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EDITORIAL

Longstanding 'outlet challenge'

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The review article by How et al. provides an overview of currently available anal insert devices on the market [1]. These products are, in principle, physical stoppers placed in anal canal or rectum to prevent leakage of stool. There are various products in different shapes, sizes, and materials available for faecal incontinence management in Europe, particularly at a community level or as one of the conservative treatments provided by a specialist continence nurse. The article is well written and the authors should be commended for giving a good overview and outlining the details.

One of the earliest inventions and the longest standing product, is the Coloplast anal plug, which expands as it comes in contact with liquid [2]. Its cup shape appears suited for collecting liquid and the attached string allows easy removal. However, the mere presence of this device at the outlet seems to cause a fair amount of discomfort in some patients. Renew Anal Insert was devised to overcome this problem using softer silicone and having franges at both ends to seal the anal canal [3]. Patients used to a larger anal plug find this product insufficient to stop leakage and having to pick this device from the toilet bowl seems to be quite off-putting for some. Other products described in the article include the Eclipse system which is a device inserted into the vagina and is relatively new. It is designed to compress the anorectum externally from vagina and is only applicable in women. Reported outcomes are limited to very short term. There are other devices that are in the pipeline and may be on the market in the near future.

The main challenge of developing these devices is to give the stopper enough strength to physically stem stool from coming out whilst makes it as comfortable as possible for patients. Stool consistency is mixture of solid and liquid, it comes out with a certain force due to bowel and sphincter contraction and the anus is a sizeable orifice. These are a few of the reasons why using the concept of similar devices for urinary incontinence or menstrual bleeding does not necessarily translate to successful innovations in faecal incontinence. Anal mucosa is a sensitive region which makes it difficult for a foreign body to be accommodated comfortably. It is simply too difficult for a soft enough device that can be tolerated comfortably, to withstand the pressure and stem the flow. It is important to consider how these devices could be removed with minimal inconvenience.

The major limitation to understanding the utility of these devices is lack of data in the literature. The review article mentioned above included only 13 studies, most with a small number of patients. All 13 studies were conducted as research projects at specialist centres, which is probably not the most appropriate setting for this type of product to be used. It is more suitable for these devices to be tried in the community, prior to referral to specialists. The availability of the products in each country/region is different and thus, findings are not always generalisable. Data synthesis in a review article does not make up for the shortage and poor quality of studies in this field.

Many of the earlier studies focused on reporting selection criteria, and looked into findings from anorectal physiology testing, number of incontinence episodes or scores as potential predictive factors of outcome. However, these data are not particularly relevant as it is unlikely that all patients will need specialist assessment prior to trying out one of these products to find out whether they like to use it. Patients stop using the devices if they find them not helpful or uncomfortable or inconvenient in their daily life.

In fact, the focus of our attention when assessing these devices should be on users' experience. Whether they understand the concept of using this device, easiness of retrieving the device after use, whether they accept cables/strings attached with an additional sensor/device, what degree of inconvenience they experience, are likely to be crucial in regard to long-term use and to have a bigger impact on product development in the future.

As the authors mentioned, the greatest value of these devices is probably the reassurance they give patients. It

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does not matter whether the devices are effective either as stand-alone or adjunct to other protective measures. What is most important is whether this device fit in to their life as a symptom management tool. We need better designed studies which evaluate anal insert devices at the community level and report on patients' perspectives.

Compliance with ethical standards

Conflict of interest The author declares no conflict of interest.

Ethical approval Not required.

Informed consent Not required.

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