iron malabsorption alteration.

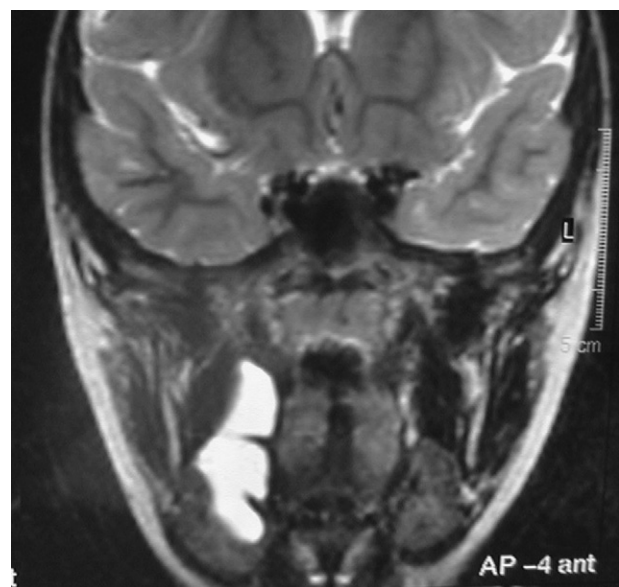


Fig. 7 Case no. 8 MRI coronal view of the right ranula.



Fig. 8 Case no. 8 MRI coronal view after 24 weeks of treatment.

In the past nickel was used in the treatment of convulsions and excitation psychomotor conditions. Nickel toxicity concerns the pharmacological dosage or the absorption dosage due to environmental pollution, not the catalytic dosage in micro doses.

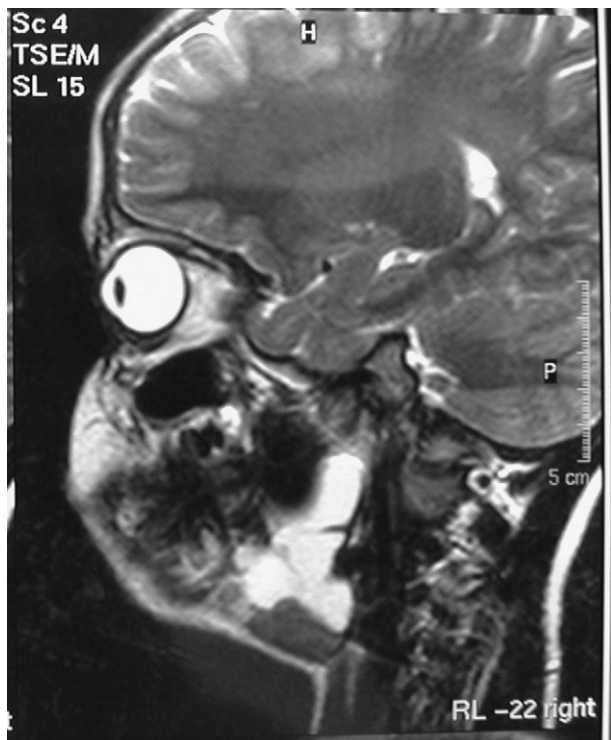


Fig. 9 Case no. 8 MRI sagittal view of the right ranula.



Fig. 10 Case no. 8 MRI sagittal view after 24 weeks of treatment.

The toxic dose by oral administration is circa 200 mg of organic nickel a day [9]. At the microdose of 0.5 mg on alternate days Nickel Gluconate is an important oxide reducer, stimulates salivary glands in case of lack and salivary amylases. It stabilizes cell membrane, stimulates the reticulum endothelial system and lymphatic tissue, and promotes protein synthesis and tissue repairing processes.

Mercurius Heel is an anti-inflammatory drug. It consists of diluted principles in order to preserve elements of phytotherapeutic activity, eliminating at the same time their side effects. The individual elements have the following effects:



Fig. 11 Case no. 4 : left ranula.



Fig. 12 Case no. 4 left ranula after 12 weeks of treatment.

- Mercurius solubilis Hahnemanni D10, 90 mg: anti-inflammatory action, controlling the development in purulent inflammation and/or in ulceration.
- Hepar sulfuris D8, 30 mg: tropisms for lymphatic and immune system, action on inflammatory processes tending to suppuration and ulceration.
- Lachesis D12, 30 mg: active in sepsis, controlling the sepsis evolution.
- Phytolacca D4, 30 mg: elective tropisms for epithelium glands and lymph epithelial tissue; anti-inflammatory action.
- Ailanthus glandulosa D3, 30 mg: active in severe ORL lymph epithelial inflammation.
- Echinacea angustifolia D3, 30 mg: tropisms for reticulum endothelial system, antiseptic and anti-inflammatory action; stimulates tissue regeneration mechanism and particularly epithelium regeneration.
- Belladonna D4, 60 mg: tropism for central and periphery nervous system, anti-inflammatory



Fig. 13 Case no. 2 : right lingual polypoid mucocele.



Fig. 14 Case no. 2 right lingual polypoid mucocele after 13 months and fibrous atrophic remnant excision.

action, operates selectively on vessel's inflammatory phase of mucosa, lymphatic and connective tissue.

PSOP D10–D30–D200 (Glandula Submandibularis Suis Injeel, Lingua Suis Injeel and Salivary Glands Suis) has a specific tropism for homologous human tissue; stimulate its protein synthesis and repairing processes. With pharmacological and immunological type mechanisms, they put into effect the recovery of the physiological function of organ as well as the restoration of the lost immunological tolerance as a result of the operated tissue damaging from the pathogenic noxae.

Homotoxicology [10], founded by Dr. Reckeweg in the first decades of the XX century, studies toxic factors for human health and represents nowadays the effective interaction between official medicine and classic homeopathy. In fact in respect to the most modern acquisitions of biochemistry and physiopathology as well as the pathogenic and immunological events of specific pathology, homotoxicology allows the performance of scientific therapies. It uses medicines whose components at low doses, according to classic homeopathy, conserve the phytotherapeutic action without collateral effects of high concentrations.

The three homotoxicological drugs, used for the primary treatment of pediatric intraoral ranula and mucocele, act synergistically on foreign body inflammation, triggered by extravasated mucus. These drugs stimulate pseudocyst reabsorption, glandular repairing and physiological function.

Nickel Gluconate at the microdose of 0.5 mg at alternate days is not as toxic as the dose of 200 mg a day by oral administration.

Dilution higher than D24 and concentrates inferior to 10 to $-24 M$, exceeding the constant of Avogadro,

Table 3 Dosage of the drugs (amount and time frame) for each patient

Case no.	Patient name	Sex/age	Nickel Gluconate	Mercurius Heel	Glandula Submandibularis Suis Injeel
Ranula					
1	P.P.	F/12 years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 4 weeks then once a week
2	M.G.	F/5 months	0.5 mg every 6 days	1/2 tablet twice a day	0.1 ng a week for 4 weeks then every 10 days
3	B.L.	M/2 months	0.5 mg every 6 days	1/2 tablet twice a day	0.1 ng a week for 6 weeks then every 10 days
4	G.A.	M/5 years	0.5 mg every 3 days	1 tablet twice a day	0.1 ng a week for 4 weeks then every 10 days
5	M.N.	M/3 months	0.5 mg every 6 days	1/2 tablet twice a day	0.1 ng a week for 4 weeks then every 10 days
6	C.M.	M/7 years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 6 weeks then once a week
7	A.M.	F/13 years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 4 weeks
8	F.F.	F/8years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 6 weeks then once a week
		Sex/age	Nickel Gluconate	Mercurius Heel	Lingua Suis Injeel
Lingual mucocele					
1	A.F.	M/15years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 4 weeks then once a week
2	R.S.	F/1 months	0.5 mg every 6 days	1/2 tablet once a day for 1 month then 1/2 tablet twice a day	0.1 ng a week for 6 weeks then every 10 days
		Sex/age	Nickel Gluconate	Mercurius Heel	Salivary Glands Suis D10–D30–D200
Labial mucocele					
1	N.F.	M/8months	0.5 mg every 6 days	1/2 tablet twice a day	0.1 ng a week for 4 weeks then every 10 days
2	T.M.	F/6 years	0.5 mg every 3 days	1 tablet twice a day	0.1 ng a week for 4 weeks then every 10 days
3	M.G.	F/17months	0.5 mg every 3 days	1/2 tablet three times a day	0.1 ng a week for 4 weeks then every 10 days
4	E.M.	M/7 years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 6 weeks then once a week
5	C.D.	M/18months	0.5 mg every 3 days	1/2 tablet three times a day	0.1 ng a week for 4 weeks then every 10 days
6	C.V.	F/6 months	0.5 mg every 6 days	1/2 tablet twice a day	0.1 ng a week for 4 weeks then every 10 days
7	M.D.	M/8 years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 6 weeks then once a week
8	B.A.	F/10 years	0.5 mg on alternate days	1 tablet three times a day	0.1 ng twice a week for 6 weeks then once a week

do not contain active principle. The dilution of Mercurius Heel does not exceed D12 and gives the drug, at a low dosage, the necessary pharmacological characteristics of phytotherapy but without the toxically side effects correlated to ponderal doses.

Concerning PSOP D10–D30–D200, we assume the pharmacological action of the D10 but we do not know how the D30 and even more the D200 react.

From the analysis of the obtained results, ranulas respond better than the labial mucoceles (89% of the ranulas compared to 67% of the labial mucoceles) to the homotoxicological therapy. Accordingly, bigger labial mucoceles seem to respond better than smaller mucoceles probably because they are more vascularized and therefore more sensitive to the drugs' action that reach lesions in the bloodstream. The reduction in size and the changing size in volume shown by the two mucoceles suggest that the therapy influences, even if not in a definite way, the lesions treated. It cannot be excluded however, that a possible resistance to the therapy, could be the glandular group trauma's persistence. The Blandin–Nuhn mucocele responded excellently to the treatment, while the polypoid variant treatment allowed the extirpation of the fibrous atrophic remnant, without the original glandular group's excision.

5. Conclusion

In literature a 5-month observation period has been proposed before surgery in case of ranulas spontaneous resolution [11]. We feel that the homotoxicological therapy stimulates the healing process and can start at diagnosis. Besides differing from the OK-432 that causes the sclerosis of the salivary glands with damage of the glandular secreting epithelium. Nickel Gluconate associated with Mercurius Heel and PSOP determines the reabsorption of pseudocyst and reinstates the salivary gland recuperating all its functions and anatomy. Encouraging results of this preliminary study require further confirm but the long follow up period of some of the treated cases makes us feel that healing of the

ranulas and of the mucoceles can be definite. Nickel Gluconate–Mercurius Heel–PSOP D10–D30–D200 thanks to its innocuity, non-invasive and therapeutic effectiveness can represent in our opinion a primary treatment of ranulas, Blandin–Nuhn mucoceles and labial mucoceles.

The therapy can also precede surgery to reduce the size of the ranulas or as in the case of lingual polypoid mucoceles to avoid the concomitant excision of the Blandin–Nuhn glands. We cannot exclude its usage in the post-operative period to contrast a possible relapse trend.

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