

## CASE REPORT

### Safety and immunogenicity of Rabies Human Monoclonal Antibody (Rabishield) in a category III rabid dog bite: A case report

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#### ABSTRACT

The purpose of this case study is to re-establish the safety and immunogenicity of Rabies Human Monoclonal Antibody in Category III dog bite. A 7 years male child presented with a lacerated wound over the left palm following bite from a suspected rabid dog. He was administered Purified Vero cell Rabies Vaccine as intra muscular regimen with Rabies Monoclonal Antibody (RMab) as per body weight. The Anti-Rabies Antibody titre was measured following RMab administration which had no side effects and was found to have Antibody levels above protective level.

#### KEYWORDS

Rabies Monoclonal Antibody, Essen Regimen, Anti Rabies Treatment

#### INTRODUCTION

Modern day Vaccines and Immunoglobulin/ Monoclonal Antibody has made the highly fatal disease, Rabies completely preventable. The mainstay of Anti-Rabies treatment following animal bite comprises of local wound care, Rabies Immunoglobulin or Rabies Monoclonal Antibody (RMab) along with Rabies Vaccine administration. The Anti-Rabies Vaccine takes 10-14 days to produce protective antibody level in an individual. The window period of this 10-14 days is taken care by administration of RIG/RMab to prevent from a deadly disease, Rabies. The cost factor of Human Rabies Immunoglobulin (HRIG) prohibits many doctors to prescribe and also the patients to purchase the same. The fear of side effects following use of ERIG is also a factor for its low use among doctors for Category III animal bite treatment. <sup>1</sup>Thus this case study on use of RMab in a Category III dog bite focuses on Safety and Immunogenicity of the newly marketed RMab named Rabishield.

#### CASE PROFILE

A male child of 7 years from Anandapur, Keonjhar reported to the physician at Cuttack with the chief complaint of being bitten by a stray dog of abnormal behavior at 8.00 pm on 15<sup>th</sup> May 2017. It was an unprovoked lacerated bite over left hand and left thigh with bleeding. It was a Category III exposure as classified by WHO categorization of animal bite injury. <sup>2</sup> The wound was thoroughly washed with soap and water by the parent of the child. He was counselled and given an option to choose among the three different rabies immunoglobulins (ERIG, HRIG, RMab) available with their cost, advantages and adverse effects. He was then treated with anti-rabies vaccines, Rabies monoclonal antibody and F Heal cream for local application. He was advised anti-rabies vaccine (Inj Zoonovac, Batch number 17GRAB016) 0.5 ml as per IM schedule on days 0,3,7,14 and 28. The child was also treated with Rabies monoclonal antibody (Inj Rabishield Batch number 1877700102) at the site of bite. The dose was calculated as per his body weight i. e 3.33 IU/KG. As the child weighed 27 Kg, a total of 89.91IU i. e 2.25 ml was administered. Out of the total required calculated RMab, 1.75 ml was infiltrated over left palm locally and rest

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0.5 ml was infiltrated over left thigh. He was also advised antibiotics (Tab. Amoxyclav 325 1 tab BD for 5 days and NSAIDS (Syp Paracetamol and Mefenamic acid 250 mg SOS) for further management. Along with the above drugs, he was asked to locally apply F Heal cream (Tritium vulgare extract and 2 penoxyethanol) at the site of bite for healing of the wound. On completion of vaccination as IM schedule on 12<sup>th</sup> January 2018, the patient was asked for anti-rabies antibody titre. The wound had completely healed with no scar marks. The tests were conducted a week later and the rabies IgG level was 17 (Normal <40 U/ml) and Rabies IgM level was 8 (Normal <40 U/ml). Hence, the reports suggested of adequate antibody production on complete treatment with anti-rabies vaccine and Rabies monoclonal antibody.

## DISCUSSION

In developing countries like India, where Government spends only 1.5% of GDP on health expenditure, cost effectiveness is a major issue. Equine rabies immunoglobulin though easily available still is a cause of concern for physicians due to its adverse effects such as anaphylaxis and serum sickness as found in the WHO- APCRI Survey in India in 2003. High cost of human RIG due to its production from human serum from immunized donors makes affordability a major issue. Alternatively, a monoclonal antibody produced from mammalian cell lines, resulted in lower cost, lesser volume and reliable source of passive antibody for rabies PEP. <sup>3</sup> However, the major challenge to its use and replacing ERIG/HRIG, was the adequate production of Rabies antibody and an equivalent level of protection which can be overcome by more of phase IV post marketing surveillance of the product in multi-centric studies. However, we found a protective level of antibody production after RMAb administration in the present case. Hence, Monoclonal Rabies Antibody offers a reliable solution to address the cost, supply and safety issues as compared to the blood derived RIG. <sup>4</sup> Our case had an unprovoked bite by dog on both upper and lower limb which was similar to the findings of DM Satapathy et al and Kaware *et al.* <sup>4,5</sup> We followed up the case for day 0,3,7,14,28, 90 days and no adverse effect was reported which was contrary to the findings of DM Satapathy among 53 patients at VIMSAR, Burla, Odisha. <sup>4</sup>

## CONCLUSION

Rabies Monoclonal Antibody thus stands out to be a new arena of scope against the safety and cost issues of ERIG and HRIG respectively. Thus RMAb has proven to be an apt alternative to the presently available blood derived immunoglobulins.

## ACKNOWLEDGMENT

We highly appreciate the cooperation of the child's father to have understood well the purpose of the investigation and willfully accepting to carry out the tests for antibody level following Rabies Monoclonal Antibody administration.

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