

# A telephone interview to assess alkylglycerols effectiveness in preventing influenza-like symptoms in Modena, Emilia Romagna, Italy, in the season 2009-2010

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## Abstract

**Objectives.** Influenza has been related to high morbidity and, in children and adults over 60 years, high mortality. It brings a great burden on medical centers, which have to sustain and provide numerous patients with continuous care, especially in winter when influenza reaches the highest peak. Vaccination is still the main preventive measure to avoid serious epidemics. We propose a retrospective phone interview to assess the effect of alkylglycerols, taken immediately before the peak of influenza, to boost the immunitary system.

**Materials and Methods.** A group of patients from Modena (Emilia Romagna, Italy) were included in this study. Fifty two patients were instructed to take Alkyrol®500 per os, twice a day, during the two principal meals. Sixty patients were chosen from the same familiar nucleus of the treated subjects and they were used as controls since they all had undergone traditional vaccination against H1N1 influenza.

**Results.** Forty two out of 52 patients, treated with alkylglycerols did not report any influenza-like symptoms, while 10 out of 52 showed mild influenza-like symptoms which disappeared after 48-72 hours without the use of any drug. In the control group, 20 out of 60 patients did not show any influenza-like symptoms, while 40 out of 60 patients did.

**Conclusions.** Alkylglycerols may bring therapeutical benefits, support the immunitary system and prevent influenza-like symptoms. Further clinical studies are needed, not only to understand if alkylglycerols can be a valid alternative to vaccination to prevent influenza, but also to study their possible application to treat other pathological conditions. *Clin Ter 2011; 162(4):e115-118*

**Key words:** alkylglycerols, influenza, immunitary system, survey/interview, telephone, vaccination

## Introduction

Seasonal influenza, caused in humans by two subtypes of influenza virus A and one of influenza virus B, can be defined as an acute and recurring respiratory disease occurring in

particular during the winter months. It has got high morbidity rates for people of all ages and, particularly, high mortality rates for children, the over 60s, patients with chronic illnesses and pregnant women. Vaccination is the best prevention strategy, although the influenza virus A, that affects humans, mutates easily. It often makes new antigenic variants of each subtype emerge, thus requiring the inclusion of such variants in annual vaccines so that it can provide immunity to people against serious epidemics (1).

Novel influenza A (H1N1) spread worldwide leading the World Health Organization to declare a pandemic on June 11, 2009. This pandemic H1N1 influenza 2009 was associated to an overwhelming burden on medical structures and resources and a consequent negative impact on mortality and morbidity (2).

Shark liver oil (SLO), containing both alkylglycerols (AKG) and squalene, has been widely used as an ancient remedy among the fishermen along the west coast of Norway and Sweden. It has been widely used by Scandinavian folk medicine for wound healing, treatment of the respiratory and alimentary tract irritations and lymphadenopathy. Recently, we have reviewed (3) the literature concerning both the experimental and clinical applications of AKG reporting their ability to act as immunity boosters among other beneficial effects in several pathologies. In fact, an experimental study has shown an increased response of neutrophils towards bacteria, an increased level of C4 component of complement in blood and the rise of total antioxidant status of serum. The same study has also shown the predominance of Type 1 cytokine IFN-gamma and TNF- $\alpha$  and IL-2 production by peripheral blood mononuclear cells after SLO intake (4). Another study involving 10 adult healthy volunteers, treated with AKG per os for one month, has demonstrated an increase of C1q level and CD4/CD8 ratio from 1.3 to 1.8 and has polarized Th1/Th2 lymphocyte cytokine secretion towards Th1. During this study no side effects have been observed supporting the idea that AKG are effective innate immunity supporting agents that are also safe (5).

Telephone surveys/interviews have been widely used in several epidemiological studies to control the prevalence of influenza in several countries in Sweden (6), assess the intention to receive pandemic influenza vaccination (7), and determine the effectiveness of vaccination in the elderly in a community in Italy (8). They have also been used in the context of drug administration outcomes, i.e. to examine the indications, baseline characteristics, duration of use, and clinical outcomes for older primary care patients prescribed benzodiazepines (9).

Basing on the existing literature about the use of AKG to support the immunitary system and their safety (3), we designed a preliminary study based on a phone interview. It assessed the possibility of AKG to boost the immunitary system promoting the human body self defence and allowing the patients to avoid influenza-like symptoms (fever, common cold, sore throat, shaking chills, short-winded, runny nose, muscle pain, in the back, arms or legs, cough). The clinical effect of AKG was evaluated referring to the pandemic flu of the winter season 2009/2010, in the Healthcare District 16 [15,000 inhabitants; (Fig. 1)] in Emilia-Romagna, a region in the north of Italy, precisely in the city of Modena. The Healthcare District 16 includes four public general hospitals, i.e. the Azienda Ospedaliera Universitaria Policlinico di Modena and two private clinics. The incidence of influenza in Emilia Romagna, (Italy) in the season 2009-2010, is shown in Figure 2.

## Materials and Methods

### Patients

A hundred and twelve volunteers, aged between 40 and 60 years [ $52.2 \pm 6.42$  (mean $\pm$ sd)] from Modena and Reggio Emilia (Italy), participated to the study. Fifty two patients were instructed to take Alkyrol<sup>®</sup>500 (capsules 500 mg – 20% Alkylglycerols - Eurohealth – Italy) per os, twice a day, during the two principal meals. Sixty patients were chosen from the same familiar nucleus of the treated subjects, and they were used as controls since they all had undergone traditional vaccination against H1N1 influenza. All the patients had a



Fig. 1 Health-care district 16 (Modena, Italy).

phone interview in the month of January. The patients who had to take Alkyrol<sup>®</sup>500 (treated group) started the therapy on 1<sup>st</sup> of August 2009 and finished on the 31<sup>st</sup> October 2009, i.e. immediately before the highest peak influenza period (November–December 2009).

### Telephone survey/interview questions

We are calling from the University of Modena regarding the study you volunteered for and we would like to ask you a few questions\* (modulated from Malone et al. [10]):

1. Did you have any influenza-like symptoms?
2. Did you complain of high body temperature (fever)?
3. Did you have shaking chills?
4. Did you have body aches and muscle pain, in the back,

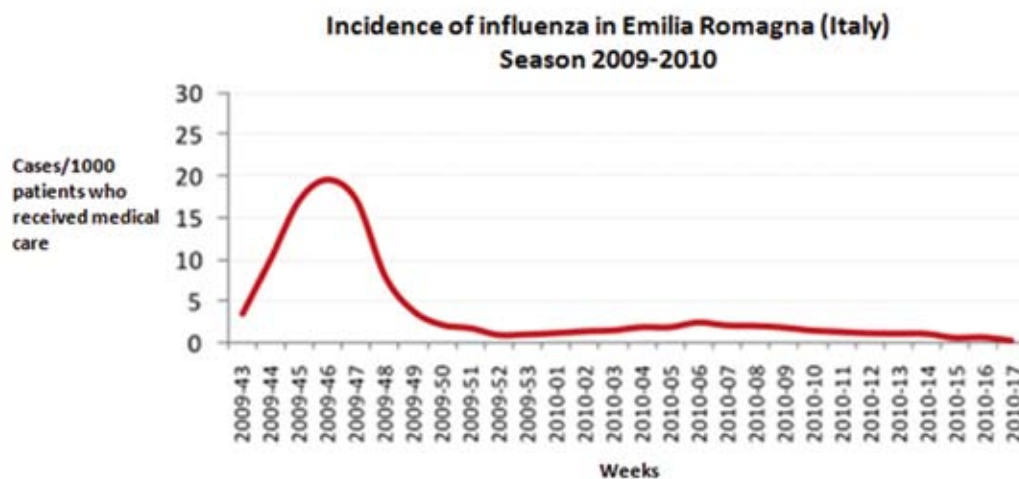


Fig. 2. Incidence of influenza in Emilia Romagna (Italy) in the season 2009-2010 (from [www.salute.gov.it](http://www.salute.gov.it) accessed on 6th June 2010).

- arms or legs?
5. Did you have a cough?
  6. Did you have a runny nose?
  7. Were you short wind?
  8. Did you have a sore throat?
  9. How long did you have these symptoms

\* Questions 1–9 were asked to all the study volunteers.

Only those ones who answered “yes” to one of the first 8 questions, were asked the last one.

## Results

Basing on the preciously described questionnaire we have collected the following results (Fig. 3):

### Treated group

- 42/52 patients did not report any influenza-like symptoms.
- 10/52 patients showed mild influenza-like symptoms which disappeared after 48-72 hours without the use of any drug.

### Control group (Vaccinated)

- 20/60 did not show any influenza-like symptoms.
- 40/60 had influenza-like symptoms (they might have not been H1N1 related). In particular 4 patients showed bronchial and pulmonary involvement, 2 were hospitalized and 10 had influenza-like symptoms for more than 8 days.

## Discussion

In this paper, we describe the use of the phone survey/ interview as a tool to conduct a preliminary study to assess the efficacy of the natural compound Alkyrol®. This study has involved subjects divided into two groups, i.e. a group treated with Alkyrol® therapy and a group undergone vaccination. Although based on a phone interview, which implies the patient's symptoms self-assessment, these results are encouraging since Alkyrol® therapy seems to boost the immunitary system providing a valuable tool to fight influenza during its pandemic period. Further pathological conditions may also benefit from the administration of this compound and they may be worth to be investigated. In fact, as we have previously reported (3) this compound has also been studied in the treatment of bacterial and fungal related infections. It is a first preliminary study and our findings need to be confirmed by further clinical trials involving larger cohorts and basing on clinical examinations in order to confirm the therapeutical effectiveness of AKG and to evaluate their beneficial and side effects.

### Ethical Approval

No ethical approval was required for this study.

### Competing Interests

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

### Funding

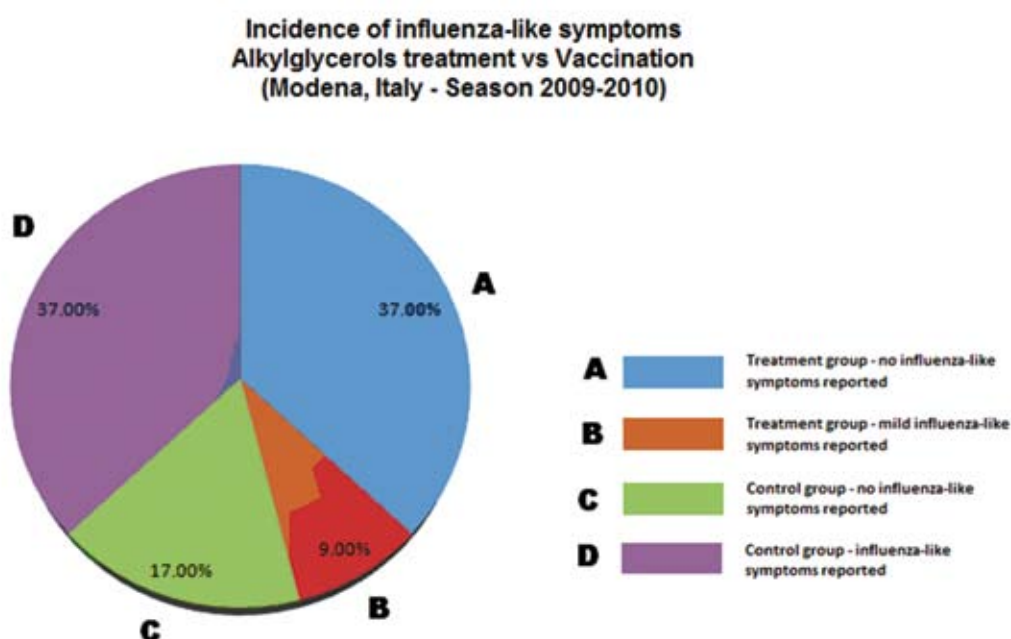


Fig. 3. Incidence of influenza-like symptoms in the two patients' groups (alkylglycerols treatment vs. vaccination) according to our telephone interview in the season 2009-2010.

The authors hereby certify that all work contained in this review is original work of Tommaso Iannitti, Stefania Capone and Beniamino Palmieri. The Authors claim full responsibility for the contents of the article. The authors contributed equally to this work. This article was not supported by grants.

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