Hypokalemic Myopathy "A Possible Complication of Clay Eating"

M.Med. (Neurology)

Mantoa Elizabeth Moagi

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Hypokalemic Myopathy "A Possible Complication of Clay Eating"

by

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RESEARCH DISSERTATION

Submitted in fulfillment of the requirement for the degree of

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in

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Supervisor: Prof DS Magazi

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DECLARATION

I declare that the dissertation hereby submitted to the University of Limpopo (Medunsa Campus) , for the degree of Master of Medicine in Neurology has not previously been submitted by me for a degree at this or any other university ; that it is my work in design and in execution , and that all material contained herein has been duly acknowledged

_____ _____

Initials & Surname (Title) Date

Student Number: 18202214

DEDICATION

This dissertation is dedicated to my beloved late parents ATI MICHAEL and NNAKI JACOBETH MOAGI. I thank them for their love, support, advises and encouragement.

ACKNOWLEDGEMENTS

I would like to thank the following people:

- Prof DS Magazi, my supervisor for his expertise, support, encouragement and guidance.
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- Prof TS Monokoane and his nursing staff, for allowing me to interview patients at the antenatal clinic (Dr George Mukhari Hospital).
- All the patients who consented to be part of my research project.
- My loving husband Mr. IS Shai, my sons Matokolo, Lebogang and Letlhogonolo for their understanding and support they displayed when I was a registrar.
- Lastly I would like to thank everyone who contributed towards my success.

Contents

BACKGROUND (geophagia/pica)

Pica is a tendency to ingest nonnutritive substances eg. chalk, paper, wood, coal *etc. The American Psychiatric Association in its diagnostic and statistical Manual* defines Pica as persistent eating of non-nutritive substances that is inappropriate for developmental level, occurs outside culturally sanctioned practice and, if observed during the course of another mental disorder, is sufficiently severe to warrant independent attention. The term pica comes from the Latin word magpie- a bird known for its indiscriminating eating habits. The deliberate consumption of earth, soil or clay is known as geophagia which is the commonest form of pica.

Hippocrates is credited with the oldest description of this ancient practice.
An ancient Roman textbook, *De Medicina,* compiled by Celsus during the rein of Emperor Tiberius (13 – 37 AD), mentions earth eating as one of the reasons for bad skin colour. It is a practice that continues to exist in modern times, the full extent however, remains unrealized most probably due to underreporting.

Geophagia has been practiced at some stage, virtually world wide eg. America (north & south), Asia, Australia, Britain, India, various parts of Africa. The epidemiology however, is still unknown due to the lack of studies in this regard.

Why do people eat clay /soil ?

Various explanations have been given for the practice of geophagia. Ranging from using soil/clay as a filler and an appetite suppressant in poor communities. Anemia is touted as a cause eg. during pregnancy. In some communities, geophagia is a culturally sanctioned practice (used as traditional medicine eg. as an antidiarrheal). There is also an association with certain mental disorders. The full understanding however, as to the causation is unknown and seems to be multifactorial.

In some countries, clay is available for purchase eg. certain parts of South Africa (see figure 1 & 2).

Complications of the practice of geophagia range from minor eg. constipation to major eg. morbidity and even death from perforation of the viscera. Other complications include lead poisoning, exposure to infectious agents and parasitic infections.

Slaves in Brazilian plantations became progressively lethargic and even died as a result of addiction to soil eating. Plantation owners even resorted to fitting face masks to prevent the slaves from practicing geophagia.

Epidemiological studies on the practice of geophagia are lacking. A study in rural Mississippi by Vermeer and Frate found the practice of geophagia to be in 57 % of women and 16 % of children (both sexes). This was however, not practiced by adolescents and men.

It is common practice in some ethnic groups of South Africa to eat clay. This is especially common in pregnant women. In the Ga-Rankuwa, Soshanguve and Mabopane areas (approximately 30 km west of Pretoria), four types of clay are available for ingestion viz. the black clay, red, white and brown. Black clay is freely available (eg. from the garden). Red and brown clay are commercially available (sourced from the nearby mountains). Information was not available as to the source of the white clay.

LITERATURE REVIEW (hypokalemia & clay eating)

There is a paucity of studies on hypokalemia and clay ingestion. What is available are a few case reports summarized below.

Geophagia With Iron Deficiency And Hypokalemia

Mengel et al (1964)

This is a presentation of a patient with gradual onset of generalized weakness associated with depressed deep tendon reflexes. There was also pain in the arms and thighs. There was a history of ingesting one or more handfuls of white clay with each meal. The serum potassium was found to be 1.5mEq/l. The patient was also anemic with low serum iron levels.

There was improvement of the weakness with replenishment of the potassium.

Clay is postulated to trap potassium hence the resultant hypokalemia.

Clay Ingestion: A Rare Cause of Hypokalemia

Gonzalez et al (1982)

A 33 year old female with a history of ingesting white clay developed weakness of the lower extremities. The serum potassium was found to be low (1.5mEq/l) with a creatine kinase of 14 044 IU/l. Potassium supplementation resulted in improvement of the symptoms. Flame photometry to analyze the effects of clay demonstrated the lowering of potassium. The conclusion was that the clay binds the potassium which resulted in the hypokalemia. A point was also made by the authors that clay can also result in hyperkalemia.

Clay Ingestion and Hypokalemia

(Gary & Eisenger 1982)

The authors wrote a letter to the editor challenging the claim by Gonzalez and colleagues that they demonstrated that clay binds potassium. A point that they make is that without the knowledge of the patient's dietary intake or urinary excretion of sodium and the plasma renin values, it then becomes difficult to interpret. A further point made is that the calculations made by Gonzalez and colleagues seem to suggest that only about 10% of the dietary potassium is bound by clay. That lead them to the conclusion that there has to be an additional factor to account for the profoundly low serum potassium.

Profound Muscle Weakness and Hypokalemia Due to Clay Ingestion

(Severance et al 1988)

A 43 year old female patient with a 25 year history of geophagia presented with severe proximal weakness and generalized myalgia. She also experienced 'skipped beats' and a 'racing heart'. The laboratory results revealed a marked hypokalemia, high muscle enzymes and a hypochromic microcytic anemia. Clay samples tested in vitro at different PH levels showed the clay to be a binder of potassium.

Hypokalemic myopathy due to ingestion of earth

(Chaushev et al 2002)

A 38 year old African female with a 10 year history of geophagia presented with weakness of all limbs. She had a generalized areflexia with sparing of cranial nerve innervated muscles. She had a marked 'extrarenal' hypokalemia and iron deficiency anemia. Earth samples provided by the patient were evaluated for 'cation – exchange capacity'. The authors demonstrated absorption of potassium and iron proportionate to the mass concentration of earth.

Hypokalemic Myopathy in Pregnancy Caused by Clay Ingestion

Ukaonu et al (2003)

A 44 year old multigravida at 31 weeks gestation presented with a month's history of weakness and a three week history of pain in the limbs. There was a low serum potassium which was at first unexplained but subsequently pinned to the patient's habit of ingesting clay daily. The ECG showed U waves following the T waves. The weakness resolved with potassium supplementation and the cessation of the habit of eating clay. The authors point out, that pregnant women with hypokalemia should be asked about pica with the awareness that patients may be reluctant to discuss the subject as was the case with their patient.

Biochemical investigations in geophagia

(Dreyer et al 2004)

An African woman with a history of ingesting black earth from her garden presenting with limb paralyses is described. Laboratory tests at PH levels 2 and 6.2 were performed on black and red clay. Black clay was shown to absorb sodium, potassium and iron. Red clay absorbed potassium slightly. The authors note that the local African population believes that there is a benefit in eating clay during pregnancy. They further concluded that red earth 'indeed had properties that might prevent iron deficiency anemia'.

Myopathy, hypokalemia and pica (geophagia) in pregnancy

(Mckenna D 2006)

A 29 year old Para 2 Gravida 3 patient presented with proximal weakness of the limbs associated with reduced deep tendon reflexes except for the plantar responses which were normal. Throughout her pregnancy, she had been regularly taking clay from outside her house. Her blood tests revealed a markedly low potassium and creatine kinase. The EMG (Electromyography) showed a myopathic picture. An MRI and a muscle biopsy showed no abnormalities. The symptoms responded to potassium supplementation. The author points out the paucity of studies on hypokalemic myopathies and geophagia pointing out that 'this is only the second report in the literature of geophagia causing hypokalemic myopathy in pregnancy'.

Figure 1. Brown clay

Figure 2. Red clay

AIM

To assess the association of clay eating by pregnant female patients and the occurrence and severity of hypokalemic myopathies.

METHODS

A prospective, descriptive study of female patients with a history of clay ingestion between July 2004 and July 2008 done at Dr George Mukhari Hospital. Twenty six black female patients with a history of geophagia were recruited for the study (twenty two from the antenatal clinic, one from the Neurology OPD, three were in patients).

An equal number (twenty six) of control patients were also assessed. A convenience sampling method was used from the same antenatal clinic on patients without a history of geophagia.

A consent form was signed by all patients participating in the study after a verbal explanation in their own language (see appendix 1).

The participating subjects had to answer (verbally) a questionnaire on the type of clay, amount, duration *etc.* (see appendix 2). A Setswana translation of the questionnaire was also made.

A standardized clinical assessment was done (see appendix 3).

Inclusion criteria

Female patients with a history of clay eating who were willing to participate in the study.

Exclusion criteria:

- Refusal to partake in the study
- Renal failure
- History of recent vomiting & / diarrhea
- Primary hyperaldosteronism
- Exposure to drugs known to cause hypokalemia such as diuretics and purgatives.

Laboratory investigations

- Serum Potassium (K)
- Serum Creatine Kinase (CK)

OBSERVATIONS

Twenty two patients with the history of geophagia, seen at the antenatal clinic were clinically normal. Three patients presented with generalized limb weakness and myalgia. The fourth patient had myalgia without weakness. The four patients with the weakness and /or myalgia were found to have low serum potassium levels (detailed description below).

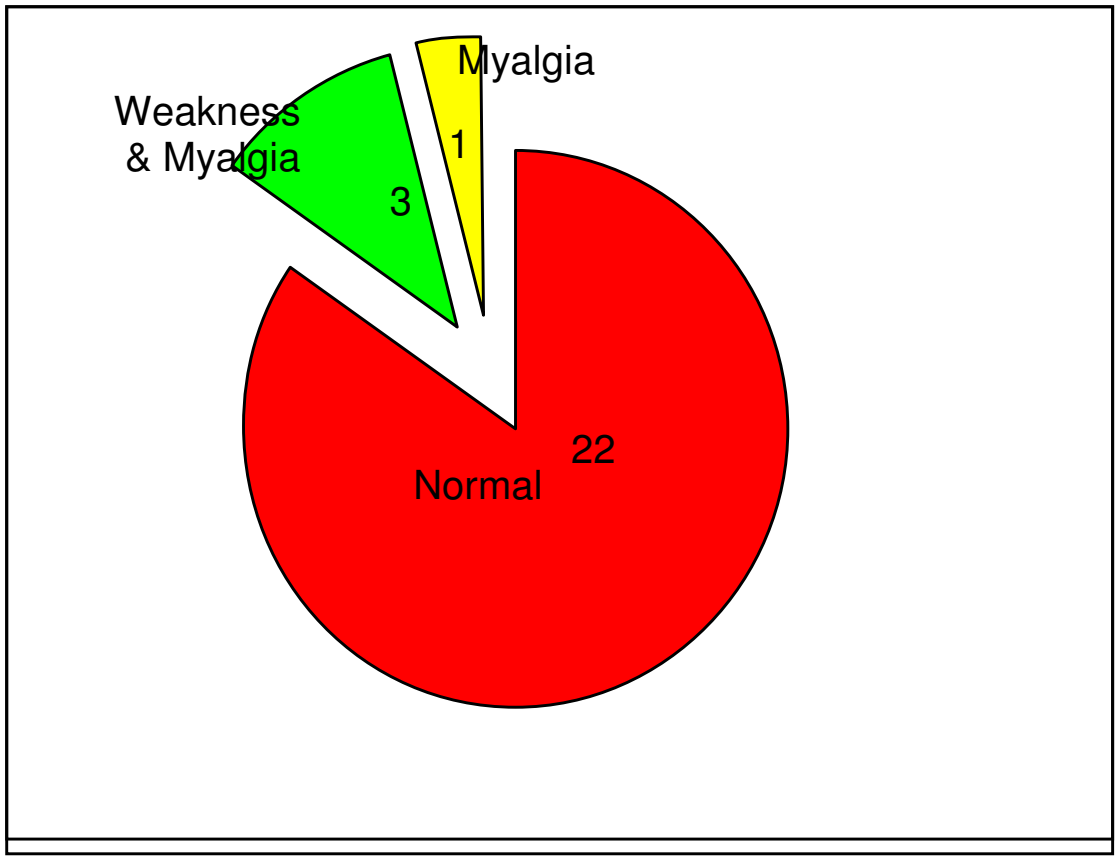

Figure 3

Mrs. SS

She presented with weakness of both upper and lower limbs. The weakness progressed over a period six days to an extend that she was unable to walk. She was at 32 weeks gestational age. This was the second episode. The first episode was in 2000 at 32 weeks gestational age. She was treated by the general practitioner and after delivery the weakness improved.

History of ingesting clay started when she was two months pregnant. She ingested both black and red types of clay. She prefers black clay more than the red one. She gets the black clay from her garden (see figure 4) and the red clay she buys from the local vendor. She ingests one cup clay per day (mostly black clay).She used to ingest clay when she was pregnant in 2000.She only craves for clay when she is pregnant.

Past medical history was non contributory.

Figure 4. Black clay from *Mrs. SS*'s garden

On examination: Vital signs normal. General condition normal. Higher function normal. Cranial nerves intact. Weakness more proximal (power 3/5) than distal (power 4/5) in the limbs.

Deep tendon reflexes retained at 2/4.Tone normal. Sensation normal.

Dorsal column intact. No cerebellar signs.

Investigations:

Serum potassium- 2.0mmol/L

Serum creatine kinase-9894U/L

Thyroid function test-Normal

Haemoglobin 10.3 g/dl

Electromyography: Nerve conduction studies-Normal. Needle examination-Fibrillation potential on insertion, myopathic polyphasic motor units of low amplitudes, short duration and full recruitment.

Treatment:

Potassium was replaced intravenously followed by oral supplements. The patient improved clinically after potassium was replenished. Within a period of five days the patient was able to walk and was discharged. The patient was advised to stop eating clay.

Mrs. JS

Thirty-two years old female patient, four days post normal vaginal delivery (NVD) at term, presented with generalized weakness of two weeks duration. Past medical history was non contributory. Positive history of clay ingestion since she was six months pregnant. She was ingesting one cup of black clay daily. She got the clay from her garden. No previous history of clay eating.

On examination:

Vitals normal and higher function normal. Weakness of neck flexion and extension (power 3/5).Patient was unable to sit from up from the supine position. Power in the arms 3/5 around all the joints. Legs more affected proximally (power 2/5) than distally (power 4/5).Generalized hypotonia and areflexia. Sensation intact. Dorsal column intact.

Investigations:

Serum potassium-1,7mmol/L

Serum creatine kinase->10 000 U/L

Thyroid function test-normal

Haemoglobin-10.4g/dl

Urine myoglobin->4000 micro gram/L

Electromyography: Nerve conduction studies-normal.

Needle examination-Fibrillation potentials on insertion.Myopathic motor units (polyphasic, low amplitudes, and short duration motor units).

Treatment

Potassium was replaced intravenously followed by oral replacement. The patient clinical condition improved with the normalization of potassium. The patient was discharged able to walk 13days after admission.

Mrs. RB

Fifty-four years old female patient presented with a five days history of sudden onset of generalized weakness prior to admission. Similar episode of weakness occurred during pregnancy in 1995.History of geophagia which started during pregnancy in 1995.She started eating clay again in 2003.She used to eat clay with her daughter who was pregnant in 2003.She consumes ½ cup of black or red daily. The black clay she gets from her garden and the red clay she buys from the street vendors. Past medical history non- contributory.

On examination:

Vitals and general examination were normal. Higher functions were normal. Limbs more affected proximally (power 2/5) than distally (power 3/5), neck flexion and extension weakness (power 3/5).Global areflexia. Sensation and dorsal column intact.

Investigations:

Serum potassium -1.7mmol/L

Serum creatine kinase ->10 000U/L

Thyroid function test -not done

Haemoglobin -10.0 g/dl

Urine myoglobin - not done

Electromyography –not done

Treatment:

Potassium was replaced intravenously followed by an oral route.

The patient clinically improved with the normalization of the potassium. She was discharged after eleven days, able to walk. Her potassium on discharge was 4.6mmol/L.

She was advised to stop eating clay.

Ms EM

Forty- three years old female patient presented with a history of painful and weakness of both arms and legs of seven days duration. She was admitted in 1997 with a similar episode associated with clay ingestion. On average she eats two cups of clay per day for several years. She gets the clay from her garden. It is black clay. She likes the smell of clay especially after it had rained. She also bakes the clay in an oven before she eats it. Under stressful situations she consumes up to four cups per day. When she realized that she was becoming weak she stopped eating clay. When she was seen at out patients she had stop eating clay for a week.

On examination:

Vitals and higher function are normal. Myalgia in the muscle of the limbs. No weakness demonstrated. Tone and sensation normal. Deep tendon reflexes retained at 2/4.

Investigations:

Serum potassium-2.4mmol/l

Serum creatine kinase 4560U/L

Urine myoglobin 78, 8 microgram/L

Haemoglobin-7.8 g/dl

Thyroid function test-normal

Electromyography-not done

Treatment:

Potassium was replaced orally (patient was clinically stable).She was advised stop eating clay. Patient was lost to follow up.

Table 1: Summary of patients with weakness and/or myalgia

Patient	**Age**	**Myalgia**	**Weakness**	**Reflexes**	**Previous episode of weakness**	**Pregnant**
Mrs. SS	30 yrs	Present	Present	Retained	Yes	Yes
Mrs. JS	32 yrs	Present	Present	Areflexia	No	4 days post delivery
Mrs. RB	54 yrs	Present	Present	Areflexia	Yes	No
Ms. EM	43 yrs	Present	Absent	Retained	Yes	No

Table 2: Summary of laboratory results of patients with weakness and/or myalgia

Patient	**Serum potassium**	**Serum creatine kinase**
Mrs. SS	2.0 mmol/l	9894 U/L
Mrs. JS	1.7 mmol/l	>10 000 U/L
Mrs. RB	1.7 mmol/l	> 10 000 U/L
Ms. EM	2.4 mmol/l	4560 U/L

Table 3: Patient with history of clay ingestion.

Patient	Age	Gestation age	Type of clay	Clay bought/Garden	Duration of clay ingestion	Amount ingested	Serum K	Serum CK (U/I)	Weakness/Myalgia
1	25	28 weeks	Black	Garden	past 7 years	½ cup /day	4.7 mmol/l	118	No
2	21	36 weeks	Black	Garden	2 months	½ cup /day	4.0 mmol/l	56	No
3	32	36 weeks	Brownish	bought local market	3 months	1-2 cups/day	3.3 mmol/l	116	No
4	23	16 weeks	Brownish	bought local market	since 2003	1 tablespoon/day	4.5 mmol/l	92	No
5	29	36 weeks	Brownish	bought local market	3 weeks	½ cup /day	4.3 mmol/l	90	No
6	29	36 weeks	Red	bought local market	4 weeks	tablespoon 3xweek	5.0 mmol/l	102	No
7	26	36 weeks	Red	bought local market	since June 2007	¼ cup/day	3.4 mmol/l	66	No
8	36	36 weeks	Brownish	bought local market	2 months	¾ cup/day	3.6 mmol/l	316	No
9	36	36 weeks	Black	Garden	1 month	tablespoon/day	4.1 mmol/l	73	No
10	32	36 weeks	Red	Garden	2 months	½ cup /day	3.6 mmol/l	84	No
11	18	36 weeks	Brownish	bought local market	started 5 years back	½ cup /day	4.1 mmol/l	113	No
12	31	28 weeks	Brownish	bought local market	2 months	¼-$^1/_2$ cup/day	4.9 mmol/l	83	No
13	19	32 weeks	Black	Garden	3 months	2 cups/day	4.1 mmol/l	249	No
14	26	36 weeks	Brownish	bought local market	since February 2007	2 cups/day	4.4 mmol/l	82	No
15	37	28 weeks	Black	Garden	1 month	tablespoon/day	4.3 mmol/l	72	No
16	33	28 weeks	Red	Garden	2 weeks	½ cup /day	3.8 mmol/l	95	No
17	35	28 weeks	Red	stem of trees	1 month	2 tablespoons/day	4.2 mmol/l	86	No
18	23	30 weeks	black, red	trees, bought	3 months	½ cup /day	4.4 mmol/l	79	No
19	34	36 weeks	Brownish	bought local market	1 month	tablespoon/day	4.3 mmol/l	69	No
20	30	32 weeks	Red	bought local market	2 weeks	½ cup /day	4.0 mmol/l	75	No
21	15	28 weeks	Red	Garden	started 2 years back	2 tablespoons/day	4.3 mmol/l	51	No
22	32	28 weeks	Whitish	special place	more than 8 years back	½ cup /day	4.7 mmol/l	69	No
23	43	not pregnant	Black	Garden	for many years	2 cups/day	2.4 mmol/l	4560	Myalgia
24	32	4 days post NVD	Black	Garden	since 6 months pregnant	½ -1 cup/day	1.7 mmol/l	> 10000	Both
25	30	32 weeks	black, red	Garden	since 2 months pregnant	1 cup/day	2.0 mmol/l	9894	Both
26	54	Not pregnant	black, red	Garden	started 3 years back	½ cup /day	1.7 mmol/l	> 10000	Both

Table 4. Controls patients without history of clay ingestion.

Patient	Age (Yrs)	Serum K	Myalgia	Weakness
1	25	3.5 mmol/L	No	No
2	27	4.1 mmol/L	No	No
3	35	4.0 mmol/L	No	No
4	19	4.2 mmol/L	No	No
5	40	3.5 mmol/L	No	No
6	41	4.1 mmol/L	No	No
7	40	3.7 mmol/L	No	No
8	30	3.6 mmol/L	No	No
9	22	4.6 mmol/L	No	No
10	21	4.2 mmol/L	No	No
11	19	4.5 mmol/L	No	No
12	25	3.9 mmol/L	No	No
13	25	3.6 mmol/L	No	No
14	32	3.9 mmol/L	No	No
15	25	4.6 mmol/L	No	No
16	21	3.5 mmol/L	No	No
17	25	4.1 mmol/L	No	No
18	26	3.8 mmol/L	No	No
19	25	3.9 mmol/L	No	No
20	19	4.6 mmol/L	No	No
21	22	4.2 mmol/L	No	No
22	20	4.1 mmol/L	No	No
23	24	4.0 mmol/L	No	No
24	25	4.0 mmol/L	No	No
25	29	3.6 mmol/L	No	No
26	40	3.9 mmol/L	No	No

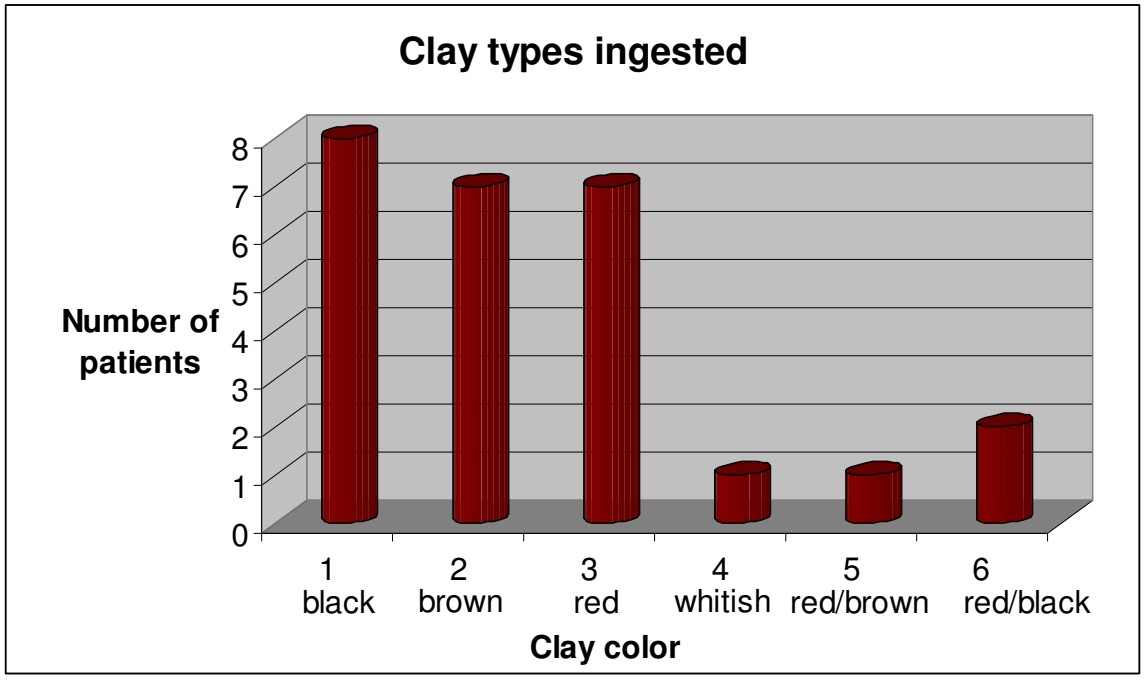

Figure 5.

Eight patients ingested black clay dug from the garden, seven used brown clay bought form the local market. Seven patients used red clay bought from the local market mostly. One patient used whitish clay, the origins of which remain unknown as the patient wasn't keen to share that information. Two patients used red alternating brown or black (see figure 5).

DISCUSSION

Our series of patients show a correlation between the type of clay ingested and the amount. The four patients with weakness and / or myalgia all ingested half a cup to two of black clay per day. The rest of the patients ingested clay of different color types (red, brown, white or black). Black clay ingested in small amounts did not result in symptoms (eg. teaspoon/spoon /day).

Normal serum levels of potassium range between 3,5 – 5,0 mmol/l and approximately 95 % of this is intracellular with remainder being outside the cells. This electrochemical gradient is maintained by the energy dependent Na^+/K^+ ATPase pump. Potassium is essential for repolarisation of the membrane after an action potential which is necessary for normal nerve and muscle functioning. A low potassium causes hyperpolarisation of the resting membrane potential whose clinical manifestations could result in weakness (see figure 6).

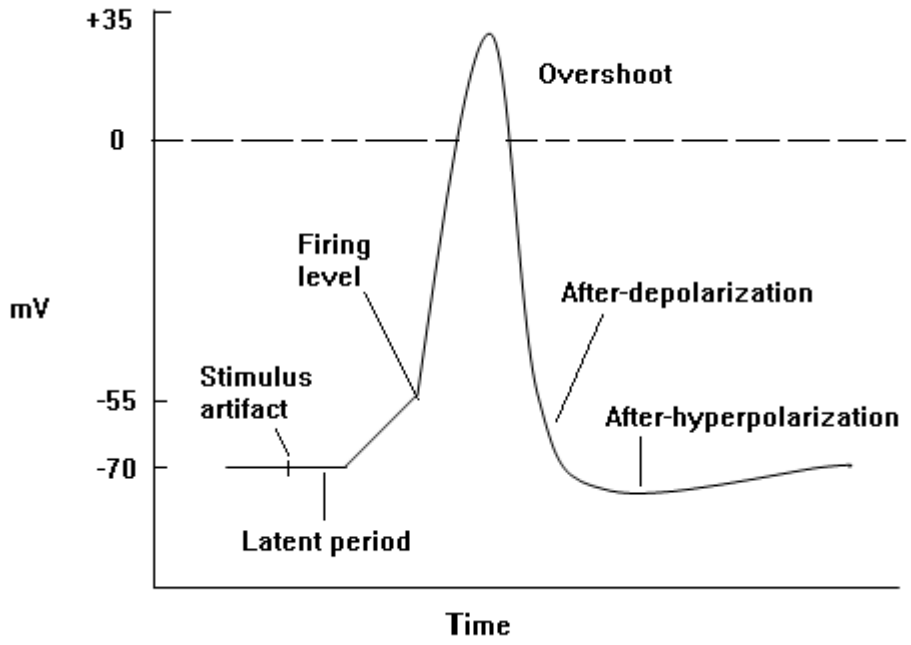

Figure 6.

Hypokalemia could be hereditary eg. periodic paralysis from an inherited channelopathy. The acquired causes could be from diarrhea, vomiting, anorexia nervosa and drugs like diuretics etc. Our patients demonstrate that there is an association between hypokalemia and clay ingestion. Another demonstration that the low potassium was directly linked to the clay ingestion is the patient who had a recurrence of weakness on resuming the habit of ingesting clay.

There seems to be a link between the type of clay ingested and the occurrence of symptoms. This is supported by in vitro tests in previous studies showing that the effects of the different clay types are not uniform. A general claim therefore as to the effects of clay in the body is likely to be incorrect. That is why one could speak of ‘good clay’ and ‘bad clay’ based on the effects and complications which now seem to be clay type specific. The black clay depletes potassium in direct contrast to the effects of the red clay which seems to absorb potassium slightly.

Two of the patients had absent deep tendon reflexes. The significance of this finding is that the presentation could lead to the erroneous diagnosis of the Guillain Barre´ Syndrome. This is an important observation to highlight to clinicians as both conditions are a potential threat to life and their management is different.

Immediate diagnosis could be delayed because patients don’t usually volunteer the history of ingesting soil as it is a culturally acceptable practice in some communities that doesn’t warrant mention.

Creatine Kinase is an enzyme found in various tissues (skeletal, cardiac, smooth muscles and brain tissue). There are different subtypes which are location specific (eg. MM for skeletal muscle, MB for cardiac and BB for brain).Creatinine Kinase is important for the conversion of Adenosine diphosphate (ADP) to Adenosine triphosphate (ATP), consuming phosphocreatin and generating Creatine. Creatine is an organic acid that was identified in skeletal muscle in 1832 by Michael Eugene Chevreul. He named the organic acid Creatine from the Greek word for flesh, *Kreas*. Creatine Kinase levels are normally low in the blood. The significant levels demonstrated by our patients in the presence of weakness are an indication of significant rhabdomyolisis, a reason why the patients had myalgia in addition to the weakness. The fourth patient with just the myalgia had lower values than the other three which suggests a direct link between the levels and the clinical presentation. Even though we didn't look at the specific creatine kinase subtype, one can assume that the rise was from the MM subtype.

Table 5: Summary of patients with hypokalemic myopathy

DUE TO GEOPHAGIA

Patient	Age(yrs)	Sex	Race	Clay type	Neurologic signs	Initial K (mmol/L)	CK (IU /L)
Mengel et al - 1964	17	Female	Black	White	Quadriparesis and hyporeflexia	1.5	NR
Gonzalez et al - 1982	33	Female	Black	White	Quadriparesis,reflexes not recorded	1.5	14044
Severance et al - 1988	43	Female	Black	NR	Quadriparesis,reflexes not recorded	1.9	9500
Chaushev et al - 2002	38	Female	Black	Black	Quadriparesis, areflexia	1.3	10289
Ukaonu et al – 2003	44	Female	NR	NR	Quadriparesis	1.5	3214
Mckenna D – 2006	29	Female	Coloured	NR	Quadriparesis	1.5	9920
Moagi ME - 2009	30	Female	Black	Black	Quadriparesis, reflexes retained	2.0	9894
	32	Female	Black	Black/Red	Quadriparesis, areflexia	1.7	>10000
	54	Female	Black	Black/Red	Quadriparesis, areflexia	1.7	>10000
	43	Female	Black	Black	Myalgia ,reflexes retained	2.4	4560

NR-Not recorded

CONCLUSION

The local community must be made aware of the findings in this study, that there are certain types of clay that are definitely detrimental to health. Also to state that even the ‘good’ clay is potentially harmful if taken in excess as it is not physiologically inert. Hypokalemia could also affect the cardiac muscle which complication could be a threat to life.

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APPENDIX 1. i

INFORMED CONSENT

I hereby confirm that I have been informed by the investigator, Dr Moagi about the nature, conduct, benefits and risks of the clinical study
Hypokalemic myopathies - a possible complication of clay eating.
I have also received, read and understood the above written information (Patient Information Leaflet) regarding the clinical trial.

I am aware that the results of the study including personal details regarding my sex, age, date of birth, name and diagnosis will be anonymously processed into a clinical report.

I may, at any stage, without prejudice, withdraw my consent and participation in the trial. However, once the test has been performed, I will not be able to withdraw as it will not be possible to identify my specific results from the other anonymous results. I have had sufficient opportunity to ask questions and (of my free will) declare myself prepared in the trial.

Patient´s Name:……(Please print)

Patient´s Signature:…….Date:…….……

Investigator´s Name:…….(Please print)

Investigator´s Signature:…….Date……..…

I Dr /Professional nurse …… Herewith confirm that the above-named patient has been informed fully about the nature, conduct and risks of the above trial.

Witness´s Name:……..(Please print)
(Consent procedure should be witnessed whenever possible).

Witness´s Signature:……**Date**……..

APPENDIX 1. ii

VERBAL PATIENT INFORMED CONSENT
(Applicable when the patient cannot read or write)

I, the undersigned, Dr …….., have read and fully

explained to the patient, named……

And/or his/her relative(s), the patient informative leaflet, which has indicated the nature and purpose of the trial in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the trial. The patient indicated that he/she understands that he/she be free to withdraw from the study during the test without jeopardizing his/her subsequent treatment.

I hereby certify that the patient has agreed to participate in the trial.

Patient´s Name:……(Please print)

Patient´s Signature:……..Date……..….

Invetigator´s Name:……(Please print)

Investigator´s Signature:……..Date…..…….

Witness´s Name:……..(Please print)

Witness´s Signature:……Date:…..…….

I ……..
The undersigned agree to participate in the study and give permission for my medical data to be used. This is with the understanding that everything will be confidential. It has been explained to me that the study will be conducted on an anonymous basis.

Signature/Left thumb print of the patient:……

APPENDIX 1. iii

TETLA

Dr Moagi wa lefapha la Neurology (Dr George Mukhari Hospital) o nthlaloseditse ka botlalo ka dipatlisiso tse di dirwang mo basading ba ba moimana ba ba jang mmu.

Ke thlaloseditswe ka mokgwa oo dipatlisiso di tla dirwang ka ona, le ditla morago tse di solofetsweng.

Ke thlaloseditswe ka botlalo gore ga se kgapeletso gore ke tseye karolo.Le teng ga ke sa batle go tsaya karolo, se se ka se dire gore ke se bone thuso mo sepetlele.

Ke filwe sebaka sa go botsa dipotso mme ke filwe thlasolo e nkgotsofatsang.

Ke rata go tsaya karolo mo dipatlisisong tsa basadi ba baimana ba ba jang mmu.

Patient´s Name:……(Please print)

Patient´s Signature:……Date:…..……

Investigator´s Name:……(Please Print)

Investigator´s Signature:……Date:……..

Witness´s Name:……(Please print)

Witness´s Signature:……Date:…..……

APPENDIX 2

QUESTIONNAIRE

1. Do you eat clay (Yes / No)?
2. What color clay do you eat (black, red, or any other color, N/A)?
3. How much clay do you eat (cup, ½ cup, tablespoon or teaspoon)?
4. How long have you been eating clay (years, months or weeks)?
5. Where do you get the clay (bought form local market, from the garden or other place)?
6. Have you eaten clay before (any history of clay eating with previous pregnancies)?

DIPOTSISO

1. A o ja mmu (Ee kgotsa nyaa)?
2. O ja mmu mmala o mojang (o montsho / o moshibidu)?
3. Ke sebaka se se kanakang o ja mmu (dijara /dikwedi dibeke)?
4. Fa o lekanyetsa o ja mmu o mo kanakang (komiki etletseng /halofo ya komiki) ?
5. O bona mmu go twa kae (Wa o reka / mo tshimong ya dijalo)?
6. O ile wa ja mmu mo dinakong tse di fitileng (Fa o ne o le moimana /a o ja mmu le fa o se moimana)?

APPENDIX 3.i

Hospital No: _____ Date: _____

Name: _____ Consultant: _____ Registrar: _____

Address: _____

Age: _____ Sex: _____ Occupation: _____ Referred by: _____

DATE	MAIN COMPLAINT	CAPACITY Education:
	History:	Neg: Underline, Pos: Circle Headache Convulsions Syncope Nausea/Vomiting Pain Paresthesias Anesthesias Lhermitte's Weakness Cramps Fasciculations Co-ordination Gait Handwriting Dyskinesias Smell/Taste Vision Diplopia Ptosis Hearing Tinnitus Light headedness Vertigo Speech Swallowing Bladder/Rectum Potency Menstruation Memory Confusion Personality Affect Insomnia Sleepy Weight loss Appetite Smoking Alcohol Previous procedures: Family History:
	Differential Diagnosis: Investigations:	Present Medication:

APPENDIX 3. ii

CORTICAL FUNCTIONS: Level of consciousness (describe)

Orientation	(/8)	______	Speech	______	Observation	______
Attention	(/7)	______	Flowing	______	Fearful	______
Learning	(/4)	______	Naming	______	Aggressive	______
Arithmetic	(/4)	______	Repetition	______	Depressed	______
Abstraction	(/3)	______	Understanding	______	Agitated	______
Construction	(/4)	______	Reading	______	Uncooperative	______
General Knowledge	(/4)	______	Writing (eg)	______		______
Recall	(/4)	______		______		______

NEUROVASCULAR

R L Pulse

Sitting ______ BP ______

Standing ______ BP ______

Rhythm

Cardiac murmur

R **MURMERS** L

______ Supraclavicular ______

______ Diffuse Carot ______

______ Focal Carot ______

______ Focal Carot ______

______ Orbital ______

______ Cranial ______

R **PULSES** L

______ Temporal ______

______ Carotid ______

______ Radial ______

______ Post tib ______

______ Dors pedis ______

R REFLEXES L

(Circle)

______ Corneal ______

______ Snout ______

______ Gag ______

______ Jaw ______

______ Brachiorad ______

______ Triceps ______

______ Biceps ______

______ Hoffman ______

______ Epigastr ______

______ Hypogastro ______

______ Cremasteric ______

______ Knee ______

______ Ankle ______

______ Int Ham (L5) ______

______ Ext Ham (S1) ______

______ Anal ______

______ Bulbokav ______

______ Babinski ______

______ Chaddock ______

R GENERAL MOTOR L

______ Toe walking ______

______ Heel walking ______

______ Hopping ______

______ Knee bending ______

______ Arm swinging ______

______ Tending ______

GAIT

Straight away ______

Turning ______

Tandem ______

Apraxia, Ataxia, Spastic, other (describe)

ROMBERG

______ One foot ______

R **TREMOR** L

Terminal	Movement	Static	Resting	Resting	Static	Movement	Terminal

R COORDINATION L

(Eyes open)

______ Finger-Nose ______

______ Heel-Knee ______

______ Toe-Finger ______

______ Rebound ______

(Eyes closed)

______ Finger-Nose ______

______ Heel-Knee ______

ALTERNATING

______ Hands ______

______ Fingers ______

______ Feet ______

RIGIDITY / SPASTICITY

______ Neck ______

______ Shoulder ______

______ Elbow ______

______ Knee ______

MUSCLES

Hypotonia, myotonia, cramps

R VERTEBRAL L

Pain localization

Straight leg raising

______ Rev SLR ______

______ Scoliosis ______

______ Lordosis ______

______ Percussion ______

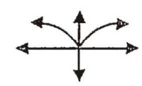
______ Brudzinski ______

______ Kernig ______

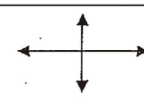
______ (Hips) ______

MOVEMENT

______ Neck ______



Lumbar



CRANIAL NERVES L

I

______ Smell ______

II

______ Visual Acuity ______

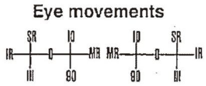
Visual fields

______ Fundi ______

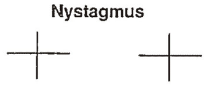
III, IV, VI

______ Ptosis ______

Eye movements



Nystagmus



Arrow for direction

R **PUPIL** L

______ Size/form ______

REFLEXES

______ light ______

______ Indirect ______

______ Accommodation ______

VIII

______ Hearing ______

______ Rinne ______

______ Weber ______

______ Bārāny ______

______ Taste ______

______ Gag ______

SPEECH

______ Phonation ______

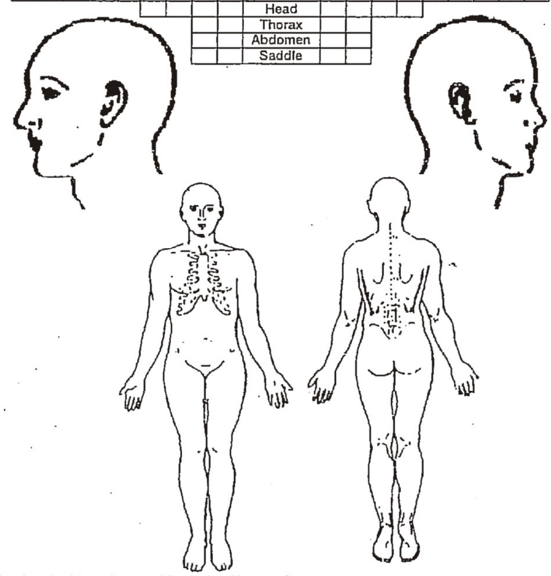
______ Resonance ______

______ Articulation ______

______ Prosody ______

Fasiculations	Size	Power	Muscle	Root	Power	Size	Fasiculations
			Temporal Mas	V3			
			Orb oculi	VII			
			Orb oris	VII			
			Pharyngs	X			
			Sternomast	SI			
			Trapezius	XI			
			Tongue	XII			
			Neck FlexNeck Ext	C1-6 / C1-T1			
			Deltoid				
			Lat dorsi	C56			
			Pectoralis	C6-8			
			Infraspin	C5-T1 / C56			
			Supraspin				
			Serrat ant	C5-7			
			Romboïd	C45			
			Biceps	C56			
			Triceps	C6-8			
			Brachiorad	C56			
			Supinator	C56			
			Pronator teres	C67			
			Wrist ext	C7-T1			
			Finger ext	C78			
			FDP	C7-T1			
			FDS	C7-T1			
			FPL	C7-T1			
			Pron quadr	C8-T1			
			Thenar (med)	C8-T1			
			Hypothenar	C8-T1			
			Interossei	C8-T1			
			Abdominal				
			Back ext				
			Rectal sphincter				
			Iliopsoas	L2-4			
			Hip add	L2-4			
			Hip abd	L4-S1			
			Hip ext	L5-S1			
			Knee ext	L5-S1			
			Knee flex	L4-S1			
			Ant tibialis	L45			
			Peronei	L5-S1			
			Soleus/gastr	L5-S1			
			Post tib	L5-S1			
			Ex hall long	L5-S1			
			Toe ext	L5-S1			
			Toe flex	L5-S1			
			/edb]	L5-S1			
			AH & Feet Muscle				

Stereognosis	Deep pain	Vibration	Position	Figure drawing	Double stim	2 Points discrim	Temperature	Superfi pain	Touch		Touch	Superfi pain	Temperature	2 Points discrim	Double stim	Figure drawing	Position	Vibration	Deep pain	Stereognosis
										Upper										
										Lower										
										Head										
										Thorax										
										Abdomen										
										Saddle										



Touch = Arabic Pain = Arabic clecled Temp = Roman

Nerves: Size, Tenderness, Tinel, Phalen

Skin: Tumors, pigmentation, sudomotor, trophic

	DYSTONIA		CHOREA	
	R	L	R	L
Face				
Neck				
Trunk				
Upper Limb				
Lower Limb				

GENERAL INFORMATION: