# SmoothX: A Promising New Positive Oral Contrast Agent for CT

*Maximizing patient satisfaction while optimizing diagnostic effectiveness*

Alec J. Megibow, MD, MPH, FACR

The purpose of this white paper is to introduce healthcare providers to SmoothX, a new oral contrast material developed for high-quality computed tomography (CT) imaging of the abdomen, stomach, bowel, rectum, and colon. This review includes general background information related to oral contrast material for CT, a description of SmoothX, and results of 2 prospective, blinded studies in 24 adult participants to compare the taste characteristics and diagnostic efficacy of SmoothX to the Readi-CAT2 Vanilla Smoothie.

**Background.** The use of oral contrast material for opacification of the gastrointestinal tract became a standard of care soon after the introduction of abdominal CT. Both barium-based and iodine-based contrast material can be used, depending on the patient's specific diagnostic imaging needs . Iodinated contrast material requires appropriate dilution, however, barium-based contrast material for CT is manufactured at the correct concentration and does not require modification. The actual dose of oral contrast material and the time delay between the first administration and the scan time is variable across institutions. Ideally, 450 mL of a 2% w/v concentration of barium is consumed orally, at least 90 minutes prior to the CT examination, followed by 300 mL 30 minutes before scanning, and lastly 150 mL immediately prior to scanning.

There are few contraindications to the use of these agents. Allergic reactions are rare but possible, especially using iodinated agents in patients with both a prior allergic reaction to intravascular iodinated agents and the diagnosis of inflammatory bowel disease where bowel mucosal disruption could lead to absorption of the agent. Adverse reactions to barium-based products are rarely allergic in nature and typically mild. When reactions do occur, symptoms such as nausea, vomiting and abdominal discomfort are most reported. (1) Barium product additives are used to improve image quality and luminal distention and are found ubiquitously in other food products. For example, the sweetener Sorbitol is a common additive that can cause abdominal cramping and diarrhea in patients who are sensitive to this compound.

The indications for the use of a positive oral contrast agent include subacute abdominal pain, suspected bowel leak, gastrointestinal fistula, abdominal fluid collections (including abscess), and oncologic staging/surveillance. Neutral oral contrast agents that have the luminal attenuation of water are useful at CT enterography for the evaluation of gastrointestinal bleeding, and in patients with known or suspected inflammatory bowel disease. Oral contrast material is not recommended in patients following blunt or penetrating trauma where the speed of imaging is critically important. Controversial indications for the use of oral contrast material to define an intra-abdominal infection, inflammatory mass, or fistula communications include patients with suspected appendicitis, small bowel obstruction, and in selected patients with known Crohn's disease. (2)

Despite a strong safety record, the use of oral contrast material has been decreasing in large part due to a desire to increase patient throughput, particularly driven by emergency room turnaround time improvement initiatives. (2) Patients receiving oral contrast material for a CT scan often need to wait 45-90 minutes after consuming the contrast agent to satisfactorily fill the small bowel. Ideally, this issue could be addressed by implementing a protocol that dictates patients presenting to the ER who are likely to receive an abdominal CT scan should receive early administration of oral contrast materials. This could reduce non-productive wait times, as these patients will often require additional services such as blood work, history and physical examination and other time-consuming testing.

Some practices have utilized a body mass index (BMI) protocol for the use of oral contrast material. In these centers, only thinner patients receive oral contrast material, while patients with more visceral fat do not receive the contrast agent. Despite these practices, studies related to body mass index and the use of oral contrast material have not demonstrated a BMI-dependent difference in imaging efficacy. (3,4)

An important issue to be considered in patient care is that emergency room physicians and other responsible care givers are not trained on the rationale and need for oral contrast material. Busy radiologists accept "no oral contrast material" orders, with the knowledge that once the ordering physician has ordered the exam without contrast, there will be time-consuming efforts involved to change the order, often requiring extensive communications and patient care delays. Radiologists often accept the sub-optimal order and interpret the scan as accurately as possible. Unfortunately, an important patient care issue is at stake—providing the highest level of radiologic interpretation at the cost of a potential minor throughput delay. Current approaches strive to provide optimal solid organ imaging techniques with pre-intravenous contrast material scans, arterial, portal venous and delayed phase imaging. However, it is common practice to neglect the hollow organs without insisting on optimal luminal distention or opacification. Collaborative discussions with referring physicians regarding the use of oral contrast material needs to occur to achieve optimal patient care.

In several studies, improved diagnostic ability and diagnostic confidence occurred with the use of positive oral contrast material compared with no contrast material. (5) In this author's experience, reduced confidence can result in report hedging, the need for repeat scanning, and imprecise or missed diagnoses. This is especially paramount in academic centers where clinicians without subspecialty expertise are interpreting abdominal and pelvic CT examinations. The indication for the abdominal CT examination should be the major criteria for determining the need for oral contrast material.

In several studies, improved diagnostic ability and diagnostic confidence occurred with the use of positive oral contrast material compared with no contrast material.[5]

Lastly, many imaging centers that use barium suspension as their oral contrast agent have testified to poor patient tolerance of the taste, viscosity, and chalkiness of the contrast. This can lead to poor compliance, and patients who have difficulty drinking the contrast often need coaching from medical staff, a nasogastric (NG) tube placement, or require rescheduling. These routine setbacks and unmet needs were factored heavily into the development of the new SmoothX oral contrast material.

**SmoothX Overview.** Voyageur Pharmaceuticals Ltd. (Calgary, Canada) has developed a new contrast agent, SmoothX barium sulfate oral suspension, for use in abdominal CT imaging. To evaluate the performance of SmoothX in comparison to the market-leading barium sulfate product Readi-CAT2 (Bracco, Milan, Italy), the investigators first conducted a prospective, blinded, controlled trial in 12 healthy adults. The study was approved by the local IRB, and each participant provided written consent to participate. The aim of the study was to evaluate the two agents for organ uniformity and filling. Participants were randomly assigned an agent (six participants received SmoothX, and six received Readi-CAT2 Vanilla Smoothie). The volunteers were asked to rapidly consume three doses of the oral contrast material: 450 mL 90 minutes before scanning, 300 mL 30 minutes prior to CT scanning, and 150 mL immediately prior to scanning (sitting on the CT table).

**CT Evaluation**. Upon completion of imaging, the CT examinations of each cohort were evaluated for diagnostic effectiveness by an independent radiologist who did not have knowledge of which oral contrast agent was administered. Each segment (distal esophagus, stomach, small bowel, colon, and rectum) of the gastrointestinal

tract was assessed for uniformity and the percentage of organ filling. Uniformity was graded on a 4-point scale (1 = markedly variable attenuation, 2=moderately variable attenuation, 3= mildly variable attenuation, 4= uniform attenuation throughout). The percentage of the bowel lumen filled with contrast material was also assessed on a 4-point scale (1 = <25% filling, 2 = 25-50% filling, 3 = 50-75% filling, 4 = >75% filling).

**CT Evaluation Results.** There was not a significant difference in the volume of contrast material ingested between the two different oral agents. Uniformity of the contrast material in both the stomach and small bowel was judged to be the same. In three of six patients ingesting Readi-CAT2, contrast material was identified in the colon, whereas none of the patients who received SmoothX had detectable amounts of contrast material in the colon. This specificity of the contrast with SmoothX can contribute to a more accurate study of the upper GI tract. The percent of organ filling in both the stomach and small bowel was similar for both agents (mean stomach and small bowel scores for Readi-CAT2 = 3 and 3.7; SmoothX = 3.3 and 3.3 respectively).

Uniformity of the contrast material in both the stomach and small bowel was judged to be the same.

**Taste Evaluation.** The second study conducted by the investigators involved twelve different volunteers who consented to taste test both SmoothX and Readi-CAT2 to assess the characteristics of each agent. Each participant, blinded to the contrast material manufacturer, quickly (5-10 minutes) drank 450 mL of one agent. Thirty minutes later they consumed another 450 mL of the alternative manufacturer's contrast material. Half of the participants started with consumption of Readi-CAT2, and the other half with SmoothX. The contrast agents were subsequently switched for the second taste test. After each taste test, the participants completed a questionnaire related to taste, texture, thickness, and aftertaste. A 7-point rating system was used to rate the various taste parameters ranging from horrible (-3), to neutral (0), to delicious (+3). The same 7-point rating system was used to rate willingness to drink two 450 mL cups of the contrast material in 30 minutes, as well as willingness to drink the contrast material again in 3 months if required for a repeat CT scan.

**Table 1. Taste Evaluation Results**

| | OVERALL TASTE | | TEXTURE | | THICKNESS | | AFTERTASTE | |
|---|---|---|---|---|---|---|---|---|
| PARTICIPANT | SmoothX | Readi-CAT2 | SmoothX | Readi-CAT2 | SmoothX | Readi-CAT2 | SmoothX | Readi-CAT2 |
| 1 | 1 | 0 | 2 | 1 | 2 | 2 | 1 | 0 |
| 2 | 2 | 1 | 1 | 0 | 0 | 0 | 1 | 0 |
| 3 | 2 | 2 | 1 | -3 | 1 | -1 | 3 | 3 |
| 4 | 0 | -1 | -2 | -2 | 2 | 2 | 1 | 2 |
| 5 | 2 | 2 | 0 | 1 | 2 | 2 | -1 | 1 |
| 6 | 1 | 2 | 2 | 2 | 0 | 1 | -1 | 1 |
| 7 | 2 | 2 | 0 | 1 | 0 | 1 | 1 | 1 |
| 8 | 0 | 1 | -1 | 2 | 1 | 1 | 0 | 0 |
| 9 | 2 | 1 | 2 | 2 | 3 | 3 | -1 | -2 |
| 10 | 3 | 2 | 3 | 1 | 2 | 1 | 3 | 3 |
| 11 | 1 | -1 | 0 | 1 | 0 | 0 | 3 | 2 |

| 12 | 2 | 1 | -1 | 0 | 0 | 1 | 2 | 0 |
|---|---|---|---|---|---|---|---|---|
| **PREFERENCE** | SmoothX | 7 | SmoothX | 4 | SmoothX | 2 | SmoothX | 5 |
| | ReadiCAT2 | 2 | ReadiCAT2 | 5 | ReadiCAT2 | 3 | ReadiCAT2 | 3 |
| | Same | 3 | Same | 3 | Same | 7 | Same | 4 |

**Taste Evaluation Results.** Seven of twelve (58%) participants rated the taste of the SmoothX contrast material higher than the Readi-CAT2 agent. Only two individuals rated the Readi-CAT2 agent higher while three individuals rated the taste the same. Minor differences between products were identified for contrast material texture, thickness, and aftertaste. In addition, there were no significant differences in willingness to consume an additional 450 mL dose or to drink the contrast again for a future repeat examination.

75% of participants overall preferred SmoothX (Voyageur) contrast material over the Readi-CAT2 (Bracco) agent.

**Summary.** When properly prescribed, oral contrast material increases diagnostic confidence and effectiveness. The new oral contrast material, SmoothX, introduced by Voyageur Pharmaceuticals, demonstrated nearly identical diagnostic imaging properties as Readi-CAT2 in the blinded study. Of note, most individuals in the taste test study preferred the taste of SmoothX and this taste preference could translate into improved patient satisfaction and compliance for abdominal CT examination.

**Acknowledgement**. Voyageur would like to thank the team at Canada Diagnostic Centre, Calgary for their participation in this study, under the leadership of Jay Zelazo, MD, FRCPC, Director of CT; Jordan Muth, MRI & CT Manager, MRT (MR) ; and Michelle Holstein, Radiological Technologist, MRT (R) (MR).

**References.**

1. ACR Manual on Contrast Media 2022. ACR Committee on Drugs and Contrast Media. ISBN: 978-1-55903-012-0
2. Pickhardt PJ. Positive oral contrast material for Abdominal CT: AJR 2020;215;69-78
3. Wolfe JM, Smithline H, Lee S, Coughlin B, Polino J, Blank F. The impact of body mass index on concor-dance in the interpretation of matched noncontrast and contrast abdominal pelvic computed tomograph-ic scans in ED patients with nontraumatic abdominal pain. Am J Emerg Med 2006; 24:144–148
4. Wang ZJ, Chen KS, Gould R, Coakley FV, Fu Y, Yeh BM. Positive enteric contrast material for abdominal and pelvic CT with automatic exposure control: what is the effect on patient radiation exposure? Eur J Radiol. 2011 Aug;79(2):e58-62. doi: 10.1016/j.ejrad.2011.03.059. Epub 2011 Apr 13. PMID: 21493028; PMCID: PMC4117209.
5. Triche BL, Annamalai A, Pooler BD, Glazer JM, Zadra JD, Barclay-Buchanan CJ, Hekman DJ, Mao L, Pickhardt PJ, Lubner MG. Positive oral contrast material for CT evaluation of non-traumatic abdominal pain in the ED: prospective assessment of diagnostic confidence and throughput metrics. Abdom Radiol (NY). 2022 Aug;47(8):2956-2967. doi: 10.1007/s00261-022-03574-6. Epub 2022 Jun 23. PMID: 35739367.

Disclosures: Authored by a radiologist member of the Voyageur advisory board.

**Figures.**

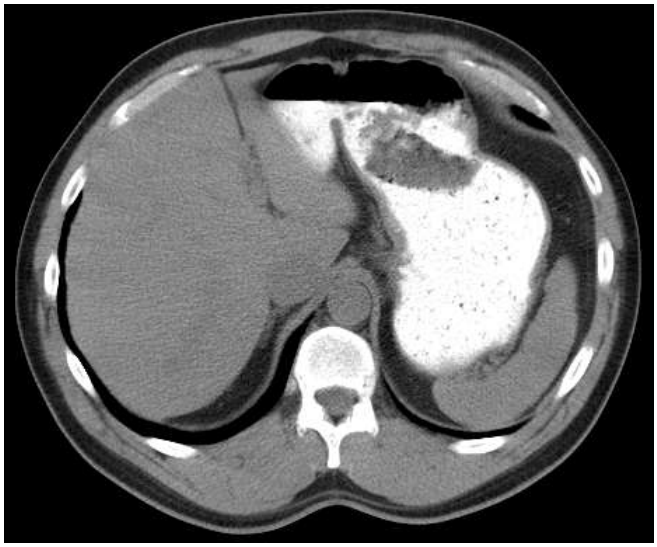

**FIGURE 1A.** CT examination of the abdomen using **SmoothX** contrast materials shows similar appearance of both contrast agents within the stomach. Homogeneous contrast media is present in the stomach as well as residual food.

**FIGURE 1B.** CT examination of the abdomen using **Readi-CAT2** contrast materials shows similar appearance of both contrast agents within the stomach. Homogeneous contrast media is present in the stomach as well as residual food.

**FIGURE 2.** Comparison of small bowel contrast agents' appearance. **A.** Coronal and axial images in two different patients using SmoothX oral contrast material. **B.** Coronal and axial images in two different patients using Readi-CAT2 oral contrast material. Both contrast agents have comparable radiographic appearances.

**FIGURE 2A**

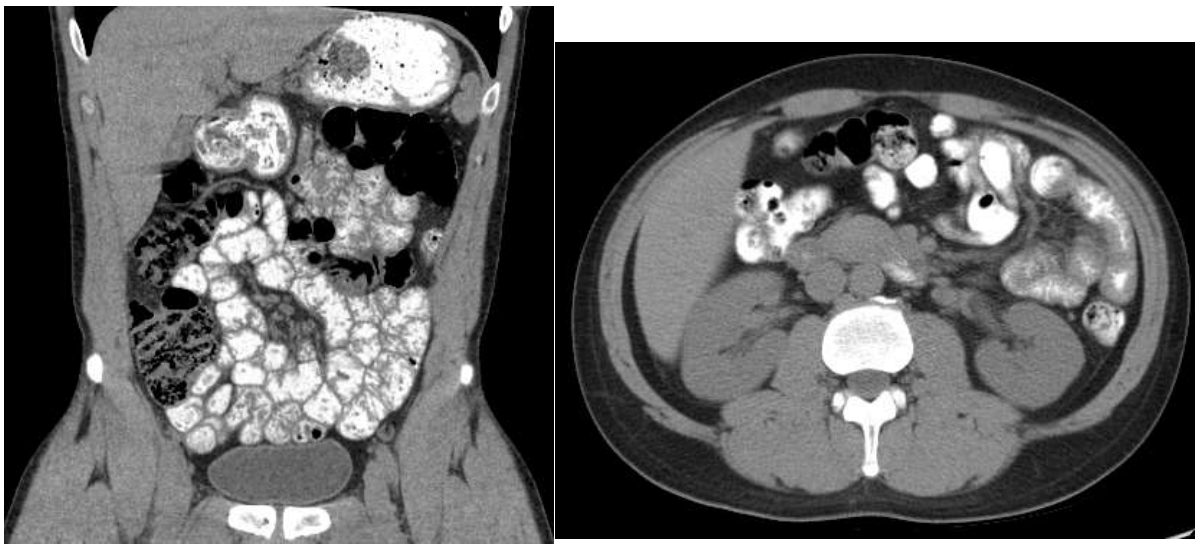

**FIGURE 2B**