

# Colon capsule endoscopy diagnoses 64 percent of total polyps detected by conventional colonoscopy

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Capsule endoscopy for exploring the colon in a minimally invasive manner diagnoses 64% of all lesions located by means of conventional colonoscopy. According to a study published in *The New England Journal of Medicine* - the specialised medical journal with greatest international impact -, the new device would need technical improvements to achieve similar efficacy to the conventional procedure undertaken with a colonoscopy and to date considered a "gold standard" technique for this medical discipline, given that this is what currently provides the most reliable results.

It has to be added that, moreover, conventional <u>colonoscopy</u> enables the undertaking of a diagnosis of the colon as well as practicing therapeutic procedures, such as the in situ extirpation of polyps during exploration or the obtaining of a biopsy when required.

Capsule endoscopy of the colon explores the large intestine in a minimally invasive manner, not being necessary to admit patients to hospital, nor to sedate or anaesthesise them; neither is any tube or air needed nor radiation.

A total of eight European hospitals took part in the research, amongst these being the University Hospital of Navarra, the only hospital throughout Spain involved and the one contributing most patients for the study - 63 from a total of 328.



### Aim of study

The goal of the multicentre study was to determine if the colon capsule could provide results similar to conventional colonoscopy when detecting polyps and neoplasic lesions (cancer of the colon), according to doctor Miguel Muñoz Navas, Director of the Department of the Digestive System at the University Hospital of Navarra.

The endoscopy capsule for exploring the colon is a device manufactured by the Israeli firm Given Imaging and which houses in its interior two cameras that enable pictures to be taken in front and behind as it passes through the colon - at a rate of 4 images per second. The pictures are recorded by a receptor which enables them to be downloaded subsequently in a computer. Moreover, it incorporates a battery which has greater life than other capsules previously on the market and used for exploring other parts of the digestive tract, such as the oesophagus or the small intestine. The dimensions of the capsule of the colon are 31 mm x 11 mm. The device began to be sold in 2008.

The procedure for this endoscopic exploration involves the oral ingestion of the capsule. The patient may then carry on his or her normal life, while the images taken by the capsule on passing through the intestine are recorded in the receptor which has to be attached to the patient that same day. That evening the person being examined takes the receptor to the medical services who download the images recorded on the computer.

As regards the use of the capsule, conventional colonoscopy has the disadvantage of involving an invasive procedure, usually carried out with sedation or general anaesthetic and presenting risks of complications. Nevertheless, in the case that the endoscopy capsule detects a lesion, it will always be necessary to undertake a subsequent colonoscopy in order to extirpate it, whether a polyp or biopsy and, in the case of a cancer,



and confirm its existence.

# Type of patients and methodology

The 328 cases chosen to take part in the study on the diagnostic efficiency of the capsule of the colon complied with the condition of being patients suspect of having lesions in the colon. Doctor Muñoz explains that in some cases the presence of a lesion is already known because they have previously been diagnosed with cancer of the colon, although a complete colonoscopy has not been effected. Other types of patients included in the study were those who showed symptoms such as rectorragia (haemorrhage of the rectum) or at risk of becoming a sufferer of colon cancer due to family history. In short, the specialist pointed out that comparing the exploration using the capsule and that of conventional colonoscopy gave particularly interesting results in patients at risk of suffering a pathology.

The methodology developed for this research involved proposing the exploration using a capsule with patients that met the set requirements. To this end, an intestinal cleaning was required the day before applying this kind of exploration. Taking advantage of this cleaning procedure, a different specialist carried out a subsequent conventional colonoscopy. In this way, a comparison was subsequently made between the lesions found with the endoscopy capsule and those diagnosed with conventional colonoscopy.

# Results for comparison of techniques

With the comparison established between the results obtained by means of one or the other exploration technique, it was found that the colonoscopy undertaken with the capsule showed a sensitivity for diagnosing polyps for 64% of existing ones, taking as a reference the



100% diagnosed with conventional colonoscopy. Doctor Muñoz pointed out that this is a relatively low percentage. However, it has to be emphasised that, for all the participating teams in the study, it was the first time that this procedure was used and that the diagnosis efficacy curve of the specialists improves with the increase in experience in using the technique. With more advanced lesions, normally larger ones, the sensitivity of the cases studied by the hospitals overall increased to 73%.

As regards specificity, i.e. coincidence between located lesions and those that really exist, the average rate provided by capsule endoscopy is 84% of those diagnosed with conventional colonoscopy.

# **Good results for the Hospital**

Of the overall results obtained by the 8 centres taking part in the study, it is significant that the University Hospital of Navarra obtained very good rates in most of the parameters evaluated. Thus, as regards sensitivity in he detection of polyps using the capsule, the Pamplona-based hospital centre obtained 88% of the locating of these lesions with respect to the 100% of the usual colonoscopy.

As regards specificity (coincidence between lesions detected and real lesions), the Hospital gave the second best result with 92% of hits - only one point less than the best. As regards positive predictive value (the probability of suffering from a lesion alter obtaining a positive result on testing, the Navarre-based centre also led the ranking of the eight hospitals taking part - 94%.

### Conclusions and proposals for improvement

Doctor Muñoz stated that this is the first study carried out on this technique and the team is aware that the way the procedure is



undertaken should be improved. In this sense, the improvements put forward as a result of the study focus on the importance of a more thorough cleaning of the colon before initiating the exploratory test, given that, with conventional colonoscopy, the specialist can clean relatively with water some of the dirty areas found during the exploration - something which cannot be done with the capsule -, but if there is a lesion hidden below a concentration of dirt, the lesion will not be observed. In fact, better results have been obtained with those patients that have a cleaner intestine.

Moreover, doctor Muñoz emphasised the need to improve the endoscopic capsule technique, using pharmaceutical drugs that regulate intestinal transit and, in this way, enabling a better control of the passage of the device through the digestive tract in such a way that it is more rapid through the small intestine and reaches the colon that much sooner.

Other aspects on which the capsule manufacturers are working to improve the device is the capture of the maximum number of images per second - currently four - and also the achieving of a greater visual angle, in such a way that the blind angles in the intestine - points that cannot be captured by the current capsule - are eliminated.

According to the prognosis of doctor Muñoz, as a result of the all the improvements being implemented in the technique of capsule endoscopy of the colon, its efficacy is greater in such a way that, in the future, it could become the ideal procedure for undertaking colon cancer prevention programmes amongst the population in general - those who do not belong to groups at risk.

Source: Elhuyar Fundazioa



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