

Probiotic supplements do not prevent antibiotic-associated diarrhea in elderly patients

August 7 2013

Some previous research has suggested that probiotic preparations—similar to those available in popular probiotic yoghurt drinks—might reduce the incidence of antibiotic-associated diarrhoea (AAD), and prescribing probiotics for elderly patients on antibiotics has become routine practice in some institutions. This is the largest trial ever to assess the effect of such supplements on AAD in a real-life setting.

The mechanism by which antibiotics result in <u>diarrhoea</u> is not well understood, but is thought to be due to antibiotics disrupting the body's normal complement of so-called 'friendly bacteria'—the population of bacterial organisms ('gut flora' or 'microbiome') which live in any healthy person's digestive system. It has been suggested that probiotic supplements might be able to reduce the incidence of AAD by restoring the <u>gut flora</u> to its normal constituency after disruption by antibiotics.

A team of researchers led by Professor Stephen J. Allen, of Swansea University in Swansea, UK, recruited nearly 3000 people to the PLACIDE trial, which took place in five hospitals located in south Wales and northeast England. Study participants were all hospital inpatients aged 65 or over—the age group for which AAD tends to cause most problems—and had been prescribed one or more antibiotics.

Around half of the study participants were asked to take one capsule containing a fixed dose of live bacteria (two strains of *Lactobacillus*



acidophilus, Bifidobacterium bifidum, and *Bifidobacterium lactis*) per day for 21 days, and between antibiotic doses where possible, while the remaining <u>study participants</u> in the <u>control group</u> received an identical placebo capsule, with the same dosing instruction.

The researchers analysed <u>stool samples</u> from around half of the patients who experienced diarrhoea, to determine whether their stomach upset had been caused by antibiotics, or by something else. This analysis also allowed the researchers to track how many participants' AAD was caused by *Clostridium difficile*, a particularly severe diarrhoea-causing infection which can be life-threatening, and which some previous research has suggested might be especially amenable to treatment with probiotic supplements.

However, the researchers found that the probiotic supplement did not appear to lessen the incidence of diarrhoea in the study group, with around 1 in 10 members of both study and control groups reporting AAD. Frequency and severity of diarrhoea were similar in both groups, and both groups scored similarly in surveys to assess quality of life during the trial.

Furthermore, the number of people whose diarrhoea was caused by *C*. *difficile* was similar in both groups, leading the researchers to conclude that there is no evidence to support a beneficial effect attributable to the probiotic supplements tested.

According to Professor Allen, "Although some existing studies of the effect of probiotic supplements on AAD have suggested that these supplements might effectively reduce the incidence of AAD, these results were based mostly on small trials conducted in single locations, many of which gave inconsistent results which are difficult to incorporate in meta-analyses."*



"Our study is by far the largest trial so far to assess the effects on AAD of so-called <u>probiotics</u>—which might better be termed microbial preparations, given the uncertainty over whether they are indeed beneficial to health—and the results do not support the use of these preparations to reduce rates of AAD in older inpatients."*

Despite this, the authors point out that the lack of understanding of the way that antibiotics cause diarrhoea means that the effects of microbial preparations on AAD may warrant further investigation. In particular, it is possible that specific strains of some 'friendly' bacteria may possess specific anti-diarrhoeal mechanisms, or that a patient's illness, diet, age, and frailty might modulate the effects of probiotic supplementation.

In a linked Comment, Dr Nick Daneman, of the Sunnybrook Health Sciences Centre, University of Toronto, Canada, points out that although the PLACIDE trial does seem to contradict results from some existing meta-analyses of the effect of probiotics on AAD, especially diarrhoea caused by *C. difficile*, this doesn't necessarily invalidate the results. He adds that, "At the very least, the low absolute risk reductions in PLACIDE question the cost-effectiveness of probiotics... PLACIDE is a large and rigorous negative study, and we must judge whether it can tip the balance of probiotic evidence."

More information: <u>www.thelancet.com/journals/lan ...</u> (13)61218-0/abstract

Provided by Lancet

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