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Quality assurance for non-contrast CT of the abdomen and pelvis during a period of supply chain disruption leading to iodinated contrast shortage in the emergency department setting

Luis Fernando Calimano-Ramirez[1], Mauricio Hernandez[1], Anmol Singh[1], Kazim Ziya Gumus[1], Wanda Marfori[1], Mayur K. Virarkar[1], Chandana Lall[1], Dheeraj Reddy Gopireddy[1]

[1]Department of Radiology, University of Florida College of Medicine Jacksonville, Jacksonville, Florida, United States.

***Corresponding author:**
Luis Fernando Calimano-Ramirez, Department of Radiology, University of Florida College of Medicine Jacksonville, Jacksonville, Florida, United States.

luis.calimanoramirez@jax.ufl.edu

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ABSTRACT

Objectives: Iodinated contrast media (ICM) shortage crisis due to COVID-19 lockdowns led to a need for alternate imaging protocols consisting of non-contrast computed tomography (CT) for abdominal complaints and related trauma indications in emergency department (ED) settings. This quality assurance study aims to evaluate clinical outcomes of protocol modifications during ICM shortage and identify potential imaging misdiagnosis of acute abdominal complaints and related trauma.

Material and Methods: The study included 424 ED patients with abdominal pain, falls, or motor vehicle collision (MVC)-related trauma who had non-contrast CT of the abdomen and pelvis in May 2022. We accessed the initial complaint, order indication, non-contrast CT results, any acute or incidental findings, and any follow-up imaging of the same body region with their results. We evaluated their association utilizing Chi-squared tests. We assessed sensitivity, specificity, and positive/negative predictive values using follow-up scan confirmation.

Results: Across initial complaint categories, 72.9% of cases were abdominal pain, and 37.3% received positive findings. Only 22.6% of patients had follow-up imaging. Most confirmed original reports were for abdominal pain. We also found three reports of missed findings. There were significant associations between complaint categories and initial non-contrast CT report results ($P < 0.001$), as well as initial complaint categories and whether the patient received follow-up imaging or not ($P < 0.004$). No significant associations were found between follow-up imaging results and initial report confirmation. Non-contrast CT had 94% sensitivity and 100% specificity, with positive and negative predictive values 100% and 94%, respectively.

Conclusion: Rate of missed acute diagnoses using non-contrast CT for patients presenting to the ED with acute abdominal complaints or related trauma has been low during the recent shortage, but further investigation would be needed to verify and quantify the implications of not routinely giving oral or intravenous contrast in the ED.

Keywords: Abdominal and pelvic computed tomography, Quality assurance, Iodinated contrast shortage, Emergency department

INTRODUCTION

Abdominal pain, falls, and motor vehicle collision (MVC)-related trauma are three of the most common presentations for patients in the emergency department (ED).[1,2] computed

tomography (CT) of the abdomen and pelvis has become the imaging modality for evaluating these patients.[2] The American College of Radiology (ACR) Appropriateness Criteria state that contrast is recommended in most cases of abdominal pain and abdominal traumas.[3] This imaging modality is also helpful in the evaluation of potentially acute causes such as infection (appendicitis, colitis, diverticulitis, and pyelonephritis); inflammation (pancreatitis and inflammatory bowel disease), masses, and malignancies; and vascular abnormalities (gastrointestinal bleeding, aortic dissection, and abdominal aortic aneurysm). However, contrast administered intravenously (IV) is not required to diagnose intestinal perforations, nephrolithiasis, or hematomas (active contrast extravasation require contrast).[3]

The recent global COVID-19-induced lockdowns have led to significant interruptions in the supply chains of numerous business sectors. Iodinated contrast media (ICM) was one of the casualties which greatly strained resources within the medical field.[4,5] In the United States, iohexol™ (Omnipaque; GE Healthcare) contrast has the largest market share.[4] Earlier this year, the production of iohexol at the primary manufacturing sites in Shanghai, China, was drastically reduced due to government-imposed COVID-19 lockdowns. Clinical institutions that rely on iohexol for their contrast-enhanced CT imaging have been most impacted, especially those that maintained a limited supply before the shortage. This situation has compelled high-volume medical institutions like ours to radically alter clinical workflow practices to conserve ICM for ED acute imaging cases.

Multiple professional interest groups, including the ACR, the American Society of Hospital Pharmacists, and others, have released guidelines on how to approach the recent ICM shortage, including various strategies for the conservation of contrast material for time-sensitive diagnostic tests and interventions, the absence of which would increase the risk of adverse patient outcomes.[5-8] A new clinical perspective published in the American Journal of Roentgenology highlights various comprehensive techniques to conserve ICM across imaging centers.[6,9] One of the principal strategies was to employ as many non-contrast scanning in the ED as possible for patients undergoing CT of the abdomen and pelvis for a wide range of indications. These included abdominal pain or distension with concern for hernia, diverticulitis, appendicitis, abscess, bowel obstruction, abdominal trauma, as well as trauma screening and reserve contrast for just the severely ill or as a problem-solving tool after a positive screening unenhanced CT.[5]

The aim of this quality assurance (QA) study at our institution, the University of Florida (UF) College of Medicine, Jacksonville, is to track the resulting clinical outcomes of these alternate non-contrast imaging protocols for the period of ICM shortage. We wanted to identify the potential for misdiagnosis or liability related to non-contrast CT imaging of the abdomen and pelvis with ordering history of acute abdominal complaints or abdominal trauma in the ED setting.

MATERIAL AND METHODS

Data collection

IRB approval was not necessary for this QA study. Per our institutional processes, we applied to the Quality Improvement Project Registry and obtained a registration certificate. Nuance mPower (Nuance Communications, Inc.), a cloud-based software database of UF Health Jacksonville Radiology imaging reports, was used to retrospectively search for non-contrast CTs of the abdomen and pelvis for acute abdominal pain and related traumas during the peak period of ICM shortage, between May 1 and May 31, 2022. We generated a list of 424 individual scans of patients that presented to the ED during that time. We used the keywords: abdominal pain, abdominal trauma, fall trauma, motor vehicle collision (MVC), nausea, vomiting, gastritis, and flank pain.

Moreover, we accessed the electronic medical records using EPIC (Epic Systems) to record the initial complaint, order indication, non-contrast abdomen/pelvis CT results, any acute or incidental findings reported, any follow-up imaging of the same body region, and results of the follow-up imaging and associated radiology reports up to 90 days after initial ED presentation. Data were reviewed and categorized within a secure spreadsheet accessible only by the research team. All patient health information was redacted as the data were recorded.

Data classification

The initial complaint was divided into five categories: abdominal pain, abdominal discomfort, abdominal trauma, fall trauma, and MVC. Abdominal pain in these categories refers to severe abdominal pain lasting from hours to a few days where the initial approach from the ED physician was to asses for life threatening causes. Abdominal discomfort refers to less serious causes of abdominal pain such as constipation, gastritis, and diverticulosis. Abdominal trauma refers to blunt trauma, impact with an object, or penetrating injuries. Fall traumas refer to blunt traumas from deceleration from different type of falls, and MVC from deceleration from a vehicle impact and collision. We removed two cases that did not fit within these categories. Initial imaging results were categorized as negative or positive. The acute positive result included radiology reports describing infection (appendicitis, colitis, diverticulitis, and pyelonephritis); inflammation (pancreatitis and inflammatory bowel disease), masses and malignancies; and vascular abnormalities (gastrointestinal

bleeding, aortic dissection, and abdominal aortic aneurysm). Positive incidental findings were categorized into hernia, cyst, nodule/mass, liver disease, renal calculi/malfunction, gastrointestinal, thoracic/chest cavity, and genitourinary issues.

We noted whether the patient had received any follow-up imaging of the same body region (up to 90 days from initial presentation and imaging). Imaging follow-up type was categorized as CT and magnetic resonance (MR) of the abdomen and pelvis with and without contrast, abdominal ultrasound, abdominal CT angiography (CTA), and abdominal X-ray. Follow-up report status either confirmed findings (negative, acute, and incidental) or identified a missed finding/false adverse finding. A board-certified, abdominal fellowship-trained radiologist re-evaluated reports and associated imaging in order to confirm any missed/false-negative results.

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) software (IBM® SPSS® version 26, Chicago, IL). We characterized the total sample based on the distribution of ED presentation categories. We utilized Chi-squared tests to evaluate associations between initial complaints and initial non-contrast CT results, whether follow-up imaging of any modality was performed for the same body region during the same hospital stay or within the following month, and whether the follow-up imaging results confirmed the original report or not. We also looked for associations between follow-up imaging modality/scan type and whether the initial report was confirmed or missed, either acute or incidental.

To assess whether we could confidently infer hypothetical counts of initial radiology report confirmation for ED patients who did not obtain follow-up imaging of the same body region, we compared initial complaint distributions between the group of ED patients who received follow-up imaging and the one that did not. Finally, we calculated the sensitivity, specificity, positive predictive value, and negative predictive value of the non-contrast CT of the abdomen and pelvis protocol across all ED presentation categories based on follow-up scan confirmation of initial report results. Finally, we used Cramer's V to test for effect size in the comparisons. $P < 0.05$ was considered statistically significant. These cross-comparisons of the data made sense within the setting of a QA project primarily, rather than a research project.

RESULTS

Across the five initial complaint categories for which patients received non-contrast CTs of the abdomen and pelvis in the ED, 72.9% of cases were abdominal pain [Table 1]. When comparing the percentage of positive findings across all categories combined, slightly over one-third (37.3%) of patients had a positive result in the initial imaging report. When separated by categories, abdominal trauma complaints had the lowest ratio of positive to negative findings (8/54, 14.9%), and abdominal pain had the highest ratio of combined acute/incidental positive results (137/172, 79.7%).

Out of 424 patients included in the study who had initial imaging, only 22.6% (96) received follow-up scans of the same body region. Of these 96 patients from the initial complaint, (45/96, 46.8%) imaging results were positive, and (51/96, 53.1%) were negative. The initial complaint categories with the highest likelihood of follow-up imaging of the same body region were abdominal pain (84/309, 27.2%) and abdominal discomfort (3/15, 20%). In contrast, the initial complaint categories with the lowest likelihood of follow-up imaging were fall trauma (0/14, 0%), motor vehicle collision (2/24, 8.3%), and abdominal trauma (7/62, 11.3%). Of the seven different scan types, a repeat non-contrast CT was favored in 29.2% (28/96) of cases, followed by contrast-enhanced CT in 22.9% (22/96) of cases. Of the patients who received follow-up imaging, 97% (93/96) of cases had confirmation of the original report acute/incidental findings. Although abdominal pain was the initial complaint with the highest number of original confirmed reports (81), it was also responsible for all three reports of missed findings. Of the three missed findings, the initial complaint results were negative and one of these could be considered clinically significant.

Chi-square tests showed significant associations between initial complaint categories and initial non-contrast CT report results ($P < 0.001$). The effect size was large ($V = 0.249$, $df = 4$). Chi-squared tests also showed significant associations between initial complaint categories and whether the patient received follow-up imaging or not ($P < 0.004$). The effect size was medium ($V = 0.189$, $df = 4$). No significant associations were found between initial complaint categories and follow-up imaging type ($P < 0.572$) or follow-up imaging result/initial report confirmation ($P < 0.931$). Finally, the sensitivity of initial non-contrast CT of the abdomen/pelvis was 94%, and the specificity was 100%. The positive predictive value of this imaging examination for the initial complaint categories analyzed was 100%, and the negative predictive value was 94%. The follow-up imaging results confirmed three misses confirmed by the radiologist [Figures 1 and 2].

DISCUSSION

The primary clinical application of iodinated contrast is to enhance the visible differences between healthy and diseased tissues, allowing the human eye to detect subtle lesions, and other pathologies.[10] Nonetheless, various studies have

Table 1: Sample distribution of ED patients that received a non-contrast CT of the abdomen/pelvis during May 2022 at UF Health Jacksonville.

Initial complaint	*n*%*	Initial non-contrast CT results**		Follow-up Imaging (Y/N)		Follow-up imaging type***								Follow-up imaging results***		
		Positive %*	Negative %	Yes %	No %	CT w/o %	CT w/%	CTA w/%	MR w/o %	MR w/%	XR KUB %	US %	No F/U %	CORI %	Miss %	No F/U %
Abdominal	15	4	11	3	12	0	2	0	0	0	0	1	12	3	0	12
discomfort	3.5	27	73	20	80	0	13	0	0	0	0	6.7	80	20	0	80
Abdominal pain	309	137	172	84	225	27	19 6.1	2	4	7	14	11	225	81	3	225
	72.9	44	56	27	73	8.7		0.6	1.3	2.3	4.5	3.6	73	26	9	73
Abdominal trauma	62	8	54	7	55	1	0	0	0	2	3	1	55	7	0	55
	14.6	13	87	11	89	1.6	0	0	0	3.2	5	1.6	89	11	0	89
Fall trauma	14	4	10	0	14	0	0	0	0	0	0	0	14	0	0	14
	3.3	29	71	0	100	0	0	0	0	0	0	0	100	0	0	100
Motor vehicle	24	5	19	2	22	0	1	0	0	0	1	0	22	2	0	22
collision	5.7	21	79	8	92	0	4.2	0	0	0	4.2	0	92	8	0	92
Total	424	158	266	96	328	28	22	2	4	9	18	13	328	93	3	328
	100	37.3	62.7	22.6	77.4	6.6	5.2	0.5	0.9	2.1	4.2	3.1	77.4	22	1	77.4
Cross tabulation Chi-square *P*=		<0.001		0.004					0.572					0.931		
Cramer's V=(df)		0.249 (4)		0.189 (4)					0.238 (18)					0.068 (3)		

N: Sample size, F/U: Follow-up, CORI: Confirmed original report/incidentals, N/A: Not applicable, df: Degrees of freedom, ED: Emergency department, UF: University of Florida. *Percentage distributions reflect the entire sample, **Findings encompass both acute and incidental, ***Patients without follow-up scans were excluded from statistical analysis, CT: Computed tomography, CTA: CT angiography

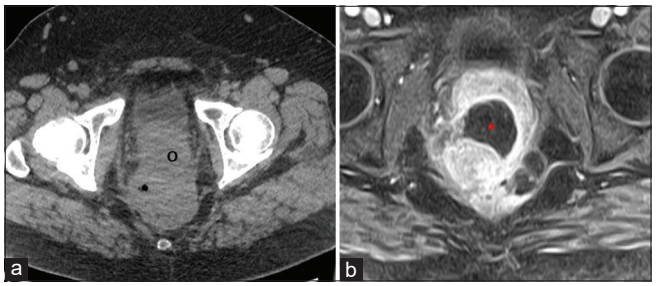

Figure 1: A 34-year-old male presenting with abdominal pain. (a) Axial pre-contrast computed tomography image shows an abscess that was not initially appreciated in this study (o). (b) Follow-up axial fat-saturated post-contrast T1-weighted magnetic resonance shows an abscess in the left pararectal space (*).

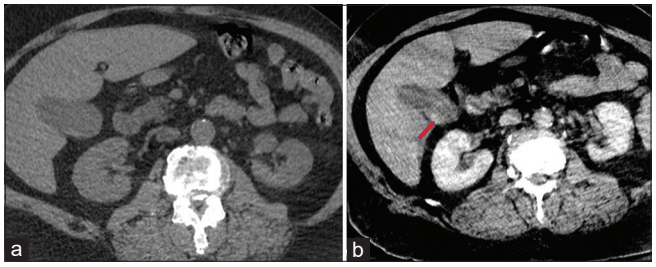

Figure 2: A 66-year-old female presenting with abdominal pain. (a) Axial pre-contrast computed tomography (CT) with no good appreciation of the gallbladder; (b) Follow-up axial pre-contrast CT with a better appreciation of the gallbladder when windowed to the soft tissue at Center 46 HU/Width 228 HU and presentation of large, faintly opaque gallstone (arrow).

demonstrated that IV contrast-enhanced abdominal CT without oral contrast material can still function as a diagnostic technique with high sensitivity and specificity in the setting of underlying conditions presenting as acute abdominal pain, such as appendicitis.[11-15] Despite these findings, according to the ACR appropriateness criteria, the majority of routine CT protocol guidelines for the diagnosis of appendicitis and other acute non-traumatic abdominal pathologies continue to rely on IV and oral contrast material, possibly due to the prevalence of "clinical imitators." If contrast-enhanced CT is recommended as a first-line investigation for abdominal pain, our findings encourage the use of alternative techniques, such as non-contrast CT in most of the cases. Still, iodinated IV contrast agents should be left to the radiologist's judgment or when special diagnoses requiring intravenous iodinated contrast material are questionable such as acute mesenteric ischemia where this type of diagnosis and which this study is underpowered to detect, since it is not very frequent and will be missed without routine intravenous contrast administration. This operational approach is quicker, because there is no requirement to conduct or wait for blood test results, and it also decreases the likelihood of iodine-induced adverse effects and radiation exposure.[16]

During the ICM shortage at our institution, patients presenting to the ED who were imaged using non-contrast CT of the abdomen and pelvis reported abdominal pain in a total of 73% of all cases. This is most likely due to this complaint encompassing a majority of underlying symptomatic pathologies, such as infection, inflammation, masses, and malignancies that require contrast-enhanced imaging per the ACR appropriateness criteria. Initial complaints with related trauma maintained the same protocols; most did not require contrast.

Our results suggest that in most instances, patients arriving to the ED during ICM shortage did not require IV and oral iodinated contrast material administration to establish a confident diagnosis. Indication for abdominal pain carried a significant likelihood ($P < 0.001$) of yielding a positive result on the radiology report. A minority of CT examinations conducted without IV and oral contrast material delivery was regarded as inadequate by the radiologists and clinicians; consequently, only 22.6% of the patients in all initial complaint categories required additional imaging of the same body region. Most patients receive follow-up imaging of abdominal pain and discomfort complaints due to unchanging pain symptoms with management and most did not need imaging based on physician examination. For most other complaints, especially abdominal-related trauma, patients requiring additional or follow-up imaging were typically performed on body regions outside the abdomen and pelvis, therefore not pertaining to our aims, and had significantly less likelihood ($P < 0.004$) not needing follow-up imaging as compared to non-traumatic complaints.

Our study compared patients who were initially imaged through non-contrast CT of the abdomen/pelvis and received follow-up imaging of the same body region, at times with a different modality, and found no significant differences between their final radiological report and initial clinical diagnoses in 93/96 of cases. There was no correlation between the patient's initial complaints and the imaging modalities used to evaluate the exact body location (CT, MR, CTA, XR, and the US). In nearly all follow-up patients with new images of the abdominal and pelvic region, the inclusion of IV or oral contrast material in 5.2% of the patients was considered by our radiologists to be insignificant. It did not contribute to a different diagnosis, confirming the original report from the non-contrast study. Only three cases were classified as a miss among the 23% of patients who were re-examined using a different imaging modality. The radiologist classified one episode of pelvic abscess as a miss of clinical significance. On the non-contrast CT, it was difficult to conclude with confidence if the hypodense lesion in between the bladder and rectum was an abscess or a mass. Post-contrast CT confirmed with certainty that it was an abscess. This miss was not related to the absence of ICM material but

rather as an initial manifestation that could be missed due to the interobserver variability and that it is easier to see with contrast MR, as Lee *et al*. concluded in their study.[17] The Lee *et al*. study prospectively evaluated 118 patients with acute abdominal pain who received CT scans before and following oral contrast administration.[17] Lee *et al*. concluded that divergent interpretations of findings by radiologists in most scans could be associated to interobserver variability and not to the presence or lack of IV and oral contrast material.[17] This also applies to the other miss of gallstones which were different imaging windowing to soft tissue must be applied to get a better appreciation of the pathology. The third miss was an incidental finding of a small hiatal hernia, which the radiologist determined was not significant.

In this study, abdomen and pelvic CT imaging without contrast showed a sensitivity of 94% and a specificity of 100%. This seemingly excellent sensitivity and specificity were attributable to the poor follow-up numbers from a large pool of ordered non-contrast CT. Despite this, the results demonstrated that our institution accurately identified the final diagnosis of different pathologies without using IV or oral contrast. The results we obtained from the 97% confirmed original reports and the minimal additional value of ICM administration from non-contrast CT scan results is consistent with the findings of a recent large prospective study that examined the diagnostic worth of unenhanced CT in elderly patients with abdominal pain. This study looked at the diagnostic usefulness of unenhanced CT in patients over 65 who were experiencing abdominal discomfort.[18] The diagnostic accuracy of unenhanced CT was as high as 80%, with 37% of patients requiring a change in treatment.[18] The inclusion of a contrast-enhanced CT helped the diagnosis in only a few individuals, according to these authors.[18] The findings are consistent with two recent retrospective studies suggesting that oral contrast is unnecessary when evaluating patients with acute abdominal pain who present to the ED and have a body mass index of 25 or higher.[19,20]

Finally, there were no significant associations ($P < 0.931$) across initial complaint categories and follow-up imaging results, which helped to validate the primary goal of this QA project. As no significant adverse outcomes came into play regarding misdiagnosis and liability, our data show that the protocol adjustments within our institution, combined with radiologists' diagnostic knowledge and experience, consistently achieved an accurate clinical diagnosis. Keyzer *et al*. also concluded that "the reader much more influences diagnostic correctness than by the use of contrast medium (oral, IV, or both)."[21]

One of the principal limitations in our study was the low number of follow-up abdominal imaging gathered in the peak of ICM shortage, which resulted in lower sample sizes to evaluate differences in diagnostic agreement between the initial non-contrast and follow-up contrast-enhanced abdominal and pelvic CT. The main reasons for this low number of follow-ups were both the nature of the patient presentation, as well as the routine clinical workflow for the assessed initial complaints. First, initial abdominal imaging was ordered either due to ED presentation involving non-specific abdominal complaint/pain or to a potential acute injury to the abdomen due to a traumatic event such as MVC or a fall. This initial abdominal imaging, according to clinical workflow, would have been used as a standalone, non-invasive method of assessing for abdominal complaint/pain. In the setting of a traumatic event, it would be ordered in conjunction with imaging across other body segments such as the head/neck, chest, or extremities, as a systemic screening tool for potential acute yet asymptomatic findings. Second, once the radiological report described any positive or negative findings, ED workflow would dictate the following steps, which would likely be conservative symptom management and discharge for solitary abdominal complaints. In the case of acute imaging findings in other parts of the body like the head, neck, chest, or extremities, in the setting of trauma, additional treatment and follow-up imaging would be carried out locally. Therefore, lower frequency of abdominal follow-up imaging was available for comparison, as clinical workflow for ED presentation of the initial complaints that we analyzed dictated the use of imaging primarily as a screening tool. A second limitation is that the radiologist knew the diagnosis when revising the images to see if there was a misdiagnosis; this could have caused bias. In addition, another limitation is that this was a QA project that did not require detailed information due to IRB submission. Due to this lack of detail, we were unable to evaluate how the lack of IV and Oral contrast affected patient turnaround times, ED length of stay, and patient safety at our institution, as other studies have investigated.[1,12,22]

CONCLUSION

This quality review project suggests that the rate of missed acute diagnoses using non-contrast CT may have been low during the recent shortage, but further investigation would be needed to verify and quantify the implications of not routinely giving oral or intravenous contrast. We hope that the results of our study, in conjunction with those of other extensive studies, will lead the way to the formulation of new medical guidelines and that continuing medical education can be used to renew the skills and knowledge required for interpreting non-contrast-enhanced CT scans.

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Declaration of patient consent

We obtained a full waiver of consent from our institutional IRB for this retrospective project. Patients' consent was not required as their identity is not disclosed or compromised.

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Conflicts of interest

There are no conflicts of interest.

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