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RESEARCH ARTICLE

EFFECT OF ALUMINUM CONTENTS ON TETANUS TOXOID ADSORBED VACCINE'S POTENCY

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ABSTRACT

Vaccines are being used from centuries ago. To manufacture and process vaccines, different types of materials are used as adjuvant in routine. Mostly in tetanus toxoid vaccine, adjuvant is aluminium base. In this study, we check only aluminium content with relation to potency of tetanus toxoid vaccine.

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INTRODUCTION

Vaccines were first introduced more than 200 years ago and since then have played a key role in the reduction of morbidity and mortality caused by infectious diseases (Gregorio *et al*., 2013). Quality of vaccines can be enhanced by using adjuvants that can selectively stimulate immunoregulatory responses (He *et al*., 2000). Hundred of materials have been used as adjuvant and used in realistic vaccination (Lindblad, 2004; Cox and Coulter, 1997). Calcium phosphate, oil emulsions, nanoparticles and molecular assemblies also have some use in human vaccinations (Powell, 2015; Siber and Gupta, 1995). Aluminium phosphate and auminium hydroxide used as an adjuvant in many vaccines licensed by the US Food and Drug Administration (Baylor *et al*., 2002). Aluminium hydroxide (alum) is most commonly used chemical as adjuvant in human such as tetanus toxoids and veterinary vaccines also (Hogen Esch, 2002). Adjuvant should be selected for routine use (Islam and Haneef, 2016). Adjuvants help antigen to elicit an early, high and long-lasting immune response with less antigen, thus saving on vaccine production costs (Siber and Gupta, 1995). Aluminium based adjuvants are the only successful materials being used globally (Petrovsky and Aguilar, 2004; He *et al*., 2015). Reason behind of the most widely used aluminium based adjuvants are their immunopotentiation and safety records since 1920s (Lindblad, 2004; Ghimire, 2015). With the use of adjuvants immune response can be selectively modulated to major histocompatibility complex (MHC) class I or MHC class II and Th1 or Th2 type, which is very important for protection against diseases caused by intracellular pathogens such as viruses, parasites and bacteria (*C.tetani*) (Siber and Gupta, 1995). Alum also activates caspase-1 and induce secretion of mature Interleukin-1β and Interleukin-18 (Li and Nookala, 2007). In vivo purified TT and $AlPO_4$ adjuvant elicited vascular permeability-increasing and toxic effects to macrophages [Siber and Gupta, 2002; Goto *et al*., 2002]. Amount of Adjuvants use depends on pH, nature and amount of anions present in mixture (Gupta *et al*., 1995). Potency of adjuvants reliant upon the physio-chemical uniqueness and electrostatic forces between adjuvant and foreign agent (Gupta, 1998). We selected this parameter only because, Aluminum is frequently used as an adjuvant in the manufacturing of Tetanus Toxoid adsorbed Vaccine and also in other vaccines.

MATERIALS AND METHODS

We took 53 batches of T.T (from T.T-122-12 to T.T-140-12 and from T.T-01-15 to T.T-34-15) from T.T Laboratory of National Institute of Health Islamabad, Pakistan. All the 53 lots sent for Q.C testing in quality control department of above mentioned institute. Following Table.1's values finally found concerned result.

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Table 1.

S.No.	Aluminum Content (mg/dose)	Potency of T.T (IU/dose)
01	0.60	172.77
02	0.62	136, 152,171, 144, 144
03	0.65	152, 143, 153, 152,160, 161,160, 160, 162, 144,143, 143,160, 149, 171,
04	0.67	135, 151, 172, 171.8, 172.6, 160, 150, 169, 160, 150, 153, 161, 152,162,152
05	0.70	172.5, 172.6, 152, 169, 160, 160, 160, 159,159, 161,162
06	0.73	170,149
07	0.78	171
08	0.84	169
09	0.86	170.39
10	0.87	170

RESULTS

In our study, at 0.60 mg/dose of Al. content, immunogenicity of the vaccine is maximum which is 172.7 IU/dose. While at highest level of Aluminum content (0.87 mg/dose), effectiveness of vaccine is 170 IU/dose. Very clearly, it is showing that Aluminium Content directly have no effect on potency of T.T vaccine. These results show that the potency of product may also depend on other factors like temperature etc, and solely aluminum contents do not produce direct effect on potency.

DISCUSSION

As the potency of product may also depend on other factors, so to judge actually what is the main parameter having direct relation to potency of tetanus toxoid vaccine, further studies can be done. Our study regarding aluminum contents do not produce direct effect on potency.

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