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Learning objectives	• Discuss primary screening for colorectal cancer and its effectiveness. • Examine pharmacological evidence from the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) Study including the outcome trials for individuals with type 2 diabetes mellitus (DM). • Apply medical management regarding spinal cord stimulator use in chronic low back pain treatment and/or cancer treatment (in the last month of life).

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Primary screening for colorectal cancer – Important update on effectiveness of colonoscopy

Results from the Nordic-European Initiative on Colorectal Cancer (NordICC) trial recently published in the New England Journal of Medicine revealed a surprisingly modest benefit of being invited for colonoscopy for colorectal cancer (CRC) screening.[1] This large (~84,500 patients) randomized controlled trial compared adults invited for screening colonoscopy versus those not invited on the outcomes of CRC incidence and death from CRC. Using an intention-to-screen analysis, over a 10-year period, the colonoscopy group had an absolute risk reduction of 0.22% and a relative risk reduction of 18% in the incidence of CRC (risk ratio, 0.82; 95% confidence interval [CI], 0.70 to 0.93) compared to the control group. The risk of dying from CRC was not significantly different between the two groups. Since only 42% of those in the colonoscopy-invited group ultimately underwent a screening colonoscopy, additional per-protocol analyses were done looking only at patients who actually underwent colonoscopy. These showed a 0.38% absolute risk reduction (31% relative risk reduction) in CRC and 0.15% absolute risk reduction (50% relative reduction) in death from CRC.

Previous articles, based on evidence from less-robust cohort studies, estimated the benefit of primary colonoscopy screening to prevent CRC at up to 69% and to prevent death from CRC at up to 88%.[2] In light of the results from the NordICC trial, these estimates need to be adjusted downwards by quite a bit. The exact numbers are unclear as there are many caveats to the NordICC trial results as summarized in the editorial in the same issue of the New England Journal.[3] The most obvious caveat is that for colonoscopy to be effective as a CRC screening tool, patients who are invited must actually undergo the procedure for it to have the desired effect. The intention-to-screen analysis revealed only a very modest benefit with regards to developing CRC and no benefit for death from CRC. This can be partially explained by the low rate of screening in the 'invited' group. That said, even the per-protocol analyses of those who ultimately underwent screening showed an unexpectedly low benefit. Another point to consider when weighing the results of this study is the adenoma detection rate (ADR) of the colonoscopists. ADR is considered a surrogate for quality of the procedure, with a minimum threshold of at least 25% considered to be adequate.[4] In the United States, the average ADR is estimated at over 39%.[5] In the NordICC trial, conducted in countries that don't use colonoscopy as much as in the U.S., almost one third of the colonoscopists had an ADR below the 25% threshold for quality.[6] This could reflect overall lower quality colonoscopies that missed potential problematic adenomas and therefore could have attenuated the benefits of screening colonoscopies in this study. In other words, if the ADR was higher (as in the U.S.), there could have been a larger effect observed.

Even with these caveats, these recent findings do call into question the prevailing preference by the medical establishment in the U.S. to recommend primary screening for CRC with colonoscopy. Compared to non-invasive stool-based tests, colonoscopy does carry a risk of significant adverse events. Colonoscopy complication rates are higher in the elderly for GI complications (e.g.; perforation, bleeding) and non-GI complications (e.g.; myocardial infarction, stroke).[7,8]

Patient preference is also important to consider. A pilot study conducted in the U.S. between 2019 and 2020 showed 76% of patients who chose to have CRC screening underwent colonoscopy. This was likely based on the recommendation of their physician. After a shared decision-making intervention provided to 207 patients, those patients chose colonoscopy only 29% of the time, with the majority choosing stool-based methods.[9] Another recent study involving 1,000 patients revealed most (~75%) preferred a stool-based test over colonoscopy for CRC screening.[10] Table 1 shows estimates of some CRC screening methods on reducing CRC and death from CRC. This table does not show all available screening methods nor differences when using multiple screening methods in a given patient (e.g.; sigmoidoscopy every five years plus FIT test in between). A comprehensive review of available CRC screening methods, indications, possible harms and benefits are beyond the scope of this article summary.

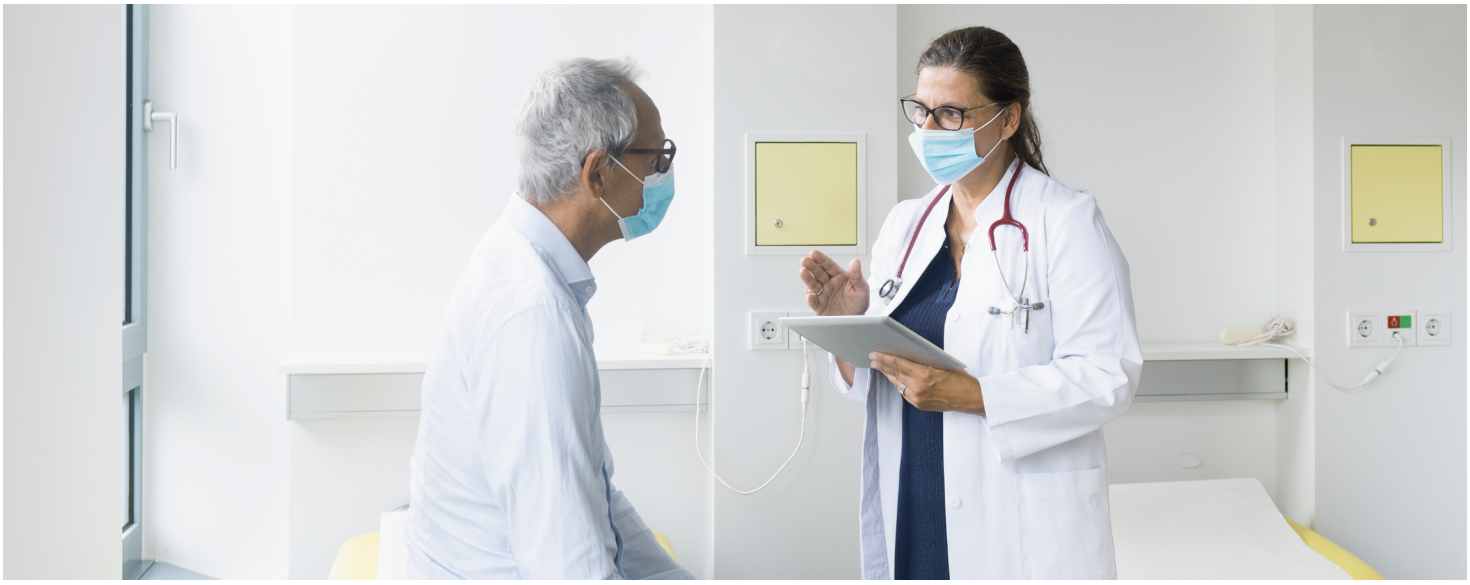
These findings reinforce the key messages in a previous edition of this publication.[11] Those key messages are:

- Colonoscopy may not be the most cost-effective primary screening tool for CRC for average risk adults.
- When patient goals and preferences are taken into consideration and shared decision-making is used, stool-based testing is often the screening tool of choice.

Of note, there is good evidence that endoscopist adenoma detection rate (ADR) improves for patients with known positive stool-based screening tests.[12] This supports use of colonoscopy as a secondary test following a positive primary stool-based CRC screening test in average-risk adults. With the new evidence from the NordICC trial, added to previous evidence of patient preference for stool-based tests, involving the patient in shared decision-making is essential, as routinely recommending only colonoscopy for CRC screening is no longer appropriate for many patients.

Table 1. Estimates of some common colorectal cancer (CRC) screening methods on reducing CRC and death from CRC, vs no screening.[13]

Method	Estimated reduction in CRC	Estimated reduction in death from CRC	Notes
Colonoscopy	• Absolute risk reduction of 0.22% • Relative risk reduction of 18%	No difference	Based on NordICC intention-to-screen
Sigmoidoscopy	22%	26%	Based on systematic review[1]
Fecal Immunochemical Test (FIT)	Not reported	10%	Based on systematic review[5]



The GRADE studies – Major new outcome trials for patients with Type 2 DM

As the therapeutic options for patients with Type 2 diabetes (DM2) have expanded, it has become more challenging to determine, for any given level of glycemic control, the balance between prevention of secondary outcomes and the cost of the drug regimen. The yearly cost of glycemic control can vary from a few hundred dollars on an all-generic regimen to over $20,000 when combining multiple branded drugs. The critical question therefore becomes – when do the higher costs of a drug regimen provide a cost-effective benefit in any given patient with respect to cardiovascular and microvascular outcomes? To help answer this question, two important companion studies, known as the GRADE studies, were published.[14,15] The GRADE studies used the same population of over 5,000 patients and examined both the glycemic outcomes, and the CV and microvascular outcomes of four different drug classes added to a background of metformin therapy.

The authors chose insulin glargine, glimepiride (sulfonylurea), liraglutide (GLP-1 RA), and sitagliptin- (DPP-IV inhibitor/gliptin) as the four comparators. Due to safety concerns at the time of randomization in 2013, the SGLT-2i's were unfortunately not included as a study arm. Patients were followed for a median of five years. It is noteworthy that, unlike the CV and renal outcomes trials that have been recently published with the SGLT2i's and GLP-1 RA's, this patient population was not selected based on established CV disease, very high CV risk, or high levels of proteinuria, and therefore is generally representative of the broader population of patients with DM2 seen in most primary care settings.

With respect to glycemic control, overall, the median HbA1c at four years into the study was 7.1% in both the glargine and liraglutide groups, as compared with 7.2% in the sitagliptin group and 7.3% in the glimepiride group. As the primary outcome, the authors looked at the percentage of patients who had an HbA1c >7% during the study. This was highest (worst control) in the sitagliptin group at 77%, next was glimepiride at 72%, with liraglutide and glargine being similar at 68% and 67% respectively. The improved glycemic control of glargine and liraglutide were both statistically significant compared to the other two comparators. However, it is important to note that these differences were small. Particularly in a senior population where guidelines suggest less stringent HbA1c control, these differences will be less significant. Severe hypoglycemia was uncommon in all four groups. It occurred in 2.2% of patients with glimepiride over the five years, 1.3 % with glargine, 1% with liraglutide, and 0.7% with sitagliptin. Weight gain was only seen with glimepiride and glargine but was minor in both groups at 0.73 kg and 0.61 kg over the five years, respectively.

In terms of CV outcomes, at baseline, 96% of patients had dyslipidemia and 77% had hypertension. In the small population of patients unaffected by these two comorbidities at baseline, most developed both conditions by the end of the study. At study entry, 6% had a prior stroke or myocardial infarction.

Major CV events (MACE) occurred in 6-8% of the aggregate population by the end of study, and there were no clinically significant differences between any of the four drug groups.

With respect to microvascular outcomes, there were also no major differences among the four treatment groups in the cumulative incidence of moderately increased or severely increased albuminuria level or other renal outcomes. Similarly, there were no major differences among the groups in the incidence of diabetic peripheral neuropathy.

So where does this leave us with respect to pharmacotherapies for DM2? The omission of the SGLT2i group is unfortunate, however the role of this drug class has been well defined in other trials as reviewed in prior editions of this Forum. In the setting of established CHF with reduced ejection fraction, established CVD, or diabetic nephropathy with significant proteinuria, patients should be treated with SGLT2i's based on established benefits and likely cost effectiveness. Importantly, this should be in lieu of or in addition to metformin. Next, one might question whether there is any role at all for the DPP-IV class. They do not reduce CV or renal outcomes, are not associated with significant weight loss, are not of high potency with respect to glycemic control, and they are expensive at ~$6,000 yearly. Rather than initiating a DPP-IV, patients might be considered instead for an GLP-1 RA, with its significantly greater glycemic-lowering potency, documented benefits in obesity, and reductions in secondary DM2 outcomes including myocardial infarction. Lastly, in an average risk population of patients with DM2, there is not established cost effectiveness for expensive branded agents. A recent cost effectiveness modeling study suggested that the incremental cost per quality-adjusted life-year (QALY) of first line SGLT2i use compared to first line metformin use in an average population of patients with DM2 was $478,000 or close to 5 times the accepted cost-effective threshold of $100,000. The QALY for the injectable GLP1-RA class could not be calculated as there was no overall benefit compared to first line metformin use, and the QALY for the oral GLP-1 RA class was over $1 million.[16] Lastly, a recent cost effectiveness analysis was done looking at the impact of the SGLT-2i's in the patient population of the EMPEROR-Preserved trial. This is the only prospective RCT showing a clinical benefit to the SGLIT-2i class in patients with heart failure with preserved ejection fraction.[17] The cost per QALY using Medicare Part D costs was over $510,000.

Perhaps the best algorithm to help determine when expensive branded agents should be considered is the BMJ meta-analysis[18] that evaluated all of the GLP-1 RA and SGLT2i CV and renal outcomes studies. Based on the CV risk burden and renal risk profile of any given patient with DM2, it makes recommendations for generic regimens, or the above two drug classes, and includes the strength of the recommendation. A formal cost effectiveness analysis was not done as part of the meta-analysis as the studies were conducted across the globe with a wide variation in drug costs from county to country. It was reviewed in the July 2021 edition of this Forum and the algorithm can be accessed at this URL.[18] bmj.com/content/373/bmj.n1091

Spinal cord stimulator use in chronic low back pain

Spinal cord stimulators (SCS's) are neuromodulation devices implanted into the epidural space with the intent of treating chronic pain that has failed conventional management. Long term studies of the outcomes of SCS implantation are lacking – a recent Cochrane review found only one small study of 44 patients that looked at pain relief at greater than one year post implantation.[19] This is problematic since over 50,000 are implanted yearly at a cost of over $3.5 billion. Among 4,000 medical devices tracked by the FDA, SCS's had the third highest rate of device related adverse events.[20]

A recent study published in JAMA Neurology describes work done by our Optum Care Research Institute in collaboration with researchers from UCSF. [21] We used the large Optum Labs Data Warehouse to conduct a "synthetic" RCT of over 1,400 patients with SCS implantation and compared them to over 6,300 patients without SCS implantation that were propensity matched on 65 variables to assure closely matched groups. This design allows for a large well-matched observational study that can approximate the results of a prospective RCT. All patients had at least two years of follow-up. By months 13-24 post implantation, the SCS group showed no reductions in opioid utilization or dosage and had increased utilization of anti-depressants and gabapentinoids. They also had no reductions in epidural steroid injections, radiofrequency ablations, or spine surgeries. Over the two years of the study, there were no reductions in ED or hospital utilization. In the year of SCS implantation, the SCS group had a $33,000 higher cost for Medicare, and a $60,000 higher cost for commercial insurance, which was almost entirely related to the cost of the implant and the surgery. The costs were no different between the two groups for the second year of the study. Over the two years of the study, 18% of patients had significant complications related to the device and 22% of patients needed a second surgery for device removal.

Given that we were unable to demonstrate a clinical benefit to SCS implantation in this large observational study, and given the observed significant complication rate and need for device removal, the routine use of SCS should be questioned. If SCS's use is to continue, a large RCT that includes a sham control limb is needed to assess whether there is any clinical benefit that outweighs the known harms of SCS implantation.

Cancer treatment in the last month of life

The use of chemo and biological therapies at the end of life is problematic. It results in potential negative impacts on both the quality and duration of life, including delays in palliative care and hospice enrollment, and is associated with increased costs of care. The median cost of a course of cancer treatment now is just under $200,000. In 2012, the American Society of Clinical Oncology and the National Quality Forum developed a quality measure that looked at the proportion of patients receiving chemotherapy in the last 14 days of life to promote reduction in chemotherapy and earlier use of palliative care and hospice. [22]

A recent study looked at data in over two million cancer patients treated between 2015 and 2019, to examine the use of chemo and biological therapies in the 30 days and 14 days before death. Despite this new quality metric, there was no reduction in treatment over the four-year study period, with 39% of patients receiving treatment within the last 30 days of life and 17% receiving treatment within the last 14 days of life. As would be expected, the percentage of patients treated with chemotherapy declined while the percentage of patients treated with biological therapies increased.

These data suggest that we need new models of oncology reimbursement which include appropriate quality and utilization metrics to improve the outcomes of our cancer patients at the end of life.

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