Contrasting US and European approaches to colorectal cancer screening: which is best?

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Contrasting US and European approaches to colorectal cancer screening: which is best?

Geir Hoff,1 Jason A Dominitz2

ABSTRACT

In the recent 1—2 decades, we have seen a considerable development in colorectal cancer (CRC) screening modalities and programme implementation, but major challenges remain. While CRC is still the second leading cause of cancer death in both the USA and Europe, there are limited data on the efficacy and effectiveness of all screening modalities except for the faecal occult blood test (FOBT). Newer screening tests, such as faecal immunochemical tests, molecular markers and CT colonography are being introduced and variably adopted, though overall rates of screening are suboptimal. Professional societies and governmental bodies have endorsed screening, though recommended approaches are quite variable, which may help to explain the great variation in screening practices. Unfortunately, quality assurance programmes are underutilised. Comparing the USA and Europe there may be more variation in CRC screening recommendation and practice within each continent than between them, but there seems to be a stronger emphasis on programmatic screening in Europe, facilitating quality assurance. The much debated need for randomised trials as new screening modalities emerge could be more easily handled if running screening programmes are regarded as natural platforms for testing out and evaluating presumed improvements in the service—including new emerging screening modalities.

INTRODUCTION

Over the past few decades, remarkable changes have occurred in the field of colorectal cancer (CRC) screening. We have moved from screening with digital rectal examinations, guaiac-based faecal occult blood tests (FOBTs) and rigid sigmoidoscopy to screening with more sophisticated FOBTs for human haemoglobin (ie, faecal immunochemical tests (FITs)), screening colonoscopy, virtual colonoscopy and even analysis of stool for mutated DNA. As CRC screening becomes increasingly common, we have seen a decline in the incidence of CRC,1 believed to result in part from the removal of premalignant polyps with colonoscopy. However, there remain significant challenges. CRC is still the second leading cause of cancer death both in the US and in Europe. There is limited knowledge on the efficacy and effectiveness of all screening modalities except FOBTs, and there is considerable disagreement as to the need for randomised trials for other screening modalities. There is tremendous variation in screening practices around the world and across different healthcare delivery systems. Moreover, many people either do not have access to, or choose to avoid, CRC screening.

Even when screening is performed, cancers and treatable neoplasms are missed, and increasing evidence suggests that important pathology is missed more often than was previously thought.2—5 Therefore, quality assurance efforts are being undertaken to improve the delivery of screening interventions and, hopefully, patient outcomes.5 Finally, as new tests are developed, the programmatic costs and cost-effectiveness of these screening tests are increasingly being considered by policy makers—also because the rapidly increasing treatment costs for advanced CRC seem to make CRC screening not only cost-effective, but cost-saving.7 8 This review compares and contrasts various aspects of CRC screening efforts in Europe and the USA and describes factors that may account for the tremendous variation in clinical practice.

BACKGROUND

CRC is the second leading cause of cancer death in Europe with 412 800 new cases and 207 400 deaths in 2008.10 The best evidence supporting CRC screening derives from large randomised, controlled trials utilising guaiac-based FOBTs.11—13 Evidence to support sigmoidoscopy comes mainly from retrospective studies.14—16 While large-scale randomised studies are currently underway,19—22 Together with retrospective studies showing lower CRC incidence and mortality among individuals who have undergone colonoscopy,2 17 23—28 and results of cross-sectional studies of screening colonoscopy,27 28 this has been taken as indirect evidence to support primary screening colonoscopy. More recently, novel CRC screening tests have been introduced, including FITs, stool tests for molecular biological changes (genetic and epigenetic changes)29 30 and virtual colonoscopy.31 32 Given the wide assortment of available screening tests with vastly different performance characteristics, cost and requirements for patient adherence, it is not surprising that CRC screening practices are quite variable.

APPROACHES TO CRC SCREENING

Screening recommendations in the USA have changed at an increasingly rapid pace. In 1980, the American Cancer Society recommended CRC screening with digital rectal examination, FOBT and sigmoidoscopy.33 In 1996, the US Preventive Services

1Department of Medicine, Telemark Hospital, Skien, Norway
2VA Puget Sound Health Care System and Division of Gastroenterology, Department of Medicine, University of Washington, Seattle, Washington, USA

Correspondence to Professor Geir Hoff, Department of Medicine, Telemark Hospital, NO-3710, Skien, Norway; hofg@online.no
Task Force recommended CRC screening, including either FOBT annually, periodic sigmoidoscopy or the combination of both. Colonoscopy was first endorsed by the US Preventive Services Task Force in 2002, when barium enema was also included as an alternative option for screening. Other professional US societies also endorsed this menu of options with the hope that providing patients with more choices would improve overall adherence to screening. The American College of Gastroenterology, however, recommends colonoscopy every 10 years as the preferred CRC screening strategy, contending that offering a preferred screening test simplifies the discussion with the patient and may increase adherence. Recently, the Multi-Society Task Force on Colorectal Cancer and the American College of Radiology jointly published updated guidelines for CRC screening endorsing several tests not previously recommended and divided tests into those that detect cancer (eg, FITs) and those that prevent cancer (eg, colonoscopy). For the first time, FITs, stool DNA tests and CT colonography (CTC) were recommended for CRC screening. However, the US Preventive Services Task Force did not endorse stool DNA or CTC. They cited insufficient evidence to endorse CTC and recommend further studies to determine the benefits, risks and costs of detecting and evaluating extracolonic lesions found by CTC. Furthermore, they state that randomised trials are needed to compare different screening modalities to determine relative benefits and harms. Their decision not to endorse CTC has had important implications, as their recommendations were a key factor in the decision of the US Centers for Medicare and Medicaid Services (CMS, formerly known as Medicare) not to pay for screening CTC for Americans covered by this government health insurance. While screening CTC is now covered by some insurers in the USA, coverage by CMS would probably have resulted in widespread investment in the necessary equipment to perform CTC and marketing efforts to attract patients for screening. Without CMS coverage, it remains to be seen how CTC will fare in the US.

In Europe, the first CRC screening programme was probably the German FOBT programme starting in 1976 and it was not until 2003 that the European Union (EU) Commission officially recommended CRC screening—limited to FOBTs and on the provision of quality assurance of all levels of the programme and requiring regular monitoring of performance indicators. In addition to the recommendations from the EU Commission there are further EU guidelines on CRC screening on the way, expected to be ready early 2010. However, there are now very few European countries that have not implemented or at least are piloting national screening programmes. Among the world’s top-ten list on CRC incidence rates, Norway (number six in the Globocan top-ten list) is the odd one out in not having a CRC screening strategy. In contrast to the other Scandinavian countries, Norway has seen a dramatic increase in CRC incidence during the past three decades. Poland (ranked number 31 on incidence out of 172 countries in the Globocan database), on the other hand, is rolling out a national colonoscopy screening programme. Germany also has a colonoscopy screening programme, but in the rest of Europe, FOBTs dominate. Finland has introduced their FOBT programme in a stepwise, randomised fashion to optimise continuous evaluation allowing evidence-based reversal or modification of the programme. In addition, by this approach, they gain time to build up capacity and quality of investigation of screen positives, treatment when needed, and surveillance. When looking for contrasts and a possible trans-Atlantic divide in value for money screening, it should be emphasised that there may be greater differences within each of the continents than between them—particularly within Europe.

Coverage of screening by insurers is only one factor accounting for the increased uptake in the USA compared with Europe. Other notable factors include widespread media coverage and public awareness, state programmes to increase screening and the adoption of the Health Plan Employer Data and Information Set (HEDIS) measure in 2004 that encourages health plans to cover CRC screening. In US Department of Veterans Affairs (VA) medical centres, providers are now mandated to offer CRC screening to their patients and financial incentives are linked to performance measures, such as the proportion of patients who are adherent to CRC screening guidelines. The VA is essentially a federally funded managed care organisation comprised of 150 hospitals and nearly 900 outpatient clinics that provides care to 6 million veterans annually.

### Variation in current average risk CRC screening recommendations from US organisations

**US Preventive Services Task Force**
- Annual screening with a high-sensitivity FOBT, or
- Flexible sigmoidoscopy every 5 years, with a high-sensitivity FOBT every 3 years, or
- Screening colonoscopy every 10 years

**American Cancer Society, the US Multisociety Task Force on CRC and The American College of Radiology**
- Tests that detect adenomatous polyps and cancer
  - Flexible sigmoidoscopy every 5 years, or
  - Colonoscopy every 10 years, or
  - Double-contrast barium enema every 5 years, or
  - CT colonography every 5 years
- Tests that primarily detect cancer
  - Annual guaiac FOBT with high sensitivity for cancer, or
  - Annual FIT with high sensitivity for cancer, or
  - Stool DNA test with high sensitivity for cancer, interval uncertain

**American College of Gastroenterology**
- Preferred CRC prevention test recommendation for colonoscopy every 10 years
- Alternative CRC prevention tests recommended include
  - Flexible sigmoidoscopy every 5–10 years
  - CT colonography every 5 years
- Alternative cancer detection tests recommended include
  - Annual Hemoccult Sensa
  - Faecal DNA testing every 3 years
Healthcare providers receive reminders when their patient is due for CRC screening. However, within the VA, there is substantial variation in how CRC screening is performed—some may offer primary colonoscopy while others rely on FOBTs. Between 1998 and 2003, the number of CRC screening tests performed in the VA increased from ~433,000 to >1.1 million tests per year. Substantial effort has been undertaken to improve overall adherence to CRC screening in the VA, and performance measure data show that in fiscal year 2007, 78% of 50- to 75-year-old VA patients had been screened compared with only 50% and 56% 50- to 80-year-old patients covered by Medicare or commercial insurance, respectively. Within another US-managed care organisation, Kaiser Permanente of Northern California (KPNC), CRC screening rates have steadily improved through the use of organised outreach efforts with FITs. This year, KPNC mailed out >400,000 FIT kits and screened >200,000 individuals (James Allison, personal communication). Like many VA facilities, tracking systems are used to help ensure that those with a positive FIT undergo appropriate evaluation.

Outside of managed care organisations with a structured CRC screening programme, it is likely that CRC screening occurs on more of a spontaneous or non-programmatic basis, where patients either self-refer for a screening test or receive a recommendation/referral for screening at the time of an unrelated healthcare visit. One major concern with non-programme-based screening is that it is not easily subject to quality control, a problem now attracting increasing attention. It could be of interest to look into major end points on a population level, comparing programmatic versus non-programmatic screening—ideally as a randomised trial. There is strong evidence that CRC screening in the USA has been increasing since 2000 and a growing proportion are choosing colonoscopic screening. Concurrently, the overall number of CRC deaths in the USA is declining. It is conceivable that some of this improvement is a direct effect of coverage of CRC screening by the CMS. Unfortunately, adherence to screening recommendations is still estimated to be only 60% in the USA. Disparities have been demonstrated in CRC screening in the USA, including lower screening uptake among those of lower socioeconomic status, lower education, Hispanics and those lacking health insurance and routine healthcare.

### BALANCING EVIDENCE AND PRAGMATISM FOR THE ADOPTION OF CRC SCREENING STRATEGIES

A prerequisite for introduction of any new treatment or healthcare intervention has been the proof of efficacy—traditionally through well-designed randomised trials. These demands were put forward first in the USA by Thorner and Remain in 1961, and Wilson and Jungner followed in 1968 with a WHO monograph. The explicit demand for randomised trials prior to national screening programmes has remained to this date in some countries. Such studies are very expensive and the hard end points (mortality or incidence) may only be evaluated after many years of follow-up. A time horizon of 10 years or more is seldom consistent with that of healthcare funding agencies and politicians. National screening programmes are therefore prone to be launched on suboptimal or limited scientific evidence. There have been sobering reminders of this pointing out that what may be gained in CRC mortality may be lost by an increase in all-cause mortality, and screening services may even reduce incentives for smoking cessation and healthy lifestyle—not necessarily advising against CRC screening, but pointing at an educational challenge to combine screening with primary prevention.

Surveys have revealed that a major reason for non-attendance at screening is a set of intrinsic and extrinsic factors giving individuals a lack of conviction that attendance, with all this implies, is worth the personal effort. In one study from California, compliance with screening could be improved by provision of additional evidence of (screening) tests’ effectiveness—suggesting a call for further evidence of the benefit of CRC screening. This may reflect a primary lack of evidence-based conviction among advising physicians rather than the patients. To improve and maintain compliance over time, the scientific approach might then be to initiate large-scale trials of CRC screening relevant for the target population with its advising physicians. The problem, of course, is that once national programmes are rolled out, then it is usually too late to provide high-quality population-based evidence relevant to the target population. The political approach may be to penalise those who are non-compliant with screening—which was attempted in the 2007 Health Reform of Germany, but abandoned due to massive opposition.

While screening programmes should be undertaken only when their effectiveness has been demonstrated, the question really is ‘when is effectiveness demonstrated?’ Do we need randomised trials with 10 year horizons for every new screening modality or may surrogate end points (and which) sometimes be sufficient? Starting an evidence-based CRC screening programme is one thing, but how effectively is the available evidence suited to convince and persuade traditional non-compliers to attend? Are the trial results relevant for them? How can high attendance be maintained beyond the novelty of a first screening round? All these considerations are commonly shared on both sides of the Atlantic—conclusions...
Recent advances in clinical practice

Prerequisites for long-term CRC screening programme success

- Proven efficacy of the screening modality, but when is proof adequate scientifically and when is it sufficiently relevant to the target population?
- High attendance rates necessary to have an impact on public health and not only capture the health-conscious low-risk population
- Quality assured for all elements of the programme
  - Education
  - Screening test
  - Diagnostic evaluation (eg, colonoscopy after a positive FIT)
  - Treatment (eg, polypectomy, surgery, chemotherapy)
  - Capacity

are not drawn, but programme-based screening is definitely easier to evaluate for provision of relevant data than non-programmatic screening.

For FOBTs, sound scientific proof of efficacy has been provided from the USA and Europe—the most frequently quoted being the Minnesota, Nottingham and Funen randomised trials showing a 15–38% CRC mortality rate reduction—the latter also demonstrating an incidence reduction. Similarly, randomised trials on flexible sigmoidoscopy screening are on the way—the American PLCO study, the UK Flexible Sigmoidoscopy Screening Trial, the Italian SCORE and the Norwegian NORCCAP-I study. Baseline findings have been published from these studies, the NORCCAP-I study also quite recently providing an interim analysis on follow-up results. Both in the USA and in Europe attempts were made in the late 1980s and early 1990s to raise funding for randomised trials on colonoscopy screening with mortality as end-point—to no avail (S Winawer personal communication). Only recently has there been some success in fund-raising in Europe. The Nordic–European Initiative on Colorectal Cancer (NordICC) has recently launched a randomised trial on colonoscopy screening, starting in Poland (June 2009) and The Netherlands (July 2009).

There are no large-scale randomised trials on the new groups of screening modalities, virtual colonoscopy (ie, CTC or magnetic resonance colonography) or molecular markers (stool DNA or blood). There are several trials on test performance, including a very recent one demonstrating the highest sensitivity with colonoscopy (using colonoscopy as the ‘gold standard’), closely followed by CTC and flexible sigmoidoscopy, while FOBTs performed poorly for detection of advanced neoplasia. Also, adding FOBTs to flexible sigmoidoscopy did not improve performance significantly compared with sigmoidoscopy alone. Test performance, however, should not be confused with programme performance. A screening modality with a poor test sensitivity like the FOBT may obtain good programme sensitivity by accumulated annual or biennial screening rounds. The current evidence for using molecular markers is very weak. Nevertheless, it is recommended in one of the US guidelines. Another major difference between the USA and Europe is the attitude towards screening CTC. Within some European countries (Germany and Switzerland) CTC is prohibited for screening purposes due to radiation-related risk of cancer.

In spite of having very limited knowledge about the natural history of colorectal adenomas, primary aims have been moving from early CRC detection and mortality reduction to prevention by intervention of the adenoma–carcinoma sequence as expressed in the US guidelines. Modelling has suggested that flexible sigmoidoscopic screening with or without the addition of a FOBT may be cost-saving—assuming identical disease progression rates in the distal and proximal colon. A recent paper from Toronto suggests very strongly that this assumption cannot be made—exposure to colonoscopy with polypectomy was associated with reduced death only from distal, not proximal CRC. Although poor quality examination of the right colon cannot be ruled out, this study emphasises the weakness of some of the assumptions of modelling. Also, extrapolation of results from the ongoing flexible sigmoidoscopic trials to colonoscopy may be difficult and even evaluation of programmatic screening has limited value since you usually only have historic or non-randomised controls to compare with once a programme is rolled out.

So, given the lack of randomised, controlled trial-based evidence of effectiveness for all screening modalities apart from the FOBT, how have we handled our shortcomings for the benefit of people on both sides of the Atlantic? In the USA, outside of managed care organisations, most screening appears to be occurring on a spontaneous basis (rather than through a programmatic approach). The choice of screening test used may be determined by the patient, the healthcare provider or the insurer. However, in Europe, programmatic screening seems to be a more dominant strategy, with screening options defined by governmental agencies.

QUALITY AND PROGRAMMATIC VERSUS SPONTANEOUS SCREENING

The overall effectiveness of CRC screening will depend upon the screening test characteristics (eg, sensitivity and specificity), the proportion of individuals willing to undergo screening (ie, adherence), the willingness of those screening positive to undergo further evaluation (compliance for investigational colonoscopy) and the quality of care delivered downstream (eg, are polyps completely removed...
In the UK programme, FOBT uptake has been described.84 85 However, quality assurance of other CRC screening tests. For example, the guaiac-based FOBT can often be misinterpreted by healthcare providers.86 The use of automated FIT processing can minimise this concern. Should screening CTC be adopted, there remain questions about the ability of community radiologists to reproduce the results seen in the landmark studies.87

Programmatic screening offers the ability to address many of these concerns. First, an effective CRC screening programme can track individuals who are due for screening, whether the screening test is annual FIT or FOBT, or colonoscopy every 10 years, and provide reminders to these individuals and their healthcare providers. In addition, programmatic screening can help discourage inappropriate screening, such as an interval FOBT soon after colonoscopy. Secondly, programmatic screening allows for tailoring the screening option to the available capacity. For example, the use of an FIT allows for large-scale population screening with only a small proportion of individuals requiring colonoscopy. Furthermore, the threshold of haemoglobin detection and the number of tests performed can be varied to control the test positivity rate.88 Thirdly, programmatic screening can incorporate quality control measures to ensure that only approved providers perform the screening tests, such as the restriction on the performance of colonoscopy in Germany to only those endoscopists achieving certain quality benchmarks.89

Fourthly, those screening positive and those found to have cancer can be monitored to ensure that they receive appropriate care (eg, diagnostic colonoscopy or cancer treatment). Fifthly, programmatic screening may help to optimise surveillance of patients with colorectal neoplasia, which has been shown to be highly variable, with overutilisation of surveillance for those at low risk and underutilisation for those at high risk.89 Finally, new screening modalities may be tested as they are developed.

The outcome of a CRC screening strategy is highly dependent upon the quality and performance of all elements of that strategy. Without having adequate quality assurance programmes in place, we really do not know what

Recent advances in clinical practice

<table>
<thead>
<tr>
<th>Table 1 Modified from Graser et al89</th>
<th>Test sensitivity for advanced neoplasia, % (95% CI)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy (OC)</td>
<td>100 (88 to 100)*</td>
<td>Very endoscopist dependent. QA essential. Great cultural differences in the need for sedation, including use of anaesthesiologists (driving costs).</td>
</tr>
<tr>
<td>CT colonography (CTC)</td>
<td>97 (83 to 100)*</td>
<td>Similar bowel preparation as for OC. Insufflation to pain threshold to compete with OC, QA needed. OC when positive findings. Irradiation. Prohibited for screening in parts of Europe.</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy (FS)</td>
<td>83 (65 to 94)*</td>
<td>'Half-way' OC only, but simple bowel prep. Endoscopist dependent—QA needed.</td>
</tr>
<tr>
<td>Faecal immunochemical test (FIT)</td>
<td>32 (15 to 54)</td>
<td>Higher cost, but some advantages over FOBT.</td>
</tr>
<tr>
<td>gFOBT</td>
<td>20 (7 to 41)</td>
<td>Several rounds of a poorly performing test may add up to an acceptable programme sensitivity. Many false positives and frequent screening rounds.</td>
</tr>
<tr>
<td>FS + FIT</td>
<td>84 (64 to 96)</td>
<td>Nothing to gain by adding FOBT or FIT to FS—may only lose attendance.</td>
</tr>
</tbody>
</table>

*Colonoscopy was the “gold standard” in this study. Therefore, colonoscopy has 100% sensitivity by definition. FOBT, faecal occult blood test; gFOBT, guaiac-based FOBT; prep., preparation; QA, quality assurance.
we are selling as healthcare providers. This is easier to establish while rolling out national screening programmes, like in most of Europe, and more difficult when there is a range of established providers of spontaneous, non-programme-based screening services as in the USA, but it could also be done in a fee-for-service setting. Individual practitioners can certainly incorporate components of programmatic screening into their practices, and managed care settings are well situated to adopt this approach. The USA has led the way, starting early with CRC screening. Europe could have grasped the golden opportunity of performing many of the important randomised, controlled studies that we and the public now would like to have to hand. The window of opportunity for having a genuinely unscreened control group for 10 years of follow-up has long gone. While such studies may have been considered too costly in the past, they are likely to still be less expensive than an ineffective CRC screening programme that is initiated today.

Considering non-compliers’ request for more evidence of CRC screening benefits before undergoing screening, taxpayers may question authorities spending their money on launching a national screening programme and may prefer that the individual should decide to spend their own money on it, as in the USA. Nationalised screening programmes should ideally be rolled out in a randomised fashion, like the Finnish programme, to allow provision of evidence lacking from neglecting to perform randomised trials. This may facilitate comparison of two or more screening modalities using a randomisation design. In addition, adequate funding should be provided for quality assurance programmes, as in the UK, where only accredited colonoscopy centres are involved with CRC screening.

While we hope that prospective data on the effectiveness of the various screening modalities will be forthcoming, it is necessary to make some decisions today for how we will screen for CRC.**WHAT SCREENING APPROACH IS BEST?**

So, what is the answer to the question we started off with? Europe has taken the lead on implementation of quality assurance efforts which will have increasing importance for outcome—particularly with regard to incidence reduction and if invasive procedures come to play an increasing role. The use of programme-based screening allows for many advantages over the sporadic screening that occurs throughout most of the US healthcare system. However, ~60% of Americans report having undergone CRC screening. Therefore, it is likely that more Americans than Europeans have benefited from CRC screening due to a head start of massive screening in the USA, but we do not know the extent of this assumed benefit and the total cost. Although an emphasis on quality assurance has recently been adopted in the USA, the implementation of quality efforts is in its infancy and the lack of programmatic screening will hamper these efforts. Nevertheless, this emphasis and the increasing use of performance measures that are linked to physician reimbursement offer hope that the quality of CRC screening in the USA will continue to improve.

As often in recent history, the USA has also taken an early lead in the development and implementation of CRC screening—an activity which now calls for continuous quality assurance and an environment facilitating testing of emerging new screening modalities—particularly when the primary focus may shift from mortality to incidence reduction, with more demands being placed on the endoscopy services. There is a dawning realisation on both sides of the Atlantic that this may be best taken care of through organised, programmatic screening. This bodes well for trans-Atlantic collaboration to speed up processes on both continents.

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**REFERENCES**


Editor’s quiz: GI snapshot

ANSWER

From the question on page 406

Plain film of abdomen revealed evidence of small-bowel obstruction with a ‘coins sign’. Computed tomography (CT) showed dilated small-bowel loops with fluid accumulation and massive ascites. Bowel loops without fluid and mesentery were incarcerated in the hernia sac (arrowheads). CT also demonstrated the narrowing of the hernia portae (arrows) (figure 1). Umbilical hernia was diagnosed, and then confirmed at laparotomy. The incarcerated bowel was reduced, the hernia defect repaired and the patient was discharged 14 days later uneventfully.

Ascites is a common complication of end-stage liver disease. Umbilical hernia was reported more often in patients with cirrhosis and ascites than in those without ascites. Major complications are leakage, ulceration, rupture and incarceration. Rapid reduction of ascites and intra-abdominal pressure have been reported to result in incarceration in the hernia sac. Causes include peptic ulceration, transpyloric hypertrophy of the stomach, and duodenitis. Incarcerated umbilical hernia usually presents as a small-bowel obstruction. CT is a useful technique to resolve clinical doubt, which should be confirmed at surgery. Physicians should be aware of this serious complication during resolution of ascites following medical and surgical treatment.

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