

Fingertip And Distal Phalanx Necrosis After Self-Inoculation With The Johne's Disease Vaccine: A Case Report And Review Of The Literature.

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Abstract

In 2002, the Australian government gave approval for the use of the Gudair™ vaccine (CZ Veterinaria, Porrino, Spain)¹ to prevent the spread of Ovine Johne's Disease (OJD). The vaccine's introduction has failed to prevent the spread of OJD and currently vaccination programs are active in most Australian states. OJD is a mycobacterial infection affecting sheep, deer and goats. It is an animal wasting disease resulting in chronic diarrhoea, decreased wool production and stock loss. Accidental human injection of the vaccine can have serious and long lasting consequences. We report on a case of self-inoculation resulting in the amputation of a fingertip and distal phalanx.

INTRODUCTION

In 2002, the Australian government gave approval for the use of the Gudair™ vaccine (CZ Veterinaria, Porrino, Spain)¹ to prevent the spread of Ovine Johne's Disease (OJD). The vaccine's introduction has failed to prevent the spread of OJD and currently vaccination programs are active in most Australian states. OJD is a mycobacterial infection affecting sheep, deer and goats. It is an animal wasting disease resulting in chronic diarrhoea, decreased wool production and stock loss. Accidental human injection of the vaccine can have serious and long lasting consequences. We report on a case of self-inoculation resulting in the amputation of a fingertip and distal phalanx.

CASE PRESENTATION

A 63 year old farmer from regional New South Wales accidentally injected himself with the Gudair™ vaccine into his left middle fingertip. The needle passed through the neck tissue of a lamb and penetrated the pulp of his fingertip. The vaccination dose was delivered but, the exact quantity of vaccine injected was unknown. The patient immediately irrigated the region with water and attempted to express the vaccine from the pulp. No vaccine was seen to emerge from the needle puncture site.

He presented to our hospital 60 hours post inoculation and underwent incision, irrigation and debridement early the next morning. The patient reported pain in the entire fingertip and

felt that it had started to swell. The finger pulp looked relatively benign with a small puncture wound from the needle and minor fingertip erythema. A direct midline volar approach to the pulp was used for debridement. No vaccine was visible. After copious irrigation the incision was left open and dressed. A repeat washout and nylon closure was undertaken two days later. There was no necrotic tissue evident on this occasion. Whilst an inpatient he received intravenous antibiotic coverage with cephazolin and was subsequently discharged with a 10 day course of oral antibiotics.

The patient was reviewed 2 weeks later in clinic. He reported no pain and despite no decrease in the size of the swelling felt that his finger was improving. The wound had healed with no discharge.

Figure 1

Fig 1. 2 weeks post initial debridement



Four weeks post inoculation, he represented with a necrotic finger from the level of the distal inter-phalangeal joint. After extensive debridement the finger was observed for an additional week prior to formal terminalisation at the level of the DIP joint. The skin to the level of the PIP joint was red and inflamed and it was unknown whether this region would later necrose requiring further amputation. Histopathological specimens (from the necrotic pulp and the border of macroscopically normal and abnormal tissue) demonstrated heavy inflammatory cell infiltrate with necrosis, granulomas and multinucleated giant cells. No acid fast bacilli were isolated and all bacterial tissues cultures were negative. At 2 month follow-up, the inflamed skin had returned to its normal color and no further procedures have been required.

Figure 2

Fig 2. Post 4 week debridement. Inflamed skin approaching PIP joint. It was unknown whether this area would later necrose



Figure 3

Fig 3. 8 weeks post inoculation and post distal phalanx amputation.



DISCUSSION

Ovine Johne's disease or ovine paratuberculosis is caused by *Mycobacterium avium* subsp. *paratuberculosis*. It is present throughout the world infecting animals in Australia, New Zealand, United Kingdom, Spain, India, North America and South America. OJD was first isolated in Australia in 1980 in New South Wales and since has spread to involve all states in Australia except Queensland. The only effective vaccine is GudairTM.

The vaccine contains a killed (heat-inactivated) suspension of *Mycobacterium paratuberculosis* combined with a mineral oil adjuvant. The milky white vaccine is delivered as a 1ml subcutaneous dose into the neck or behind the ear of the animal. Half of the vaccinated animals will develop a reactive mass at the injection site and in approximately 5% this mass will form a discharging abscess. These masses may persist for years and can reach dimensions comparable to a golf ball.²

Mineral based adjuvants are considered too reactive for use in humans so given the reaction observed in animals it is of little surprise that human inoculation could produce such a severe reaction. Our patient received a needle stick injury with a contaminated needle with no macroscopic evidence of subcutaneous vaccine. Despite this apparent low volume injection, he subsequently developed an aggressive combination of an acute inflammatory reaction to the mineral base and a subacute granulomatous reaction. This resulted in extensive tissue necrosis and thrombosis of the digital vessels (observed at operation) that ultimately resulted in amputation. All necrosis was non infective in origin.

Human Gudair™ inoculation is rare in medical literature and consists of a few cases.^{3,4} Several reports are present in veterinary journals reporting varying degrees of inoculation occurring mostly in the lower limb. Vaccine reservoirs are typically hung around the neck of the vaccinator with a syringe gun to deliver the dose. When the syringe gun is dropped or dislodged from the hand it swings on it's tubing with the needle sticking into the lower limb. To date, there have been no reported cases requiring amputation. The adverse reactions observed ranged from an inflammatory reaction appearing similar to cellulitis, to large ulcers requiring surgical debridement and skin grafting. Needle scratches produced small skin ulcers that required no surgical intervention

Windsor et al.³ concluded that common to more severe reactions were a failure to appreciate the injury pathology and a delay to surgical debridement. The condition of those patients treated with oral antibiotics failed to improve which resulted in delays to surgical intervention and greater areas of necrosis.

It is believed that the mycobacterial cell wall antigens attach to oil droplets and stimulate a prolonged immune response.³ Indeed, the mineral oil also known as Freund's incomplete

adjuvant, stimulates an intense reaction alone without any antigen. Surgical debridement is the only method to remove the vaccine and should be performed as soon as practical. Migration of the oil in the subcutaneous tissues was believed to have resulted in multiple non confluent areas of necrosis in a patient's leg. To date, no one has established the role of immune suppression with corticosteroids. This may well have a protective effect in decreasing the necrotic zone.

The risks to humans is well documented in the safety manual provided by the distributors. "accidental self injection may result in a severe, intense and persistent granulomatous reaction at the site of injury. ...may last for a prolonged time. (some reports have been 6 to 24 months). There may also be general ill-health during this time."⁵

The prognosis for our patient's finger must be guarded as further reaction may occur. Similar injections of Freund's Complete Adjuvant (mineral oil with mycobacteria antigen) into the finger pulp resulted in wasting of the digit, palpable subcutaneous nodules and restricted movement of the digit that took 18 months to develop.⁶

Needlestick injury rates amongst vaccinators are difficult to measure. In the literature, values from 1 in 1000 to 1 in 500,000 can be found. A survey of Gudair™ users in Australia found one incident per 7046 vaccinations.^{3,7} However, given that 7 million vaccinations had been performed in Australia as of 2005⁸ the large numbers guarantee more cases will present in the future.

RECOMMENDATION

Whilst there is no direct evidence that necrosis severity is diminished it makes sense to debride early and closely follow up expecting the need for further surgery.

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