PrescQIPP Community Interest Company

Probiotics

In England and Wales, over £600k is spent annually on probiotic preparations (NHSBSA January to March 2020). QIPP projects in this area are aimed at reviewing the continued need for a probiotic preparation and discontinuing prescribing of preparations due to insufficient good quality evidence for their use. This bulletin reviews the place in therapy of probiotics and offers guidance and support material for organisations considering reviewing probiotic prescribing as a QIPP project.

Recommendations

- Review all patients prescribed probiotic preparations (including VSL#3® and Vivomixx®) for any indication and discontinue prescribing, with an explanation that there is insufficient evidence to support their continued use.
- Patients wishing to continue taking probiotics should purchase them over the counter but should be advised about the lack of evidence of clinical benefit.
- As with all changes, these should be tailored to the individual patient.

National guidance

Probiotic preparations are not eligible for prescribing on an NHS prescription and are no longer listed in Part XV (Borderline Substances) in the Drug Tariff[1] as there is a lack of robust evidence to support their use.[2]

NHS England have classified probiotics as items of limited clinical effectiveness and stated that they should not be routinely prescribed in primary care. This is because there is insufficient evidence to support the prescribing of probiotics within the NHS for the treatment or prevention of diarrhoea of any cause.[3]

In addition, the NICE clinical guidelines for the management of ulcerative colitis and Crohn's disease have not covered use of probiotics for either condition.[4,5]

In terms of the use of probiotics for treating or preventing Clostridium difficile infection or antibiotic associated diarrhoea, there is insufficient robust evidence to support their use. Consequently, the Public Health England updated guidance on the management and treatment of Clostridium difficile infection states that it cannot recommend the use of probiotics.[6]

Certain probiotics were previously listed as borderline substances in the Department of Health Drug Tariff and, as such, were permitted to be prescribed on the NHS for the specific indication of ileoanal pouchitis. However, as of November 2018, these products are no longer eligible to be prescribed under an ACBS (Advisory Committee on Borderline Substances) indication as a review concluded that the evidence did not sufficiently demonstrate that the products are clinically effective.[1,2]

Clinical effectiveness

Probiotics are not regulated as medicines and are therefore not subjected to the same strict regulations. This can lead to variation in preparations that make it difficult to standardise treatment.

A British Dietetic Association systematic review of the use of probiotics in the management of irritable bowel syndrome in adults found that symptom outcomes for dose-specific probiotics were heterogeneous and concluded that specific probiotic recommendations for IBS management in adults were not possible at this time.[7]

A Cochrane review investigated the use of probiotics for the induction of remission in active ulcerative colitis. They assessed the efficacy of probiotics against both placebo and standard medical treatment of 5-aminosalicylates, sulfasalazine or corticosteroids. None of the included studies reported any statistically significant differences in remission or clinical improvement rates between probiotic and placebo or active comparator groups.[8]

A further Cochrane review in May 2019 concluded that the effects of antibiotics, probiotics and other interventions for treating and preventing pouchitis are uncertain and that well designed, adequately powered studies are needed to determine the optimal therapy for the treatment and prevention of pouchitis.[9]

There is currently insufficient robust evidence of effectiveness for probiotic preparations for any indication.[3]

Safety

There is no requirement for supplements to prove their efficacy in order to be made available for sale. In addition, there is also no requirement for them to prove that they are safe.

The use of probiotics has not been extensively evaluated and therefore there are some concerns around the safety of probiotics in disrupting the gut microbiome, the potential to transfer antibiotic resistance genes or cause serious adverse effects, particularly in patients who are already immunocompromised.[10]

There is also some concern over the potential contamination of these unregulated products containing live microorganisms, based on a case report in 2014 of an infant fatality resulting from a contaminated probiotic supplement.[11]

Patient factors

Probiotic preparations are available to purchase over the counter as supplements but patients should be advised of the lack of sufficient evidence to support their use.

Alternative options

Alternative standard treatments should be used appropriate to the indication being treated and in accordance with national guidance, where available (although clinicians may choose other options according to the clinical need of the patient).

Savings

There is a significant cost associated with probiotic preparations. In England and Wales, around £600k is spent on probiotics per year (NHSBSA January to March 2020). **Discontinuing these prescriptions could release savings of up to £600k nationally. This equates to savings of £965 per 100,000 patients.**

Summary

There is insufficient robust evidence to suggest that probiotics are safe or effective for any indication. In addition, they represent a significant cost to the NHS. Consequently, probiotic preparations are not recommended for prescribing. This includes the brands VSL#3® and Vivomixx®, which are no longer eligible for prescribing under ACBS.

References

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Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-262-probiotics/
Implementation tools	
Data pack	https://data.prescqipp.info/#/views/B262_Probioticsupdate/FrontPage?:iid=1

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