

The Disappointing Performance of the new „Magnetic Sphincters”: a Wrong Idea or a Wrong Realization?

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In these last years devices based on magnetic activity have been proposed and marketed to reinforce weak gut sphincters, as the lower esophageal sphincter (LES), to prevent gastroesophageal reflux (GER) [1], and the anal sphincter to prevent fecal incontinence [2], with the purpose of replacing previous surgical solutions. However, these artificial sphincters have revealed some drawbacks and inadequacies that sap the validity of this innovative idea.

The device for LES, also called „magnetic collar”, consists of a chain of magnets interlinked between themselves with titanium wires that sliding through holes allow the magnets to attach and detach, so tightening or widening the collar around the cardia, which, consequently, is closed or opened. The first results demonstrated that the device is able to decrease the esophageal acid exposure and increase LES pressure in patients with gastroesophageal reflux disease (GERD) improving the GER related quality of life, but 42% of patients continued to have GER and 30% esophagitis at one year [1]. In addition, 68% of the patients developed postoperative dysphagia, which in 27% of cases requested esophageal dilation and in some cases removal of the device. The cause of the device dysfunction could lie in a progressive encapsulation in fibrous tissue, as observed in a swine model 44 weeks after

implantation [3], and also in human cases where the device was removed [4]. Fibrin deposition around the wires could have hampered the movements of the magnets blocking the „magnetic collar” in a closed or open position causing, respectively, dysphagia or GER. However, despite the block in an open position the device may continue to prevent GER with a mechanism similar to that of the Angelchik prosthesis [5], a collar made of silicone surgically fixed around the distal esophagus, largely used in the eighties and afterwards withdrawn from the market for more or less severe complications [6]. The maintenance of the antireflux activity probably is due to the posterior “padding” with compression of the “collar” on the posterior wall of the distal esophagus, with occlusion of the lumen, as the Angelchik prosthesis does [7]. However, this compression on the esophageal wall may be the cause of an esophageal erosion [4].

The “magnetic collar” was adapted to be inserted at the level of the anal sphincter in patients with anal incontinence [2, 8], but did not show a better performance than other methods for incontinence, such as artificial bowel sphincter (ABS) [9] and sacral nerve stimulation (SNS) [10]. In fact, the preliminary report [2] showed an improvement at 6 months after operation in only 5 of 14 patients with an average increase of only 12 mmHg in anal resting pressure, whereas in another study [8], the Wexner score decreased only in about 50% of 19 patients controlled at 6 months with problems of difficult evacuation in some patients [2, 8]. These disappointing results could be explained also in this case by the fibrous tissue encapsulation of the moving parts of the device [3], that can remain blocked in an open or closed position, causing, respectively, incontinence or stenosis.

However, another way of exploiting the magnetic force for reinforcing the weak sphincters was devised in 2006 [11] in a bench study where two magnetic small plaques were applied in opposite positions around the wall of a rubber tube with opposite polarities facing, so they attracted one other closing the lumen of the tube, and were also able to detach themselves when the endoluminal pressure increased above the force of attraction. These small plaques were able to be surgically inserted around the cardia or the anal sphincter making up a “magnetic flap valve” with a dynamic closure sufficient to stop the flux of contents, without the risk of a block of magnets in open or closed position by fibrosis, because they were separated by the gut lumen. In an experimental study [12], two small magnetic plaques were implanted on both lateral sides of the

anal canal between the internal and external anal sphincters of a swine anatomical preparation, with opposite polarities facing. The endoanal pressure measured with a manometric catheter showed values depending on the attraction force of the magnetic stuff: it was 79.7±13.1 mmHg with neodymium magnets, 43.1±5.6 mmHg with ferrite magnets and 21.6±4.6 mmHg with plastoferrite magnets. In another experimental study [13], the cardia of a swine esophago-gastric specimen was maintained closed by two small magnetic plaques made of plastoferrite implanted by means of a special endoluminal device in the submucosa close to LES with opposite polarities facing. This device generated a high-pressure zone of about 14 mmHg at manometry, that could be increased with stronger magnets. Alternatively, the small magnetic plaques may be simply surgically fixed externally to the wall of the lower esophagus at the LES level with proper stitches and/or biological glue.

In conclusion, we believe that the responsibility of the not so exciting results of the “magnetic sphincters” at present available on the market does not lie in this innovative idea, but in its realization, which does not take into account the pathophysiology of the tissues around the inserted device. This in fact creates a fibrotic reaction progressively hampering the activity of this kind of “magnetic sphincters”. On the other hand it could be possible to create a “magnetic flap valve” with small plaques adapted in format and dimensions, covered by a biological sheet and adequately fixed around the incompetent sphincters, to prevent gastroesophageal reflux and faecal incontinence, without the risk of a block of magnets by the fibrosis. We believe that it is worth considering experiments with this system *in vivo* in animals and then in patients to evaluate if it works as expected and to see if there are further complications.

Conflicts of interest: No conflict to declare.

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