

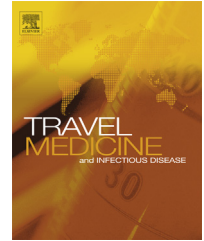


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Effects of pre-deployment loperamide provision on use and travelers' diarrhea outcomes among U.S. military personnel deployed to Turkey

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KEYWORDS

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Summary Objective: This study assessed the efficacy of education and self-treatment with loperamide on diarrhea morbidity and healthcare utilization in a deployed military setting.

Method: In this prospective, controlled study, volunteers from military personnel deployed to Incirlik Air Base received either travelers' diarrhea education (non-loperamide group) or education plus a supply of loperamide (loperamide group). Volunteers were surveyed to determine frequency and outcomes of diarrheal illness.

Results: 109 deployed personnel were enrolled with 48 assigned to the loperamide group, and 61 to the non-loperamide group. Overall, 41 (38%) service members had at least one diarrheal episode. Only 10 (9%) service members sought treatment from a healthcare provider and the distribution was similar in both groups. Loperamide use for self-treatment was more common in the loperamide group (85%) vs. (57%), [$p = 0.02$] but use of antibiotics was similar in both groups (loperamide (30%) vs. non-loperamide (20%).

Conclusions: Provision of loperamide and education did not significantly affect healthcare utilization or antibiotic use to manage diarrheal episodes, when compared to education

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alone. Further prospective studies will either need a very large patient population to power them or should use other primary end points such as a functional assessment in addition to seeking care.

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Background

Acute infectious diarrhea is the most common illness affecting deployed military personnel. The short-term morbidity, increased healthcare service utilization, and loss of work-hours can create transient critical shortages in deployed forces. One strategy to mitigate the impact of travelers' diarrhea (TD) is through timely and effective treatment [1]. Published guidelines on the general approach for the treatment of TD in US military personnel exist, but these need to be optimized for military deployments and overseas operations [2,3].

Traveler education on self-treatment (with provision of medication) is an acceptable strategy for those who are at risk for TD and feel comfortable with self-diagnosis and treatment. A study among 784 Americans who traveled for less than 90 days and received pre-travel advice found that 83% of travelers indicated self-treatment was effective, and there was no difference in response with anti-motility agents alone, antibiotics alone, or in combination [4].

In the U.S. military, self-treatment with provision of medication and pre-travel education has not been a widely implemented practice. There are several potential advantages and disadvantages to self-treatment for military personnel. Self-treatment of mild cases with anti-motility agents could theoretically result in timelier therapy (i.e. members would not have to wait and go to sick call), disease impact could be minimized, improved antibiotic stewardship, and unnecessary medical system utilization could be avoided. However, balancing the potential advantages are concerns about inappropriate self-treatment, side effects, treatment-failure, and subsequent illness prolongation [5]. More information is needed to inform the decision on guidelines for self-treatment of mild diarrhea in deployed US military populations.

This clinical trial was designed to evaluate if the provision of loperamide to U.S. military personnel at the outset of a deployment would reduce the impact associated with travelers' diarrhea (as measured by self-reported diminution of ability, time lost from work, and healthcare resource utilization, including antibiotic therapy) compared to education alone.

Methods

The Naval Medical Research Unit-3's Institutional Review Board in Cairo, Egypt approved this study prior to commencing. US soldiers deployed to the Incirlik Air Base, Turkey from May 2005 until April 2006, were randomly assigned to receive education regarding TD (education group) or education and loperamide for self-administration (loperamide group) along with supplemental education on its use. Exclusion criteria included a history of allergy to

loperamide, active duty military member on flight status, or if the subject was unwilling to comply with study procedures. All groups were addressed by one of the study personnel on-site during the mandatory in-briefing that all members receive. During this briefing, study personnel provided a standardized presentation on TD in the military which specifically addressed causes, prevention, and treatment. Education to minimize risk of acquiring TD consisted of avoiding high risk food, proper food and beverage choices, and personal hygiene. Although the benefits of this type of education have not resulted in a reduction of disease incidence [6], it was presented for comprehensiveness along with the perils of dining in public eateries due to poor preparation and handling of food. Afterward, the study was described to potential subjects and those volunteering to participate asked to sign a consent form and give appropriate contact information for follow-up.

Subjects, by arrival cohort, were randomly assigned to the education-only or education plus loperamide groups. For those who were allocated to the loperamide group, study personnel provided an educational presentation along with a personal supply ($n = 10$ caplets) of loperamide. Researchers instructed the subjects to use loperamide without seeking medical advice only for mild diarrhea. They were told to go to the clinic for moderate or severe diarrhea related symptoms. These include over four loose stools in a 24-h period, fever, dehydration, hematochezia, or any other concerning symptoms for a complete assessment by a healthcare provider. Study participants that developed moderate, severe, or prolonged diarrhea or failed self-treatment, reported to an on-site medical treatment facility. Study personnel reviewed all encounters and those who presented with diarrhea were contacted to complete a short survey. Prior to leaving Incirlik, or at 90 days (whichever came first), all study participants were contacted and completed a survey questionnaire either in person or via phone call detailing their diarrhea history, self-treatment and medical service utilization during their deployment (Fig. 1).

Statistical analysis

Descriptive analyses were performed on demographic characteristics of the participants in each of the two groups to assess for any baseline differences between these two groups. Our primary endpoints were number of visits to a medical treatment facility among those who had a TD episode as well as the satisfaction with self-treatment. Self-treatment outcomes between the groups were compared by evaluating the proportion of episodes that were self-treated over total number of episodes meeting the case definition. In addition, the proportion of diarrhea events that required treatment by a physician were

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