The Brazilian Pilot, an update

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Possible conflicts of interest

There is no conflict of interest

Financial Support

• São Paulo Research Foundation (FAPESP)
Background
Colorectal cancer

- Most frequent GI malignant neoplasia
- 8% of all cancer deaths
- Incidence: Worldwide and Brazil: 3º ♂; 2º ♀

<table>
<thead>
<tr>
<th>Localização primária</th>
<th>Casos</th>
<th>%</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Próstata</td>
<td>68.220</td>
<td>31,7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traqueia, Brônquio e Pulmão</td>
<td>18.740</td>
<td>8,7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cólon e Reto</td>
<td>17.380</td>
<td>8,1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estômago</td>
<td>13.540</td>
<td>6,3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cavidade Oral</td>
<td>11.200</td>
<td>5,2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esôfago</td>
<td>8.240</td>
<td>3,8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bexiga</td>
<td>6.690</td>
<td>3,1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laringe</td>
<td>6.390</td>
<td>3,0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leucemias</td>
<td>5.940</td>
<td>2,8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sistema Nervoso Central</td>
<td>5.810</td>
<td>2,7%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Localização primária</th>
<th>Casos</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mama Feminina</td>
<td>59.700</td>
<td>29,5%</td>
</tr>
<tr>
<td>Cólon e Reto</td>
<td>18.980</td>
<td>9,4%</td>
</tr>
<tr>
<td>Colo do Útero</td>
<td>16.370</td>
<td>8,1%</td>
</tr>
<tr>
<td>Traqueia, Brônquio e Pulmão</td>
<td>12.530</td>
<td>6,2%</td>
</tr>
<tr>
<td>Glândula Tireoide</td>
<td>8.040</td>
<td>4,0%</td>
</tr>
<tr>
<td>Estômago</td>
<td>7.750</td>
<td>3,8%</td>
</tr>
<tr>
<td>Corpo do Útero</td>
<td>6.600</td>
<td>3,3%</td>
</tr>
<tr>
<td>Ovário</td>
<td>6.150</td>
<td>3,0%</td>
</tr>
<tr>
<td>Sistema Nervoso Central</td>
<td>5.510</td>
<td>2,7%</td>
</tr>
<tr>
<td>Leucemias</td>
<td>4.860</td>
<td>2,4%</td>
</tr>
</tbody>
</table>

Rabeneck et al., The World Bank 2015
Arnold et al., Gut 2017; 66:683-91
Brazilian National Cancer Institute, 2018
Background

Colorectal cancer - Incidence

Men

Women

Brazilian National Cancer Institute, 2018
Background
Mortality rate

Crude mortality rate estimated for the CCR in Brazil, adjusted for age, by the adjusted world and Brazilian population of 2010, per 100,000 men and women
Brazilian National Cancer Institute, 2014

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Background

Colorectal cancer - stage

Colorectal cancer stage at diagnosis

Number = 5854 patients

Sao Paulo State Cancer Institute (ICESP - HCFMUSP), 2009 – 2018

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Background

- Screening programs using a quantitative fecal immunochemical test (FIT) have been performed with high sensitivity.

Quintero et al, Gastroenterology 2014;147:1021-3
Cubiella et al, Cancer Epidemiol Biomarkers Prev 2014; 23:1884-92
Hilsden et al, Am J Gastroenterol 2016; 111:1743-9
Passamonti et al, Gut 2016; 312716
Shahidi et al, Canadian J Gastroenterol & Hepatol 2016; 4650471
Aronsson et al, Br J Surg 2017; 104:1078-86
Grobbee et al, Gastroenterology 2017; 153:1251-9
Pellat et al, Sci Rep 2018; 8:4162
Viguier et al, Curr Oncol Rep 2018; 20:16
Larsen et al, Gastroenterology 2018, in press
Aims

• To evaluate the implementation of an organized CRC screening through FIT

• To analyze the colonoscopic findings of a positive FIT screened population
Patients and Methods

• Pilot study of an organized screening program for CRC
• To aware the Community Health Agent and the population
• Individuals 50 - 75 years old, who lived in a Eastern Sao Paulo neighborhood - community public health care – were invite to participate

Community Health Agent
Patients and Methods

• Recruitment in home visits by the Community Health Agent
• Informed consent
• Delivery of kits and questionnaire
• Samples taken to 12 Basic Health Units
Patients and Methods

- Of a total intended 10000 people ➔ 8539 have already been submitted to FIT test
- 59.2% - incomplete elementary school or never attended
Patients and Methods

- 8539 individuals included: 5531 (64.8%) female
Patients and Methods

Very engaged professionals
Patients and Methods

• Device for stool sampling
Patients and Methods

• Patients with positive FIT (≥ 50 ng/mL): forwarded to colonoscopy
  – Endoscopy Unit - University of São Paulo

• High definition endoscopes with magnification

• All lesions ≤ 2 cm: resected at the procedure

• Suspected malignant lesions or > 2 cm:
  – biopsied
  – rescheduled the patient for endoscopic or surgical resection

• Surgical and oncologic treatment:
  – Sao Paulo Cancer Institute (ICESP - HCFMUSP)
Results
FIT

• 661/8539 (7.7%) patients: positive FIT and were scheduled for colonoscopy

• Of them, 473/661 (71.6%) patients already underwent colonoscopy
Results

N = 473 patients

|                |   
|----------------|---
| Mean Age       | 62 y
| Cecal Intubation | 99.6%
| Boston Scale (8-9) | 96%
## Results

### Adenoma Detection Rate (ADR)

<table>
<thead>
<tr>
<th></th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>282 (59.6%)</td>
</tr>
<tr>
<td>ADR+ (2-16 lesions)</td>
<td>163 (34.5%)</td>
</tr>
<tr>
<td>ADR Advanced</td>
<td>127 (26.8%)</td>
</tr>
</tbody>
</table>

**N=473**

**Criteria – advanced adenoma:**

- >10 mm, villous component, high grade dysplasia

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Low grade tubular adenoma
## Results

### Malignant Lesions

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced adenocarcinoma*</td>
<td>17 (3.6%)</td>
</tr>
<tr>
<td>Early lesions</td>
<td></td>
</tr>
<tr>
<td>High grade dysplasia</td>
<td>21 (4.4%)</td>
</tr>
<tr>
<td>In situ carcinoma</td>
<td>5 (1.1%)</td>
</tr>
<tr>
<td>Intramucosal carcinoma</td>
<td>8 (1.7%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>51 (10.8%)</td>
</tr>
</tbody>
</table>

* 2 patients with invasive synchronous lesions

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Moderately differentiated tubular adenocarcinoma - rectum - T2N0

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Results
CCR Screening

Total Intended 10000 people

8539 FIT test

661 (7.7%) Positive FIT

473 (71.6%) Colonoscopy

51 (10.8%) Malignant Lesions

7878 (92.3%) Negative FIT

Invasive moderately differentiated tubular adenocarcinoma - sigmoide

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Results
FIT x Malignant Lesions

473 Colonoscopy

159 (33.6 %) FIT (50-99 ng/mL)
- 7 (4.4 %) Malignant Lesions

314 (66.4 %) FIT (≥ 100 ng/mL)
- 44 (14.0 %) Malignant Lesions

7/51 (13.7 %) Malignant Lesions
FIT (50-99 ng/mL)

Moderately differentiated tubular Invasive adenocarcinoma
Results
FIT x Adenoma

473 Colonoscopy

282 (59.6 %) Adenoma

87 (30.9 %) FIT (50-99 ng/mL)
195 (69.1 %) FIT (≥ 100 ng/mL)

282 Adenoma

127 (45.0 %) Advanced Adenoma

29 (22.8 %) FIT (50-99 ng/mL)
98 (77.2 %) FIT (≥ 100 ng/mL)

87/159 (54.7 %) - FIT (50-99 ng/mL) Adenoma

29/159 (18.2 %) - FIT (50-99 ng/mL) Advanced Adenoma
Low grade tubular adenoma
Low grade tubular adenoma
Low grade tubular adenoma
Low grade tubular adenoma
Low grade tubular adenoma
Sessile serrated adenoma – ascending colon
Sessile serrated adenoma - cecum
LST - Low grade tubulovillous adenoma
Low grade tubulovillous adenoma

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Low grade tubulovillous adenoma
Low grade tubulovillous adenoma

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Low grade tululovillous adenoma
Low grade tululovillous adenoma
High grade adenoma

FIT = 59 ng/ml

Ascending colon

Low grade adenoma

Sigmoid colon

High grade adenoma

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High grade tubular adenoma
High grade tubulovillous adenoma
In situ adenocarcinoma - descending colon
Adenocarcinoma in adenoma
Tubulovillous adenoma with in situ adenocarcinoma
LST – Well differentiated tubular adenocarcinoma
Free margins – SM1 - pT1b pNx pMx

FIT = 69 ng/ml

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Adenocarcinoma - SM2

FIT = 56 ng/ml

Descending colon
Advanced adenocarcinoma at descending colon

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Conclusions

1. Partial results of this study demonstrated high adenoma detection rate in a screened positive FIT population;

2. Diagnosis of pre and malignant lesions strengthen the importance of screening program of colorectal cancer in our country.
Thank you
very much!