A RETROSPECTIVE STUDY ON THE NATIONAL COLORECTAL SCREENING PROGRAMME:
ANALYSIS OF PARTICIPATION AND FINDINGS

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ABSTRACT

Colorectal screening in Malta is a population-based screening programme using faecal immunochemical test as the primary screening tool. In this retrospective study, records and datasheets of patients undergoing screening colonoscopies at Gozo General Hospital in 2016 were inspected. The extracted data reflected national participation, as an integration between Mater Dei and Gozo General Hospitals was introduced, to reduce patients' waiting time. Both Maltese and Gozitan patients were eligible for screening at Gozo General Hospital. Outcomes were collected into excel spreadsheets and statistically analysed. Participation rates, positivity rates and detection rates for colorectal cancers were compared with other European Union countries. Comparison showed that Malta has a higher detection rate for colorectal cancer for asymptomatic patients;- however, a significant number of cancer-positive patients were retrospectively also found to have been symptomatic.

KEYWORDS

FIT, Colorectal cancer, Screening, Detection rate, Comparison to EU member states.

INTRODUCTION

Colorectal screening in Malta is a population-based screening programme modelled on the European Council guidelines of colorectal cancer management.[1,2] Screening aims primarily at an early diagnosis when treatment is more likely to work (secondary prevention) and also for tertiary prevention with detection and management of metachronous lesions.

The use of Faecal Immunochemical Tests (FIT) to detect blood in stools is the primary screening tool. It has good patient compliance as patients do not need to undergo dietary or medication restriction unlike the guaiac-based Faecal Occult Blood test where Aspirin, anti-inflammatory medications and vitamin C preparations have to be stopped 7 days prior to test, and also undergo dietary restrictions.[3,4]

In 2016, written invitations were sent to those born between 1957-1959 (aged 59-61 years), to perform a FIT. Those who scored above 100ng/ml were then invited to undergo colonoscopy.

METHOD

Patient records and Colorectal Cancer Screening Programme datasheets for colonoscopies done at Gozo General Hospital between January and December 2016 were accessed. Data fields inspected retrospectively included patient demographics, date of the pre-assessment at the Lascaris deparment, waiting time to and date of colonoscopy, medication history, surgical, medical and family history and, relevant symptoms (including diarrhoea, constipation, bleeding, rectal irritation, mucus, tenesmus, abdominal pain). Other data included histology results, FIT values, MCV value, platelet count, bowel cleansing preparations which were used, extent of colonoscopic examination, as well as any colonoscopic findings including lesions or tumours or diverticuli, inflammation, bleeding, number and type of polyps, their location and whether the polyps were resected or not during the colonoscopy. Data was entered in an excel sheet for statistical processing.

RESULTS

362 patients with a FIT result above 100ng/ml presented for colonoscopy at Gozo General Hospital.

GENDER

53.3% who had a positive FIT result were females while 46.7% were males.

SYMPTOMATIC VERSUS ASYMPTOMATIC PATIENTS

156 patients (43%) were asymptomatic while the remaining 206 patients (57%) were symptomatic. 11 from 362 patients (3%) cases were diagnosed with colorectal adenocarcinoma; only 2 of these were asymptomatic. Patients who were symptomatic included the following:

- 119 from 362 patients (33%) complained of bleeding
- 61 patients (17%) complained of tenesmus
- 71 patients (20%) complained of rectal irritation
- 48 patients (13%) complained of abdominal pain
- 30 patients (8%) complained of change in bowel habit – of which 10 patients suffered from diarrhoea and the remaining 20 patients suffered from constipation.

The following results show that each individual's histology may have fallen in more than one of the mentioned categories. During colonoscopy specific patients had polyps of a different histological nature.

POLYP TYPE	OVERALL	ASYMPTOMATIC	SYMPTOMATIC
Carcinoma	11	2 (0.6%)	9 (2.5%)
Metaplasia/Dysplasia	86	31 (8.6%)	55 (15.2%)
Adenoma	99	37 (10.2%)	62 (17.1%)
Other: Hyperplastic & Inflammatory polyps	300	110 (30.4%)	190 (52.5%)

Figure 1: Comparison of types of polyps identified in asymptomatic vs symptomatic patients as a percentage of a total of 362 patients undergoing colonoscopy. Patients in whom no polyps were identified were not listed in the above table.

POLYP TYPE	OVERALL	ASYMPTOMATIC	SYMPTOMATIC
Carcinoma	11	18%	82%
Metaplasia/Dysplasia	86	36%	64%
Adenoma	99	37.4%	62.6%
Other: Hyperplastic & Inflammatory polyps	300	36.7%	63.3%

Figure 2: % Asymptomatic vs % Symptomatic with positive findings at colonoscopy

AVERAGE FIT VALUES

The average FIT for asymptomatic patients was 184ng/ml.

AVERAGE FIT IN INDIVIDUAL CATEGORIES OF ASYMPTOMATIC PATIENTS

Carcinoma	827
Metaplasia/Dysplasia	629
Adenoma	713
Other: Hyperplastic & Inflammatory polyps	373

FIT levels alone are not indicative of colonic tumours: whether benign or malignant. In fact this is why a patient with a positive FIT value is afterwards invited to undergo a colonoscopy. Latter will confirm the histological type of the polyps, as having an elevated FIT value, does not necessarily mean carcinoma. Patients with haemorrhoids or inflammatory bowel disease (IBD) can also have elevated FIT values. Sometimes FIT values are higher in these patients rather than in those patients with a colonic malignancy. The values obtained above could be due to the fact that most of the patients were asymptomatic at the time of screening but had either haemorrhoids or IBD or had both carcinomatous polyps and hyperplastic and inflammatory polyps.

OTHER FINDINGS

Average time gap between the pre-assessment and endoscopic date was 43 days. During the procedure, bowel abnormalities and caecal intubation rate of 360 patients (from 362 patients) were recorded. Colonoscopy exit time was 22 minutes. 26 colonoscopies did not have any exit time documented.

AVERAGE DURATION OF COLONOSCOPY

- Less than 10 min: 27 or 7.5%
- Between 11-30 min: 242 or 67%
- Between 31 and 60 min: 65 or 18%
- Over 1 hour: 2 or 0.6%
- Not recorded: 26 or 7%

DISCUSSION

In 2016, 14,844 letters were sent to the Maltese and Gozitan population, aged 59-61 years to participate in colorectal screening. 557 (3.8%) invites were returned back undelivered. Therefore the total number of eligible invites were 14,287 (96%). From the latter, 12,209 accepted the invitation and their stool kits were sent to the lab. Those who had a positive FIT test were then invited to have a colonoscopy. All patients were asked whether they prefer undergoing their colonoscopy at either Mater Dei Hospital or Gozo General Hospital. Screening colonoscopies in Gozo helped in reducing waiting time; in fact the majority of patients that participated in the screening programme at Gozo, resided in Malta.

The average FIT for symptomatic patients was 166ng/ml.

AVERAGE FIT IN INDIVIDUAL CATEGORIES OF SYMPTOMATIC PATIENTS

Carcinoma	902
Metaplasia/Dysplasia	205
Adenoma	215
Other: Hyperplastic & Inflammatory polyps	288

COMPARISION OF DATA WITH OTHER EU COUNTRIES

The results of the Maltese population were compared to other European countries which either follow a non-population based colorectal screening i.e. Greece and Latvia, or a population-based screening i.e. Austria, Belgium, Croatia, Cyprus, Denmark, Finland, France, Hungary, Ireland, Germany, the Czech Republic, Italy, the Netherlands, Poland, Portugal, Slovenia, Spain, Sweden and the UK. Lithuania, which adopts a population-based colorectal screening, has been excluded from the analysis, as screening registries did not exist at that time and the call-recall system which ensures active invitation of the entire target population at regular intervals was not implemented. [5]

A) Positivity Rate: Rates of positive screening test results, reflect the cut-off level chosen in each member state for the adopted test. These rates are consistent across the member states using gFOBT, ranging between 1.8% and 4.1%. However higher variability can be observed across member states adopting FIT, ranging between 3.3% to 9.8%. 931 out of 12,209 (7.6%) Maltese and Gozitan patients had a positive FIT. This is similar to the EU average.[6]

B) Detection rates for colorectal cancers: Colorectal cancer detection rates across the member states ranged between 0.09 – 0.19 % using gFOBT and 0.12 – 0.47% using FIT based programmes.[6] In Malta and Gozo, patients who took part in the screening programme and who had a positive FIT (931) were then invited to undergo a colonoscopy. Out of 931, 723 (77.6%) patients accepted to undergo a colonoscopy. A total of 12 (1.7%) of these patients were diagnosed with colorectal cancer (Mater Dei and Gozo General Hospital; one was histologically diagnosed in Malta while the other eleven were diagnosed in Gozo. Of these eleven patients, two were Gozitan while the rest were Maltese).

Compared to the EU, a significant higher detection rate for colorectal cancer was noted. This could be due to the limited size of the gene pool as most people marry within the same population rather than foreigners.

Overall, the detection rate and the positive predictive value for colorectal cancers and adenomas are influenced by characteristics of the screened population and by the screening protocol adopted.[6,7]

In European countries, detection rate of colorectal carcinomas and advanced adenomas is similar, where endoscopy screening is adopted either by flexible sigmoidoscopy or total colonoscopy. Detection of any other type of adenomas is higher with total colonoscopy rather than with flexible sigmoidoscopy.

In general, the prevalence of target lesions is lower among screenees having previous negative examination reports. Independent of subjects' screening history, the prevalence shows an increasing trend with age, both among men and women.[6-8] In the Maltese islands the average age for both adenoma and colorectal carincoma detection was 61 years.

PARTICIPATION RATES

A) Gender: Women show a higher uptake than men in all countries using the faecal test while males show a higher uptake in those countries implementing endoscopy screening. [6,9] In this study, where the FIT test was used as the initial screening investigation, participation was highest amongst women (53.3% who had a positive FIT were females while 46.7% were males).

B) Age: In 2003, the EU Council recommended biennial screening with faecal occult blood testing to all subjects aged 50-74 or, based on national prioritization for a narrower age band. Recently, based on a comprehensive review of available evidence, the EU Council is recommending that programmes should start screening between age 50 and 60, with a 2-year interval, if the screening test is gFOBT or FIT, or a 10-year interval, or more, if the screening test is flexible sigmoidoscopy or total colonoscopy, and to continue sending invitations to screen up to the age of 70–75 years.[6,10] In 2016, the targeted age population in the Maltese islands included those between 59-61 years.

C) Screening Protocol: The type of screening protocol affects participation. Participation in a single invitation round is generally higher for programmes offering faecal tests as compared to programmes offering flexible sigmoidoscopy or total colonoscopy screening. However, a sigmoidoscopy or total colonoscopy can ensure a long lasting protection to those who attend.

From a public health point of view a proportion of non-responders will attend at least once over repeated invitations. But non-invasive faecal tests for primary screening will require colonoscopy assessments of positive subjects. Issues related to colonoscopy capacity are also influencing the choice of the method, as well as the target age range, in different countries. For example Italy is providing a choice of different methods for screening to improve participation rates. Ideally all countries should adopt this method for a more reliable comparison.[11] In 2016, 14,287 Maltese and Gozitan individuals received their invitation to undergo a FIT test. 12,209 (85%) accepted their invitation and participated. Participation rates across European countries exceeded the acceptable minimum of 45%, but neither country reached the desired target (>65%). Screening programs must employ specific strategies to attract the target population and encourage participation in screening programs.[5] Although the participation rate in the Maltese islands was approximately 85%, one must remember that 557 invites were not delivered. So if the latter 557 invites were to be considered with the total, the participation rate decreases to 82%. In screening methods that employ faecal tests, patients need to be followed up, while in endoscopic methods, no follow-up is needed. From the 931 (6.3%) patients who resulted FIT-positive, 208 patients (22.3% of the FIT-positive patients) did not undergo a colonoscopy. This clearly shows that with faecal tests there is the risk that patients do not undergo a colonoscopy and follow-up is lost.

The quality of screening reports has to be consistent and linked with the European health interview survey and national health interview surveys to obtain more precise information. Screening monitoring should be continuous and updated at regular intervals. Comparision of the data collected from various programmes needs to be enhanced. The coverage (by invitation and by examination) and the detection rates in different settings could be misleading unless due consideration is given to the different tests which are adopted, screening intervals and target ages that different programmes may adopt. Furthermore, opportunistic screening should also be accounted for.[6]

CONCLUSION

The high incidence of findings in asymptomatic patients and high percentage of symptomatic patients brings to question these patients' lifestyle, their awareness and their management in primary care. In keeping with the study results, it is suggested that symptomatic patients, particularly those who experience rectal bleeding should be fast-tracked to a colorectal investigation, skipping the immunochemical screening phase. Absence of fast-tracking may have led to the increased rate of colorectal cancer detection rate in the Maltese and Gozitan population. The increased detection rate of colorectal cancer may also be due to the limited size of the gene pool. Patients with a positive family history should seek medical advice for early screening even if asymptomatic.

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