

Continuity in the healthcare assistance service provided by the digestive endoscopy and bronchoscopy units to pediatric and adult patients

Department of Diagnostic and Therapeutic Aids

Hospital Pablo Tobón Uribe

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and bronchoscopy units to pediatric and adult patients

Content

| | |
|---|----|
| 1. PRESENTATION | 3 |
| 1.1 PROJECT SUMMARY | 3 |
| 1.2 PRESENTATION OF THE DEPARTMENT IN CHARGE OF THE PROJECT | 4 |
| 2. DESCRIPTION | 6 |
| 2.1 PROJECT CONTEXT: | 6 |
| 2.2 NAME OF THE PROJECT: | 8 |
| 2.3 AREA OF COOPERATION: | 8 |
| 2.4 PROBLEM | 8 |
| 2.5 RATIONALE | 9 |
| 2.6 PROJECT OBJECTIVE | 14 |
| 2.6.1 SPECIFIC OBJECTIVES | 14 |
| 2.7 PEOPLE WHO WOULD BENEFIT FROM THE PROJECT | 14 |
| 2.8 EXPECTED RESULTS | 15 |
| 2.9 TOTAL PROJECT EXECUTION DURATION | 16 |
| 2.10 ANALYSIS OF ALTERNATIVES | 16 |
| 2.10.1 ALTERNATIVE No. 1 | 16 |
| 2.10.2 ALTERNATIVE No. 2 | 16 |
| 2.11 BUDGET | 17 |

1. PRESENTATION

1.1 PROJECT SUMMARY

Name of the project: Continuity in the healthcare assistance service provided by the digestive endoscopy unit to adults and by the bronchoscopy unit to both adults and children.

Proposing and executing entity: Hospital Pablo Tobón Uribe

Name of the people in charge: María Luisa Escobar Martínez and Héctor Andrés Sánchez Garrido.

Positions: Chief of the Department of Diagnostic and Therapeutic Support, and Chief of the Department of Diagnostic and Therapeutic Aids, accordingly.

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Summarized description of the project:

The purpose of the project is to ensure the sustainability of the high-complexity assistance in the procedures related to the diagnosis and therapeutic endoscopic interventions performed to both children and adults in the upper and lower digestive tract and in the respiratory tract. In addition, the aim is to maintain the quality and safety standards that allow giving support in cases of complex pathologies such as cancer, solid organ transplants and all pathologies that are susceptible to endoscopic intervention without the need to perform open surgery, thus entailing shorter hospital stay times and lesser impact on morbidity and mortality.

Endoscopic interventions reduce the costs for the healthcare system and improve the clinical outcomes of patients. Additionally, the state-of-the-art endoscope technology is focused on improving the diagnostic sensitivity due to the new high-resolution magnification techniques and the reduced size of the devices, which allow to access narrow anatomical spots and cavities that were previously inaccessible.

Our hospital strives to become consolidated as a flagship healthcare center of excellence for Colombia and its neighboring countries based on its good practices in terms of safety and quality of both assistance and service.

Hospital Pablo Tobón Uribe
Continuity in the healthcare assistance service provided by the digestive endoscopy
and bronchoscopy units to pediatric and adult patients

Project budget:

Donation request: \$ 59,425.58

1.2 PRESENTATION OF THE DEPARTMENT IN CHARGE OF THE PROJECT

Digestive Endoscopy Unit and Pulmonology Unit

The Digestive Endoscopy and Diagnostic Pulmonology Units are formed by a broad interdisciplinary group of clinical gastroenterologists who treat both adults and children, gastrointestinal surgeons who are sub-specialized in digestive endoscopy, colorectal surgeons and pneumologists who treat both adults and children, along with the support from all other HPTU specialists.

These units are located on the second floor of building B, within the Department of Diagnostic and Therapeutic Aids, which has five rooms that allow performing simultaneous procedures: Four (4) rooms for digestive endoscopy procedures and one (1) room for pulmonology procedures. One of them has a C-arm for procedures that require fluoroscopy in the bile duct or the bronchial tree, and the pulmonology room has an air replacement system for managing aerosols.

Gastroenterology unit: High-complexity procedures (by type of procedure):

Endoscopic ultrasonography (endosonography)

Advanced diagnostic and therapeutic endoscopy technique that allows, by means of an ultrasonography performed from within the gastrointestinal tract (esophagus, stomach, small intestine and rectum), screening and analyzing deep structures of the mentioned organs with low-risk and high-performance levels. It can be carried out by gastroenterologists or pneumologists. The experience of this procedure for patients is almost identical to a conventional endoscopy.

What is it for? It allows exploring virtually the entire gastrointestinal tract and the bronchial tree, enabling to screen deep structures that are not accessible through direct endoscopic visualization. Therefore, this procedure is essential in cases pose the need to screen for submucous lesions and for esophageal, gastrointestinal, pancreatic and bronchial tumors, among other type of tumors, and duly stage them. It plays an

important role in the screening for the pathology of the bile duct and in the analysis of fecal incontinence.

This procedure is only available in a few specialized healthcare centers in the country. Its indications, which include the ones previously mentioned, are always defined by a surgeon, a gastroenterologist or a pneumologist, and the screening for deep or tumor-related lesions is its main advantage.

Advantages with respect to other diagnostic and therapeutic screening procedures: The radiological techniques that use contrast agents draw the outline of the lesion and its surface, while the endosonography provides a dynamic representation of the surface of the lesion and the total thickness of the gastrointestinal tract in real time. It is relatively similar to the CT scan (computerized axial tomography scan), but the CT scan is a static imaging technique that only allows exploring cross-sectional images but it does not enable distinguishing the different strata of the gastrointestinal tract wall. Conversely, the endoscopic ultrasonography allows obtaining multiple images in real time, depending on the modification of the position of a high-frequency radial transducer that provides a better resolution and allows distinguishing the layers in the tissues with a high level of detail.

For instance, in the case of advanced gastric cancer, the correlation between the endosonography and the pathology with regard to the tumor intrusion is high. It allows the diagnosis of invasion in cases of early stomach cancer when it is located on the mucosa or submucosa, which is not possible through other techniques such as the simple endoscopy. The endosonography has proven to be an important breakthrough for the visualization of the gastrointestinal tract ganglia, which are only 3 to 4 mm in size. It also allows defining the treatment strategy, surgical or non-surgical, and formulating a therapy by means of endoscopy for lesions that, through other means would require open biopsy procedures, which entail greater risks and costs for patients.

Diagnostic and Therapeutic Endoscopy Procedures

The upper digestive endoscopy is also known as gastroscopy and it corresponds to tests that have the purpose of diagnosing and treating upper gastrointestinal tract diseases, that is, in the esophagus, the stomach and/or the duodenum.

It is performed using an endoscope, which consists of a flexible tube with a diameter of approximately one centimeter and around one meter long. The endoscope is inserted through the mouth all the way down to the upper intestine. The device allows

Hospital Pablo Tobón Uribe
Continuity in the healthcare assistance service provided by the digestive endoscopy
and bronchoscopy units to pediatric and adult patients

visualizing the inside of the intestine by means of a video camera located in its tip, and the image can be seen on a monitor.

What is its purpose? It has a service channel through which therapeutic procedures can be performed without the need to conduct surgical interventions in patients. Such procedures include: infiltrating an artery to stop a hemorrhage, removing benign or malignant lesions, collecting biopsy samples, placing stents to fix gastrointestinal tract obstructions, removing foreign bodies, divert or bypass bile duct obstructions, removing kidney stones, ligating esophagus varicose veins, inserting catheters for advanced feeding through the stomach, among other.

Advantages:

- Relatively easier procedures from the technical perspective;
- Less invasive than surgery for the patient;
- Easy access;
- Short duration times;
- Important in the outpatient environment because patients do not require to remain hospitalized and the procedures are performed under sedation;
- Significantly safe and economic.

2. DESCRIPTION

2.1 PROJECT CONTEXT:

Hospital Pablo Tobón Uribe, one of the main healthcare centers in Medellín, provides healthcare services to patients suffering from high-complexity pathologies, and operates as a referral center for both the city and the country. For managing high-complexity illnesses, it is indispensable to have modern endoscopy units as they allow offering comprehensive medical assistance services by providing diverse quick and less invasive options for managing diverse conditions.

These assistance services include the treatment of pathologies that entail high costs in terms of health and social impact. The following are some examples of said pathologies: gastric, duodenal and bile-duct cancer; other types of cancer related to the rest of the gastrointestinal tract; tumors in the airway; long-term damages caused by burns in the gastrointestinal tract; major trauma; cirrhosis; autoimmune diseases (lupus, rheumatoid arthritis); infectious diseases (AIDS, hepatitis B and C, fungi, sepsis, organizing pneumonia, pulmonary and extrapulmonary tuberculosis); and support in the treatment of cerebrovascular and cardiovascular disease.

Hospital Pablo Tobón Uribe
Continuity in the healthcare assistance service provided by the digestive endoscopy
and bronchoscopy units to pediatric and adult patients

According to the World Health Organization (WHO), cancer is one of the main causes of morbidity and mortality worldwide. In 2012, there were approximately 14 million new cases and 8.2 million cancer-related deaths. Moreover, it is estimated that the annual cases of cancer will increase from 14 million in 2012 to 22 million over the next two decades.¹ In Colombia, according to the WHO's Globocan project, it was calculated that this disease afflicted approximately 80,000 people, causing the death of 42,500 people in 2015.²

Cancer in children is different to that in adults in terms of type of pathology, clinical behavior, treatment and survival. However, the most important difference lies on the fact that cure rates for children are about 30% higher than those for adults in general, but cure rates can be as high as 85-90% in some cases. In 2009, according to the DANE (Colombia's National Administrative Statistics Department), the country's estimated total population amounted to 48,982,063 people and 2,000 new cancer cases were recorded, 38% in people under 19 years old, 17% passed away during the first year, 35% quit the treatment and the general survival rate did not exceed 43%, in comparison to the 85% rate of more developed countries. The currently aggravating issue is not treatment desertion, but the transfer of patients to other institutions. Comprehensive, timely and adequate healthcare assistance to children can prevent avoidable deaths (National Center for Research on Health-Related Evidence and Technologies, CINETS, 2003).³

With the aim of expanding the coverage and the timeliness of the healthcare service and producing a positive impact on the treatment of high-complexity pathologies, Hospital Pablo Tobón Uribe has planned a department with: 4 rooms for endoscopy procedures, 1 bronchoscopy room, 1 digestive physiology room, 1 recovery room with 14 gurneys, 1 C-arm (ionizing radiation device for angiography procedures) and 1 room for washing and processing endoscopes.

As described in the statistics (see Appendix 4), the trend of the number of performed procedures exhibited a drop in the period from 2017 to 2018. Among other causes, this drop is explained by the lacking availability of the equipment necessary to maintain the operation, a high device malfunction rate and the difficulty to find spare parts and supplies due to the technological obsolescence of the available devices.

1 World Cancer Report, 2014, IARC. WHO - <https://www.who.int/news-room/fact-sheets/detail/cancer>

2 <http://hsbnoticias.com/noticias/ciencias/oms-para-2015-el-c%C3%A1ncer-afectar%C3%ADa-80000-personas-m%C3%A1s-en-colombia-124096>

3 National Center for Research on Health-Related Evidence and Technologies (CINETS), April 2003, Ministry of Healthcare. Taken on May 16, 2016, from the practical clinical guide for the timely detection, diagnosis and monitoring of acute lymphoblastic leukemia and acute myeloid leukemia in children and adolescents, http://gpc.minsalud.gov.co/Documents/Guias-PDF-Recursos/Leucemia/GPC_Comple_Leucemia.pdf

Hospital Pablo Tobón Uribe

Continuity in the healthcare assistance service provided by the digestive endoscopy and bronchoscopy units to pediatric and adult patients

2.2 NAME OF THE PROJECT:

Continuity in the healthcare assistance service provided by the digestive endoscopy and bronchoscopy units to both pediatric and adult patients.

2.3 AREA OF COOPERATION:

Healthcare sector. Financial cooperation sought: Non-reimbursable funds.

2.4 PROBLEM

Discontinuity in the provision of assistance services to patients suffering from pathologies suitable for diagnosis and minimally-invasive therapeutic management with endoscopic techniques at Hospital Pablo Tobón Uribe:

Respiratory tract and upper and lower gastrointestinal tract illnesses among children and adults constitute a heterogeneous group of pathologies that deteriorate patients' quality of life due to their chronicity and to the direct compromise of the nutritional condition. In addition, such pathologies cause restrictions that entail the loss of productive life and have a significant mortality rate related to stomach cancer that, in Colombia, ranks 10th among all the general causes of death and is the first cause among all neoplasias (see Chart 1).

What causes most of the deaths?

¿Qué causa la mayoría de las muertes?



10 principales causas de muerte en 2017 y porcentaje de cambio, 2007-2017, todas las edades, número

10 main causes of death in 2017 and percentage of change, 2007-2017; all age groups, number

Chart 1. Causes of death in Colombia for 2017 and percentage of change (2007-2017) among all age groups (Source: <http://www.healthdata.org/colombia?language=149>).

The early and timely diagnosis of cancer determines the possibility of improving the survival rate. Other chronic pathologies such as the eosinophilic esophagitis, food allergies, the reflux disease, intestinal metaplasias, ulcerative colitis and other chronic gastrointestinal tract illnesses depend on a rapid diagnosis for being controlled before negatively affecting the nutritional condition, the metabolism and the brain growth, particularly in vulnerable populations such as children in their early infancy. The fact of having endoscopic services based on versatile technologies with greater image resolution and smaller devices allows offering access to a greater number of patients, some of whom cannot be covered due to the lack of such technology.

In the case of pathologies such as esophagus, stomach and colon cancer, early diagnoses can be achieved, thus producing a positive impact on the survival rate and avoiding major and invasive surgical procedures. These new magnifying endoscopic techniques improve the sensitivity of the diagnosis and raise hope regarding minimally invasive procedures because they eliminate the need to create abdominal incisions, shorten the hospital stay times and reduce the complications, also providing benefits in terms of the costs covered by the healthcare system.

Hospital Pablo Tobón Uribe, being aware of the current healthcare problem the mentioned pathologies represent and considering the possibility of offering these minimally-invasive endoscopic technologies (gastroscopy, esophagoscopy, duodenoscopy, enteroscopy, colonoscopy and bronchoscopy), needs to improve and broaden its medical equipment inventory. Due to their reduced size, easy operation, image resolution, such state-of-the-art devices (and their new-generation supplies) will enable the Hospital to perform procedures that offer great benefits to vulnerable populations, providing better diagnostic timeliness, less-aggressive alternative therapies for patients who were previously considered to be inoperable by means of conventional techniques.

2.5 RATIONALE

New global trends in terms of the technology of both devices and techniques, including advanced endoscopy imaging (new generations of endoscopes).

The new endoscopy technologies allow:

- **A better visualization and characterization of the mucosa**, favoring the detection of subtle abnormalities that would be impossible to detect by means of standard methods.
- The precise optical diagnosis allows collecting samples in targeted biopsy procedures in cases of suspicious lesions, increasing the diagnostic performance

and reducing the endoscopic times with regard to other methods that use protocols with **multiple random biopsies**.

- When the lesions are detected in early stages, they can be addressed with **less-invasive endoscopic** methods, avoiding surgeries that entail higher levels of morbidity and mortality, and ensuring a better outlook.

General information

Resolution: Standard image: 100,000 to 400,000 pixels vs HD endoscopes: 850,000 to 1 million pixels. Magnification: ranges from 1.5x to 150x.

Optical chromoendoscopy: It consists in the use of light filters or the electronic processing of images incorporated in the endoscopes to obtain images of mucosas with enhancement of the vascular and glandular ultra-structure.

Multiple uses in the cases of high-impact illnesses and diseases: **Barrett's esophagus**

- The condition known as Barrett's esophagus has an increasingly significant impact on our context and it is associated with the gastroesophageal reflux disease.
- The occurrence of esophageal adenocarcinoma has been increasing over the past four decades, with an impact 6 times greater from 1975 to 2001.
- The monitoring is performed through endoscopy procedures based on a protocol with an image quality that improves the diagnostic sensitivity.
- The methods based on chromoendoscopy (technique achieved by means of filters and the better image quality provided by the new-generation devices) and magnification (NICE) allow classifying it with a 90% accuracy and a high level of agreement among observers.

These techniques double the detection of high-degree dysplasia and esophageal squamous-cell carcinoma.

Examples:

Image obtained with old devices

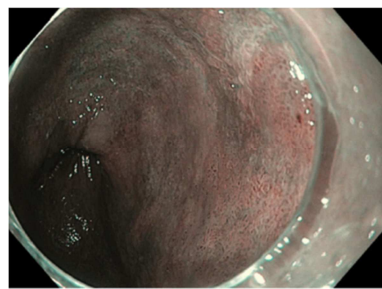
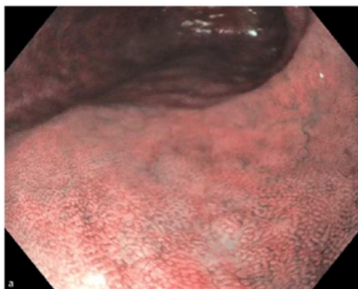
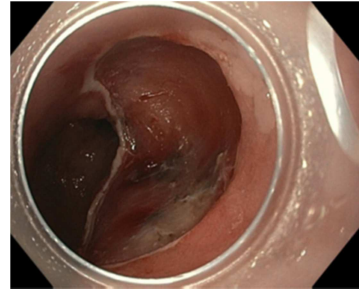
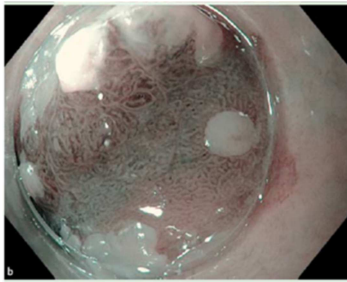


Image obtained with state-of-the-art devices

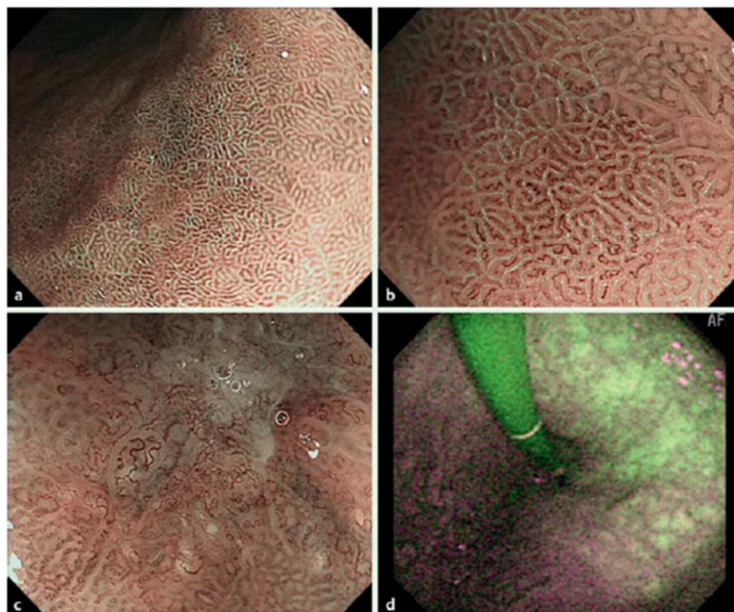


Impact on gastric cancer: Gastric cancer is the third cause of death due to neoplasia in the worldwide context and the first in Colombia. With the current methods (standard endoscopy), there is a low detection rate of intraepithelial cancer. With the **HD magnifying endoscopes**, a 78% sensitivity has been reported with 100% specificity for the detection of intraepithelial cancer. In other words, almost 80% of the initial lesions are detected during screening, which would not be detected by means of the old methods and, when a sample of these lesions is collected through a biopsy, it is confirmed in 100% of the cases.

The diagnostic criteria applied when analyzing the images obtained with the magnifying devices allow finding out if there is loss of the fine structure of the mucosa, microvascular dilation and microvascular heterogeneity, and they also help in determining the lateral extension of the lesion.

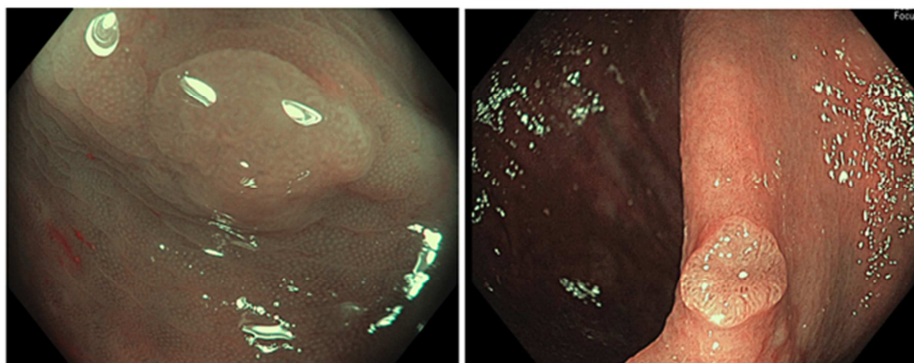
Standard devices

Modern magnifying devices

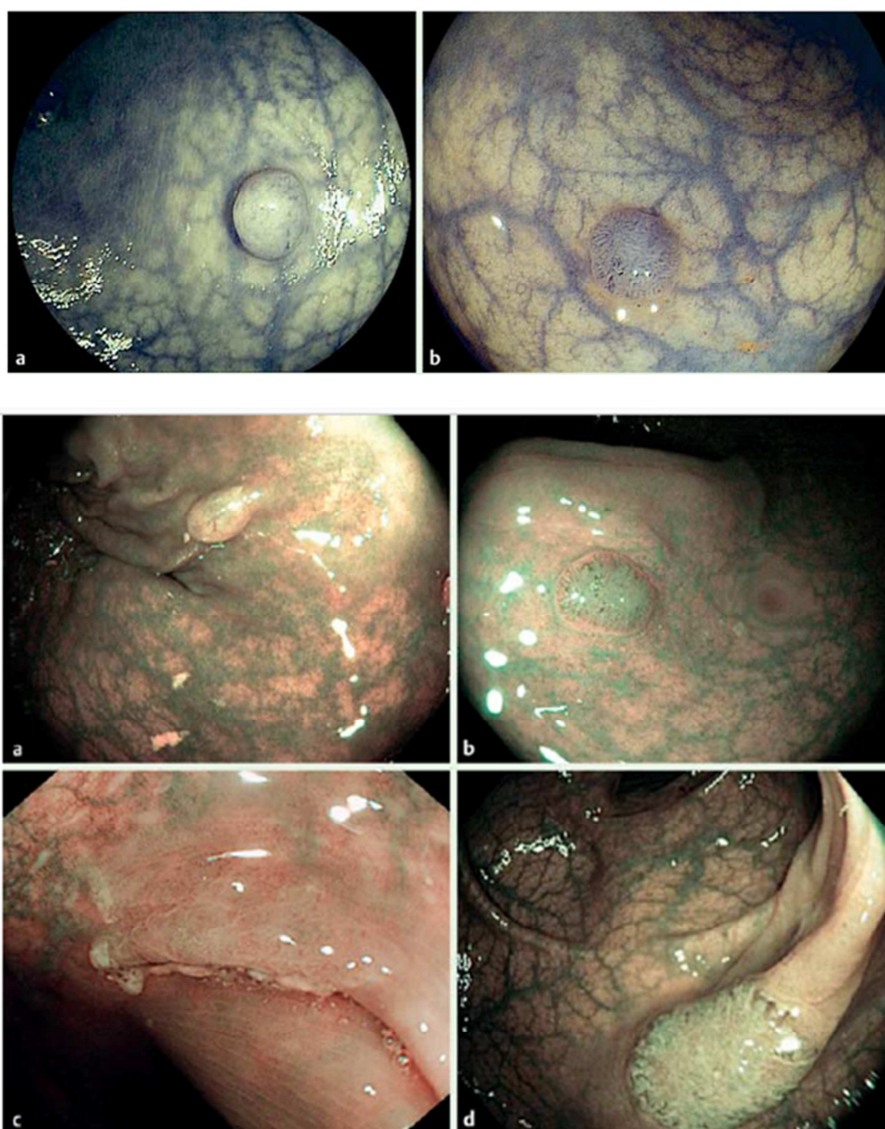


Impact on the screening for polyps in the upper or lower gastrointestinal tract.

IMAGES OBTAINED USING STANDARD ENDOSCOPES



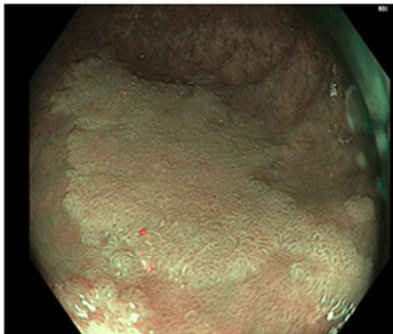
IMAGES OBTAINED USING ADVANCED TECHNIQUES



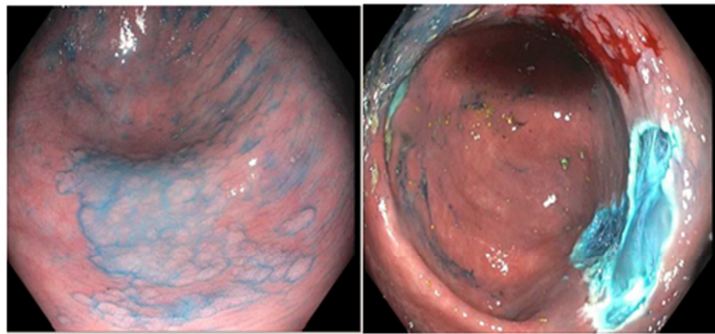
Impact on patients with suspected ulcerative colitis

- Approximately 5% of the patients develop cancer after 20 years.
- The current screening is performed based on biopsies of the four quadrants every 10 cm (low sensitivity), it is performed blindly.
- Random studies have shown an increase in the detection of dysplasia (2-3 times) when the lesion is analyzed with the new-generation endoscopes with chromoendoscopy and magnifying filters.

Conventional techniques



Techniques with magnification and filters



Digestive illnesses and diseases constitute a heterogeneous group of entities with an increasing impact on the quality of life, morbidity and mortality of the population.

Impact aimed to be achieved:

1. Maintaining the high-complexity capabilities;
2. Early diagnosis of illnesses and diseases: early scenarios with better clinical outcomes;
3. Less-invasive high-complexity procedures;
4. Higher levels of quality and safety in the assistance services;
5. Positive impact on adverse events and complications due to image-based techniques.

2.6 PROJECT OBJECTIVE

To enable patients suffering from pathologies that are susceptible to diagnosis and treatment with minimal intervention and lesser infection and adverse-event risks to have access to such procedures, thus improving the health-related outcomes in terms of survival expectancy, morbidity and hospital stay time.

2.6.1 SPECIFIC OBJECTIVES

- To improve the early diagnosis of illnesses and diseases: early scenarios with better clinical outcomes;
- To become the flagship healthcare center for the treatment of pathologies susceptible to minimally invasive treatment through endoscopic techniques, which today can only be handled surgically or through invasive procedures in Medellín;
- To maintain the high-complexity capabilities;
- To maintain the Hospital's operation based on less-invasive high-complexity procedures.

2.7 PEOPLE WHO WOULD BENEFIT FROM THE PROJECT

The endoscopic interventions reduce the costs for the healthcare system and improve the clinical outcomes of patients.

Target population of this project:

- **Newborns (weighing more than 750 g at birth) with or without congenital pathologies:** Diaphragmatic hernias, esophageal atresias, intestinal malfunctioning, ulcers caused by stress, duodenal atresias, biliary atresias, esophageal stenoses, pyloric stenoses, Meckel's diverticula.
- **Children and adults suffering from:**

Pathologies that negatively affect the gastric or bronchial lumen: Stenosis or stricture, extrinsic compressions, esophageal rings, esophageal hiatal hernias, increased tone of the esophageal sphincter, foreign bodies (batteries, coins, blades, stones, bones, fish bones, etc.).

Pathologies that negatively affect the mucosas: Endobronchitis, esophagitis, gastritis, duodenitis, colitis, candidiasis (fungi), Barrett's esophagus (pre-malignant changes in the mucosa), planar lesions such as ectopic mucoid plaques in bronchi, stomach, small and large intestine, scars, diverticula, ulcers, all types of erosion, treatment of fistulas (which were formerly treatable only through major surgery) and fissures.

Pathologies that produce protruding lesions: Nodules, tumors, masses, esophageal varicose veins, polyps, papules, fold thickening, hemorrhoids, condylomata.

Pathologies that negatively affect the bile duct and the pancreas, including bile duct cancer: choledocholithiasis (lithiasis in the common bile duct, microlithiasis unseen in the magnetic resonance cholangiopancreatography), acute pancreatitis, chronic pancreatitis, pancreatic cancer, cholangiocarcinoma, obstruction of the bile duct with etiology pending clarification, pancreatic nodules with origin pending clarification, screening for pancreatic insulinomas and other pancreatic carcinoids, benign cystic pancreatic tumors (serous cystadenoma, mucinous cystadenoma, intraductal mucinous neoplasm of the pancreas), pancreatic pseudocyst.

Neoplastic pathologies (early-stage cancer), early diagnosis: Esophageal cancer, Barrett's esophagus, stomach cancer, colon cancer, submucous tumors in the gastrointestinal tract (GISTs, leiomyomas, lipomas, carcinoid tumors, ectopic pancreas, duplication cysts, etc.). Significantly important due to the difficulty of their diagnosis.

Other pathologies: Unclarified chronic abdominal pain suggesting biliopancreatic etiology; papillary adenomas and malignant papillary tumors (ampulla of Vater); screening of the internal anal sphincter for patients suffering from incontinence; screening for anorectal fistulas and abscesses; esophageal, gastric or duodenal cancer that are susceptible to timely intervention; precancerous lesions; polyps; elevated lesions; plicae; chronic ulcers.

The success on the target population consists in providing it with access to timely services based on cutting-edge technologies that enable new imaging techniques for minimally-invasive healing treatments.

2.8 EXPECTED RESULTS

- Increasing by 10% the number of therapeutic endoscopy procedures;
- Increasing by 10% the number of diagnostic endoscopy procedures that result in the early diagnosis of intraepithelial cancer or pre-malignant injuries;

Hospital Pablo Tobón Uribe
Continuity in the healthcare assistance service provided by the digestive endoscopy
and bronchoscopy units to pediatric and adult patients

- Becoming the flagship healthcare center for the treatment of pathologies susceptible to minimally invasive treatment through endoscopic techniques, which today can only be handled surgically or through invasive procedures in Medellín;
- Maintaining the indicator of quality in the detection of polyps and planar lesions at least in 20% of the diagnostic colonoscopy procedures.

2.9 TOTAL PROJECT EXECUTION DURATION

The project will start in September 2019 and will end in December 2020.

2.10 ANALYSIS OF ALTERNATIVES

2.10.1 ALTERNATIVE No. 1

The project is not executed and the Hospital continues to provide healthcare assistance to patients suffering from illnesses and diseases related to the gastrointestinal tract or the respiratory tract as it has been providing it to date. This would entail risks associated with the total operation time of the equipment and devices, which may cause noncompliance situations with regard to the demand, and could, have a negative impact on the timeliness of the diagnosis and therapeutic treatment procedures.

2.10.2 ALTERNATIVE No. 2

Enhancing the access availability for patients suffering from pathologies suitable for diagnosis and minimally-invasive therapeutic management with endoscopic techniques.

According to the rationale statement, this option is the most cost-effective and, thus, the Hospital supports its execution.

Minimizing patients' risks as much as possible and offering an environment suitable to their needs becomes necessary.

Hospital Pablo Tobón Uribe
Continuity in the healthcare assistance service provided by the digestive endoscopy
and bronchoscopy units to pediatric and adult patients

2.11 BUDGET

| | item | Quantity | Total Pesos (COP) |
|--------------------------|---|----------|--------------------|
| Equipo # 1 Completo | | | |
| Digestive endoscopy unit | Pediatric Gastroscope Video (ultra-thin for use After nasal and neonatal (EG-530N) | 1 | \$32,771.46 |
| | Irrigation Pump (for therapeutic endoscopy, for long-term ex-endoscopes) REF 10325-00 | 1 | \$ 4,915.72 |
| | CO2 insufflator pump / Ref. GW-100) | 1 | \$ 8,356.72 |
| | Transport car | 1 | \$ 2,403.24 |
| | 27-inch Flat Medical LCD Monitor | 1 | \$ 9,831.44 |
| | Leak and Water Tank Tester | 1 | \$ 1,147.00 |
| Total | | 6 | \$59,425.58 |