

COLORECTAL CANCER

Incomplete screening flexible sigmoidoscopy associated with female sex, age, and increased risk of colorectal cancer

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Background: Several previous studies have found that females and older individuals are at greater risk of having incomplete flexible sigmoidoscopy. However, no prior study has reported the subsequent risk of colorectal cancer (CRC) following incomplete sigmoidoscopy.

Methods: Using data from 55 791 individuals screened as part of the Colon Cancer Prevention (CoCaP) programme of Kaiser Permanente of Northern California, we evaluated the likelihood of having an inadequate (<40 cm) examination by age and sex, and estimated the risk of distal CRC according to depth of sigmoidoscopy insertion at the baseline screening examination. Multivariate estimation of risks was performed using Poisson regression.

Results: Older individuals were at a much greater risk of having an inadequate examination (relative risk (RR) for age 80+ years compared with 50–59 years 2.6 (95% confidence interval (CI) 2.3–3.0)), as were females (RR 2.3 (95% CI 2.2–2.5)); these associations were attenuated but remained strong if Poisson models were further adjusted for examination limitations (pain, stool, and angulation). There was an approximate threefold increase in the risk of distal CRC if the baseline sigmoidoscopy did not reach a depth of at least 40 cm; a smaller increase in risk was observed for examinations that reached 40–59 cm.

Conclusions: Older individuals and women are at an increased risk of having inadequate sigmoidoscopy. Because inadequate sigmoidoscopy results in an increased risk of subsequent CRC, physicians should consider steps to maximise the depth of insertion of the sigmoidoscope or, failing this, should consider an alternative screening test.

Screening by flexible sigmoidoscopy is associated with both decreased incidence of^{1,2} and decreased mortality from^{3,4} colorectal cancer (CRC). However, the efficacy of sigmoidoscopy is dependent on adequate visualisation of the colorectal mucosa so that colorectal polyps can be identified and removed before they progress to invasive cancer. Therefore, an inadequate examination (that is, one that has a limited depth of insertion of the sigmoidoscope or is hindered by poor bowel preparation or patient discomfort) may lead to a reduction in efficacy.

Previous studies have found that women and older individuals are more likely to have an inadequate sigmoidoscopy, usually defined as an examination reaching less than 50 cm depth of insertion (for a 60 cm sigmoidoscope), or limited by poor bowel preparation, pain, and/or angulation.^{5–9} The choice of 50 cm as a cutoff is somewhat arbitrary, however, and to our knowledge no prior study has correlated the definition of “inadequate” or “incomplete” sigmoidoscopy with the future risk of distal CRC (that is, cancers within reach of the sigmoidoscope). The purpose of this study was to evaluate cross sectionally risk factors for inadequate sigmoidoscopy at baseline screening, and further to conduct a cohort analysis of the association of sigmoidoscopy depth of insertion and examination limitations with distal CRC diagnosis within an approximate five year period post-sigmoidoscopy, using data from a large health maintenance organisation.

METHODS

Subjects and data sources

The study included men and women aged 50 years and older who were considered not to be at high risk of developing CRC and who participated in Kaiser Permanente of Northern

California's (KP) Colon Cancer Prevention (CoCaP) programme.¹⁰ KP is a large prepaid health plan of approximately 2.75 million members in the San Francisco Bay area of California; the CoCaP programme offers a screening flexible sigmoidoscopy to all KP members aged 50 years and older once every 10 years.

In 1994 and 1995, reports from all sigmoidoscopies performed in KP facilities were entered into a CoCaP computerised database. These reports included patient reported medical history and indications for examination (screening versus symptoms), plus endoscopist recorded indications for examination and results, including depth of insertion, limitations of the examination (due to spasm/pain, stool, or angulation), and number and depth of any polyps identified. Histological findings from any removed or biopsied polyps were linked back to the sigmoidoscopy data form. Additional demographic data (age and sex) and provider data (gastroenterologist, non-gastroenterologist physician, or nurse) were obtained from other KP databases, and incident cases of CRC to 31 December 2000 were identified using the KP Tumor Registry.

The study included screening sigmoidoscopies (as determined by both patient and endoscopist reported indication for examination) performed in 1994 and 1995 among CoCaP participants. Either patient or endoscopist report that the examination was being done as a result of symptoms resulted in exclusion. If a patient had more than one sigmoidoscopy during this time period, only the first was considered. Patients at high risk of developing CRC were excluded, based on the presence of inflammatory bowel disease, prior

Abbreviations: CoCaP, colon cancer prevention; CRC, colorectal cancer; KP, Kaiser Permanente of Northern California; RR, relative risk

Table 1 Baseline patient and sigmoidoscopy characteristics

Characteristic	No (%)
Age (y)	
50–59	26 141 (46.9)
60–69	20 452 (36.7)
70–79	8381 (15.0)
80+	817 (1.5)
Sex	
Male	29 537 (52.9)
Female	26 248 (47.1)
Endoscopist specialty	
Gastroenterologist	15 199 (27.2)
Non-gastroenterologist MD	29 036 (52.0)
Nurse	8111 (14.5)
Unknown	3445 (6.2)
Family history of CRC*	
No	51 486 (92.3)
Yes	4305 (7.7)
History of prior sigmoidoscopy	
No	41 836 (76.1)
Yes	13 121 (23.9)
Depth of sigmoidoscopy insertion (cm)	
<30	1733 (3.1)
30–39	3897 (7.0)
40–49	6061 (10.9)
50–59	8522 (15.3)
60+	35 578 (63.8)
Most advanced finding	
No polyps	45 863 (82.2)
Non-adenomatous polyp	5035 (9.0)
Non-advanced adenoma	3970 (7.1)
Advanced adenoma†	923 (1.7)
Examination limited by	
Spasm/pain	9967 (17.9)
Stool	7959 (14.3)
Angulation	8030 (14.4)

*Colorectal cancer (CRC) in one first degree relative diagnosed at age 55 years or younger.

†Size ≥ 1 cm, villous histology, and/or severe dysplasia.

colorectal polyps or cancer, or history of CRC in more than one first degree relative or one first degree relative diagnosed at age 55 years or younger.¹¹ Additionally, we excluded those who had CRC diagnosed at baseline, as identification of a lesion suspected of being cancer often results in termination of the examination prior to the maximal possible depth of insertion. Finally, we excluded those who had no indication of insertion depth recorded on the sigmoidoscopy report. This research was approved by the institutional review boards at Kaiser Permanente of Northern California (Oakland, California, USA) and at the Fred Hutchinson Cancer Research Center (Seattle, Washington, USA).

Statistical analysis

We chose to define “inadequate” sigmoidoscopy as those examinations that reached a depth of less than 40 cm, based on the subsequent incidence rates of distal CRC according to sigmoidoscopy insertion depth (see below). The proportion of individuals who had inadequate sigmoidoscopy was calculated for groups defined by both age and sex, and 95% confidence intervals (CI) for the proportions were calculated. Finally, we calculated the adjusted relative risk (RR) of an inadequate examination, and corresponding 95% CI, using Poisson regression with the robust estimator of variance. These models allow for valid estimation of RR and CI when the outcome of interest is common (that is, when the odds

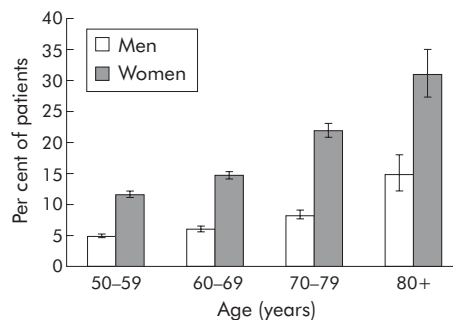


Figure 1 Proportion of men and women with inadequate sigmoidoscopy, by age. Error bars represent 95% confidence intervals for the proportion.

ratio is a poor approximation of the relative risk).¹² All Poisson models were adjusted for age (50–59, 60–69, 70–79, and 80+ years), sex, history of prior sigmoidoscopy, and family history of CRC.

Incidence rates of distal CRC (that is, cancers of the rectum and sigmoid colon, ICD-0–2 codes C18.7, C19.9, and C20.9) were calculated by categories of sigmoidoscopy depth of insertion and examination limitations. Rates were calculated by dividing the number of distal CRC cases by the total amount of person-time at risk. Study subjects were followed until 31 December 2000 or until the time of death, KP membership termination, or CRC diagnosis. Poisson regression was used to estimate the rate ratios, with 95% CI, for sigmoidoscopy depth of insertion and examination limitations. All Poisson models were adjusted using indicator variables for age (as parameterised above), sex, and family history of CRC. Analyses were conducted using the statistical software package STATA, version 8.0 (Stata Corporation, College Station, Texas, USA)

RESULTS

Results from 55 791 sigmoidoscopies were included in this analysis. Mean age of study subjects was 61.7 years, and 47.1% of subjects were women. Just over one half of examinations were performed by non-gastroenterologist physicians. Less than 10% of patients had a history of CRC in one first degree relative diagnosed after the age of 55 years, and approximately 25% had undergone previous sigmoidoscopy. Almost two thirds of sigmoidoscopic examinations reached 60 cm or greater; examinations to greater than 60 cm (3% of all examinations) largely occurred due to the use of a 65 cm sigmoidoscope in a small proportion of patients. Approximately 10% of sigmoidoscopies were to less than 40 cm. Eighteen per cent of screenees had polyps identified at sigmoidoscopy; about 50% of those with polyps had adenomas, and less than 2% had an advanced adenoma detected (defined as a tubular adenoma, ≥ 1 cm in size, or with villous histology or severe dysplasia) (table 1).

The proportion of inadequate sigmoidoscopies increased dramatically with increasing age and female sex (fig 1), ranging from 5% in men aged 50–59 years to 29% in women aged 80 years and older. These patterns were very similar if alternate definitions of “inadequate” were used. For men aged 50–59, 12% had examinations to less than 50 cm, and 25% of examinations did not reach 60 cm or more. In women aged 80 years and older, 47% and 65% of examinations did not reach 50 and 60 cm, respectively.

In the multivariate Poisson model, there was a greater than twofold increase in the risk of inadequate sigmoidoscopy for both women and for those over age 80 years. There was no evidence of an interaction between sex and age. The risk was also increased when the provider was not a

Table 2 Relative risk of inadequate sigmoidoscopy by patient and examination characteristics, with and without adjustment for examination limitations

Characteristic	Proportion with inadequate sigmoidoscopy (%)	Not limitations adjusted		Limitations adjusted	
		RR*	95% CI	RR*	95% CI
Age (y)					
50–59	8.1	1.0	Ref.	1.0	Ref.
60–69	10.3	1.2	1.2–1.3	1.2	1.1–1.2
70–79	14.6	1.7	1.6–1.8	1.5	1.4–1.6
80+	22.0	2.6	2.3–3.0	1.8	1.6–2.1
Sex					
Male	6.1	1.0	Ref.	1.0	Ref.
Female	14.6	2.3	2.2–2.5	1.6	1.6–1.7
Endoscopist specialty					
Gastroenterologist	7.8	1.0	Ref.	1.0	Ref.
Non-gastroenterologist MD	10.0	1.3	1.2–1.4	1.2	1.2–1.3
Nurse	7.9	1.0	0.9–1.0	1.0	0.9–1.1
Unknown	26.5	3.3	3.0–3.5	2.1	1.9–2.3
Family history of CRC†					
No	10.2	1.0	Ref.	1.0	Ref.
Yes	9.4	0.9	0.8–1.0	0.9	0.8–1.0
History of prior sigmoidoscopy					
No	9.7	1.0	Ref.	1.0	Ref.
Yes	11.2	1.1	1.0–1.2	1.0	1.0–1.1
Examination limited by					
Spasm/pain					
No	5.6	–	–	1.0	Ref.
Yes	30.8	–	–	3.1	2.9–3.3
Stool					
No	8.6	–	–	1.0	Ref.
Yes	18.8	–	–	2.9	2.7–3.0
Angulation					
No	6.1	–	–	1.0	Ref.
Yes	34.1	–	–	2.9	2.8–3.1

CI, confidence interval; RR, relative risk.
 *Adjusted for all other variables in table, with or without adjustment for examination limitations.
 †Colorectal cancer (CRC) in one first degree relative diagnosed at age 55 years or older.

gastroenterologist, especially for those providers for whom specialty could not be determined from the sigmoidoscopy report; neither family history nor history of prior sigmoidoscopy was a strong risk factor for inadequate sigmoidoscopy. Further adjustment of the full Poisson model for sigmoidoscopy limitations resulted in attenuation of all relative risks; however, the associations with sex, age, and unknown specialty remained quite strong. Each individual limitation was independently associated with an approximate threefold increase in risk (table 2). These relationships were quite similar if the sample was restricted to those who had no polyps identified at sigmoidoscopy, or to those with no limitations noted on the sigmoidoscopy report.

When sigmoidoscopy limitations were considered as an outcome in Poisson models, increasing age was a risk factor for examinations limited by spasm/pain, angulation, and

especially by stool. Female sex was a risk factor for examinations limited by pain or angulation, but not by stool (table 3).

Depth of sigmoidoscope insertion was associated with the discovery of polyps at baseline. While there was a tendency for polyp prevalence to increase with increasing depth of insertion, those with examinations to less than 30 cm had a higher prevalence of polyps than all but those with examinations to 60 cm or more. Polyps were identified in 17.7% of sigmoidoscopies with a depth of insertion less than 30 cm, and 14.2%, 14.6%, 15.9%, and 19.2% of examinations to 30–39, 40–49, 50–59, and 60 cm or more, respectively. This increased prevalence among those with examinations to less than 30 cm was most pronounced for advanced adenomas; the corresponding advanced adenoma prevalences for increasing depth of insertion categories were 2.9%, 1.7%,

Table 3 Relative risk of sigmoidoscopy limitations by patient age and sex

Characteristic	Limitation					
	Spasm/pain		Stool		Angulation	
	RR*	95% CI	RR*	95% CI	RR*	95% CI
Age (y)						
50–59	1.0	Ref.	1.0	Ref.	1.0	Ref.
60–69	1.0	1.0–1.1	1.2	1.1–1.2	1.1	1.0–1.1
70–79	1.1	1.1–1.2	1.5	1.4–1.6	1.2	1.1–1.3
80+	1.3	1.2–1.5	2.3	2.0–2.5	1.5	1.3–1.7
Sex						
Male	1.0	Ref.	1.0	Ref.	1.0	Ref.
Female	2.2	2.1–2.3	0.8	0.8–0.8	2.2	2.1–2.3

CI, confidence interval; RR, relative risk.
 *Also adjusted for endoscopist specialty, family history of colorectal cancer, and history of prior sigmoidoscopy.

Table 4 Rate ratios for distal colorectal cancer (CRC) by baseline sigmoidoscopy characteristics

	No of cases of distal* CRC	Distal* CRC incidence†	Rate ratio‡	95% CI
Depth of insertion (cm)				
<30	3	33.2	2.9	0.9–9.9
30–39	7	33.8	3.0	1.2–7.2
40–49	5	15.5	1.4	0.5–3.8
50–59	9	19.9	1.9	0.8–4.1
60+	21	11.0	1.0	Ref.
Examination limited by				
Spasm/pain	12	22.7	1.7	0.9–3.4
Stool	4	9.5	0.5	0.2–1.5
Angulation	10	23.5	1.7	0.8–3.5

CI, confidence interval.

*Defined as rectum or sigmoid colon.

†Per 100 000 person years.

‡Adjusted for sex, age, and family history of CRC.

1.5%, 1.4%, 1.7%, and 1.7%. These patterns persisted after adjustment for age, sex, and family history of CRC using Poisson regression (data not shown).

By the end of follow up, 45 cases of distal CRC had been diagnosed (15 rectal, seven rectosigmoid junction, 23 sigmoid colon). Although prior studies have considered examinations to less than 50 cm as inadequate,^{5–7} we found that the risk of distal CRC for those with examinations to 40–49 cm was similar to that in those with examinations to 50–59 cm, and considerably lower than the risk in those with examinations to less than 40 cm (table 4). For this reason, we have chosen to define “inadequate” examinations as those reaching a depth of less than 40 cm. An indication that the examination was limited by pain, stool, or angulation was not predictive of a further increased risk of distal CRC, once depth of insertion was included in the model. These risks, which were adjusted for age, sex, and family history of CRC, remained essentially unchanged after further adjustment for baseline histological findings, although there was some suggestion that the presence of polyps at baseline was independently associated with subsequent distal CRC diagnosis (RR 1.7 (95% CI 0.7–4.1) for non-adenomatous polyps, RR 2.1 (95% CI 0.9–5.1) for non-advanced adenomas, RR 1.3 (95% CI 0.2–9.3) for advanced adenomas).

DISCUSSION

Female sex and increasing age were strong risk factors for inadequate sigmoidoscopy, as was unknown provider type and, to a lesser extent, examinations performed by non-gastroenterologist physicians. An increase in the number of examinations limited by pain, stool, or angulation only partially accounted for these increased risks; models that either adjusted for limitations or were restricted to those with no limitations showed some attenuations in the risk estimates, but age, sex, and unknown provider type remained strongly associated with inadequate sigmoidoscopy. There was an increased risk of distal CRC among those who had a sigmoidoscopic examination that reached a depth of insertion of less than 40 cm. The presence of limitations of the examination, including spasm/pain, stool, and angulation, did not predict future distal CRC, apart from their association with depth of insertion.

This study has several strengths, most notably the large sample size and availability of follow up data to allow us to quantitate the subsequent risk of distal CRC post-sigmoidoscopy. However, there were several limitations that should be mentioned. Firstly, depth of insertion is only a crude measure of the amount of the colorectum that has been examined. Even among patients with examinations that reach similar depths, the anatomical segment of the colon that is visualised

varies. Prior studies have estimated that about 50–75% of sigmoidoscopies view the entire sigmoid colon, while only a minority of examinations (10–40%) visualise the entire descending colon.^{13–15} Furthermore, when the CoCaP programme began in 1994, endoscopists were instructed to measure insertion depth based on a straightened sigmoidoscope, with all loops removed. However, no specific quality control measures were instituted to ensure that endoscopists were adhering to this protocol, so it is not known to what degree endoscopists recorded depth of insertion while loops remained. Thus a number of examinations coded as “adequate” may truly have been inadequate according to the actual amount of colon visualised. The net effect of this misclassification however would likely have been to weaken the strength of our observed association, rather than to strengthen it.

Secondly, the possibility of additional misclassification exists in the data, especially because the data were primarily collected for clinical rather than research purposes by multiple endoscopists. For example, underreporting may have occurred in the collection of data regarding limitations of the examination if clinicians failed to note this on the sigmoidoscopy report. Nevertheless, a standardised form was used for all sigmoidoscopies, with items such as limitations in “checkbox” format, to allow clinicians to record data in a consistent and efficient way.

Thirdly, some sigmoidoscopies may have been terminated at the time when a polyp that was not suitable for immediate removal was discovered; these patients would likely have been referred for colonoscopy, making continuation of the sigmoidoscopy unnecessary. Our data support this assertion. Although the prevalence of polyps tended to be greater with increasing depth of sigmoidoscope insertion, those with examinations to less than 30 cm actually had a higher prevalence of polyps (and especially of advanced adenomas). Thus it seems likely that some small fraction of these shorter examinations was terminated prior to the maximal possible depth of insertion. We attempted to reduce this problem by excluding those sigmoidoscopies that resulted in the diagnosis of cancer. Furthermore, this problem did not result in a large bias; the risk of inadequate examination according to age and sex was almost identical if we restricted to those study subjects who had no polyps identified by sigmoidoscopy, and adjustment for the baseline findings had no impact on the rate ratios for distal CRC according to sigmoidoscopy depth.

Finally, the analyses that examined the risk of distal CRC according to depth of insertion were based on a relatively small number of cases ($n = 45$). Thus our estimate of 40 cm as the most appropriate cut point in defining “inadequate”

examinations may have been affected by the limited precision of our risk estimates. Our data are consistent with more modest elevations in cancer risk in those with examinations reaching between 40 and 59 cm insertion. None the less, this study is, to our knowledge, the first to attempt to quantify the risk of subsequent cancer according to depth of endoscopic insertion.

Our results are largely consistent with those of prior studies examining age⁵⁻⁷ and sex⁵⁻⁹ as risk factors for incomplete sigmoidoscopy. In another recent analysis from the Clinical Outcomes Research Initiative (CORI), Walter *et al* used data from over 15 000 examinations in asymptomatic persons performed in multiple sites throughout the USA to assess the risk of inadequate sigmoidoscopy (less than 50 cm) by age and sex.⁵ In this population, the proportion of inadequate examinations ranged from 10% in men aged 50-59 years to 32% in women aged 80 years and older. Other recent analyses have had similar findings,^{6,7} although several other small studies failed to find an association with age^{9,16} and/or sex.¹⁶ These results for sigmoidoscopy are also similar to those of several studies that found that older age and female sex were predictive of incomplete or difficult colonoscopy.¹⁷⁻²⁰

Our results are also consistent with those of Schoen and colleagues²¹ who found an increased risk of subsequent advanced colorectal pathology following an inadequate baseline sigmoidoscopy, defined as an examination to less than 50 cm and/or an examination in which less than 90% of the colorectal mucosa was visualised due to inadequate preparation (odds ratio 2.7 (95% CI 1.4-5.4)). This study, conducted among participants in the ongoing PLCO screening trial in the USA,²² was based on 72 advanced adenomas; six cases of invasive cancer were also included.

What then accounts for this decreased depth of insertion of the sigmoidoscope in women and older individuals? As suggested in our data, pain, suboptimal bowel preparation, and angulation of the colon account for some, but not all, of these associations. There is other evidence to support these findings; women are more likely to have tortuous colons^{17,23} and to experience pain during sigmoidoscopy,^{24,25} while older individuals are more likely to have suboptimal bowel preparation.^{5,8,26} However, other variables are also clearly important predictors. Previous pelvic or abdominal surgery,⁶⁻⁹ patient comorbidities,⁵ experience of the endoscopist,^{9,27} and body weight⁷ have all been reported to be associated with inadequate sigmoidoscopies. We were unable to directly assess these variables with the possible exception of endoscopist experience. Unknown provider type may have provided an estimate of limited endoscopist experience, as those with a lower procedure volume may be more likely to fail to enter a provider identification number on the sigmoidoscopy form or to enter an untraceable number. As certain potentially relevant variables were unavailable to us, it remains possible that at least part of the observed association with age and sex is due to uncontrolled confounding. However, other studies that have controlled for the variables above still found associations with age and sex,⁵⁻⁸ although admittedly no study has controlled for all of the above variables. Additionally, it is possible that under-reporting of examination limitations by clinicians (as discussed above) could lead to residual confounding when this variable is included in the multivariate models, resulting in risk estimates that are too high.

Despite this, the large magnitude of the associations observed, the precision with which we were able to estimate these associations, and the agreement with prior studies provides strong support for an association of age and sex with inadequate screening flexible sigmoidoscopy. Clinicians should be aware of the potential for limited examinations

in older and female individuals, and should consider steps to maximise the potential for an adequate screening examination. For example, several small randomised controlled trials have reported reductions in pain during sigmoidoscopy associated with the use of smaller diameter endoscopes in women,²⁸ or with the use of medications^{29,30} or audiovisual stimulation³¹ to minimise pain and/or anxiety; in the case of examinations limited by stool, an alternate preparation strategy, such as oral sodium phosphate, could be used.³² Alternatively, if an adequate sigmoidoscopy proves difficult, other screening tests can be considered. Because spasm/pain, angulation, and stool cannot fully explain the association between age/sex and inadequate sigmoidoscopy, additional research is needed to better characterise the reasons for inadequate examinations. However, regardless of the reasons, a sigmoidoscopy examination to less than 40 cm is a cause for concern, due to the increased risk of subsequent CRC.

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EDITOR'S QUIZ: GI SNAPSHOTS.....

Robin Spiller, Editor

A challenging presentation of left upper quadrant pain

Clinical presentation

A 21 year old female was admitted with a 48 hour history of severe left upper quadrant and loin pain with radiation to the shoulder tip, nausea, and vomiting. She was para 1+0 with a past medical history of a negative laparoscopy for investigation of menorrhagia seven weeks prior to admission. Physical examination revealed a pyrexia of 38.4°C and sinus tachycardia of 120 beats per minute. She had severe tenderness and guarding in the left upper quadrant and loin, in addition to left sided basal crepitations. Blood tests revealed a white cell count of $23 \times 10^9/L$, platelet count of $312 \times 10^9/L$, and C reactive protein of 300 mg/l. The remainder of her blood investigations were within the normal range.

Chest x ray revealed left basal consolidation. Abdominal ultrasound scan showed a left sided subdiaphragmatic collection associated with other abnormalities which were investigated further by subsequent computed tomography scan (fig 1).

Question

What are the abnormalities noted at A and B in fig 1? What is the diagnosis and management?

See page 1317 for answer

This case is submitted by:

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Figure 1 Splenomegaly (A) and extensive thrombus within the splenic vein (B).

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