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THE INTRODUCTION OF CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF SUSPECTED APPENDICITIS IN FEMALE PATIENTS MAY INFLUENCE COMPUTED TOMOGRAPHY USAGE

General Surgery

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ABSTRACT

Introduction- Concerns about the radiation exposure have led to decrease in use of computed tomography (CT) in appendicitis, with increased reliance on the ultrasound. Females with appendicitis should be risk stratified using the combination of the clinical signs and symptoms, white blood cell count (WBCs), and ultrasound in order to show further evaluation and management.

Material and Methods-We prospectively evaluated the clinical guideline in female patients with suspected appendicitis. Patients were risk-stratified based on the history, physical examination findings, and laboratory results. Imaging was ordered selectively based on the risk category, with ultrasound as initial imaging modality. Computed tomography was ordered if US was indeterminate or negative.

Results- One hundred and twenty patients were involved in the study with 49 patients having had appendicectomies for appendicitis while 71 were not diagnosed with apendicititis. CT usage was less in the post guideline implementation. There was not much difference between the sensitivity and the specificity of Ct and USG findings.

Conclusion- We concluded that hospitals with the high CT usage rates for appendicitis may reduce their CT usage to be reliable with national average & clinical practice guidelines.

KEYWORDS

abdominal pain, appendicitis, clinical decision rule, diagnostic testing

INTRODUCTION

Appendicitis was first described in 1886, with prompt surgical management recommended as definitive treatment.[1] Until the late 20th century, diagnosis was purely based on history and physical examination, with an acceptable negative appendectomy rate of 20% - 25%. The increase in utilization of computed tomography (CT) over last 2 decades led to a steady decrease in rate of negative appendectomies.[2]

Some authors support routine CT in patients with suspected appendicitis. However, there are conflicting data on whether increased use of the CT has improved the diagnostic accuracy in females.[3]

The increased use of the ionizing radiation in females is especially concerning due to radiation exposure can increase future risk of malignancy.[4,5] The American College of Radiology developed the evidence based imaging guidelines for the patients with the right lower quadrant pain. In females requiring imaging, guidelines favor the right lower quadrant graded compression ultrasound, followed by the CT if US is indeterminate.[6] Multiple protocols been published for the selective imaging of females with appendicitis to limit the radiation exposure while avoiding misdiagnosis.[7]

Computed tomography (CT) scanning has high sensitivity & specificity for diagnosis of appendicitis.[8] It's been shown to reduce the negative rate of appendicectomies without increasing the rate of perforation.[9] However, there is associated long term cancer risk which is greater for younger patients and in females (approximately 1 in 1000 for each CT scan of abdomen/pelvis[10]). In addition, there is also risk of allergy, anaphylaxis and nephrotoxicity.

It was hypothesized that implementation of the guideline would lead to a lower rate of CT usage in such patients. If this is true then it can be the argument to develop & implement the clinical practice guidelines for management of the other presentations like epigastric pain, small bowel obstruction, suspected diverticulitis and colitis to further reduce number of the unnecessary CT scans.

MATERIAL AND METHOD

This was the prospective cohort study and we describe the presentation characteristics of the novel clinical practice guideline developed for diagnosing the female appendicitis in general hospital attending radiology and female patients' surgery coverage in a teaching hospital, Uttarpradesh University of Medical Sciences,Saifai in north India in a duration of 24 months between April 2017 to March 2019. Patients in the study group were questioned about age, duration of marriage, level of education, number of births, and status of menstruation and the results were recorded on prescribed proforma.

Sample size calculation: The sample was calculated on basis of prevalence using the formula:-

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Z (Confidence Level) is 1.96, d (error) is 0.04, **n = 120 for each group.**

Inclusion Criteria:

- A final diagnosis of appendicitis,
- The patients referred to surgical unit with appendicitis
- Patients presenting to emergency department with abdominal pain & tenderness.

Exclusion Criteria:

- Previous appendicectomy.
- The Abdominal surgery in last 6 weeks.
- The diagnosed urinary tract infection.
- Pregnant patients.

Study Protocol:

All the relevant clinical details of history, clinical examination findings and provisional clinical diagnosis were followed.

Procedure Methodology

Multidisciplinary committee of the radiologists, surgeons, and the emergency physicians developed clinical practice guideline for the evaluation of the patients being assessed for appendicitis. The patients were classified under being at low, medium and high risk for the appendicitis based on the physical examination findings, white blood cell count, duration of pain and the differential count. Historical and physical examination findings were reviewed with attending physician & recorded on data collection form in the real time before laboratory and the radiology results were available. Preliminary, not final, the radiology reports were entered into study database to reflect the information available at time of clinical decision making.

Outcome Measures

The performance of clinical practice guideline was assessed using the

primary outcome measures of the rates of missed appendicitis (false negatives), the negative appendectomy (false positives), CT use, and the rates of appendicitis in each.

Ethical clearance
The research procedure followed was in accordance with approved institutional ethical committee.

Statistical Analysis:
For CT scan, age, diagnosis (appendicitis, the alternate diagnosis and abdominal pain of the unknown aetiology) was carried out. The data were analyzed using Statistical Package for the Social Sciences (SPSS) version 23 for Windows, $p<0.05$ rule was applied to detect significant differences.

RESULTS/OBSERVATION

Of 133 eligible patients presenting during the 24 months study period, 120 were enrolled. Just All of the enrolled patients were females, and the personal history was found to be abdominal pain (100.0%) followed by Nausea and Greater than 13 hours of abdominal pain 80.8% in majority of patients while abdominal tenderness and rebound were observed in majority of patients in physical examination. Factors associated with an increased likelihood of appendicitis included decreased bowel sounds; rebound tenderness. Low risk (0-4) Alvarado score was in 53.3% Intermediate risk (5-6) 19.2% and High risk (7-10) 27.5% Final Diagnosis shows that appendicitis was in 49 patients out of 120 enrolled patients. Sensitivity, Specificity and Accuracy of USG was observed as 72.88%, 87.29%, 83.46% respectively while that of CT scan it was 83.76%, 92.19% and 87.26%. Computed tomography (CT) is more precise than ultrasonography and has a diagnostic accuracy rate of 93 to 98 percent for acute appendicitis but radiation is the main factor that effect the use of CT over USG.

Table No. 1 Clinical and laboratory profile of study patients

	Parameters	Frequency (n=120)	Percentage
Personal History	Abdominal pain	120	100.0%
	Nausea	97	80.8%
	Vomiting	83	69.2%
	Anorexia	94	78.3%
	Obstipation	23	19.2%
	Diarrhea	33	27.5%
	Greater than 13 hours of abdominal pain	97	80.8%
Physical examination	Fever (in ED)	41	34.2%
	Absent or decreased bowel sounds	54	405.0%
	Abdominal tenderness	120	100.0%
	Guarding	78	65.0%
	Rebound	120	100.0%
	Positive psoas sign	42	35.0%
	Positive obturator sign	27	22.5%
	Positive Rovsing's sign	33	27.5%
Laboratory tests	White cells counts (≥10,000/µl)	87	72.5%
	Polymorphonuclear Leukocytes (≥ 67%)	99	82.5%
Alvarado score	Low risk (0-4)	64	53.3%
	Intermediate risk (5-6)	23	19.2%
	High risk (7-10)	33	27.5%

Table No. 2 USG and CT Findings of Appendicitis in Females patients

Final Diagnosis	USG Findings			CT Findings		
	RLQ Positive	RLQ Equivocal	RLQ negative	RLQ Positive	RLQ Equivocal	RLQ negative
Appendicitis (n=49)	41	5	3	42	6	1
No-Appendicitis (n=71)	5	3	63	1	3	67
Total (n=120)	46	8	66	43	9	68

Table No. 3 Surgical and follow up Findings

Parentheses		Patients (n = 120)	Percentage
Appendicitis Presents	Acute appendicitis	31	25.8%
	Perforated appendicitis	18	15.0%
Appendicitis Absents	Ovarian cyst rupture	5	4.2%
	Corpus hemorrhagicum cyst rupture	3	2.5%
	Adnexal torsion	1	0.8%
	Normal	62	51.7%

Table No. 4 Sensitivity, Specificity and Accuracy

	Clinical findings (Alvarado score)	USG Findings	CT Findings
Sensitivity	76.97%	72.88%	83.76%
Specificity	89.63%	87.29%	92.19%
Positive predictive value	85.67%	83.46%	87.26%
Negative predictive value	83.59%	80.56%	88.32%
Accuracy	87.29%	84.19%	91.69%

DISCUSSION

Abdominal pain comprises 4.0%-8.0% of adult admissions to emergency service.[11,12] For patient admitted with right lower quadrant abdominal (RLQ) pain, acute appendicitis is most frequently considered diagnosis. Appendicitis is the common cause of the acute abdominal pain in the women of reproductive age (WORA). Appendicitis is the emergency situation with highest misdiagnosis rate, even though the clear diagnosis & treatment strategies have been established for over 100 years.[13]

The diagnostic accuracy varies depending on the clinical experience of the surgeon and is reported to range from 71.0% to 97.0%.1 Adjunctive laboratory tests and scoring systems, like the Alvarado score, have been of some benefit, but are not superior to an experienced surgeon's clinical judgment.2,3 Previous studies1,4-12 have reported the effectiveness of computed tomography (CT) and ultrasonography (US) for diagnosis of appendicitis. However, these reports have not clearly established the indications for using these tests.[14]

Appendicitis remains a diagnostic challenge for pediatric acute care clinicians. In this article, we reviewed historical perspective & epidemiology of the acute appendicitis in females. We have then outlined a basic framework for diagnostic approach to females with appendicitis, which integrates the clinical findings, laboratory studies & imaging modalities. We have used the prospective cohort design of study which is a type of observational study, because it suited the most to our purpose. **Santillanes G et al**[15] performed the prospective cohort study to the performance of the clinical practice guideline for assessment of possible appendicitis in females. **Hatipoglu S et al**[16] did a retrospective study in differential diagnosis of the acute right lower abdominal pain in the patients of reproductive age. **Wilson EB et al**[14] also did the prospective cohort study for indications exist for the ultrasonography and computed tomography in diagnosis of appendicitis. Other than the above mentioned studies mostly were the case reports in which one or two patients were analyzed. We haven't gone for case and control study because it was not feasible for us to perform USG or CT on healthier person without any concrete reason for taking the sample. This implies that cohort study was ideal to perform in this particular topic.

After explaining the study and getting written consent, all patients who had a CT, ultrasonography, ordered in the ED for abdominal pain was identified using a query of electronic medical record and a Radiology Department database. Ultrasounds of right lower quadrant were done on the scanner using graded compression technique with the linear transducer. More recently, efforts have been done to improve rates of diagnostic accuracy through clinical scoring systems such as Alvarado and Pediatric Appendicitis scores.[17] Unfortunately, most of the studies prospectively assessing these scoring systems showed sensitivity & specificity of around 80.0%, which was similar to that of an experienced clinician. **Russell WS et al**[18] and **Santillanes G et al**[15] in their respective studies used the similar tools to analyze the apendicititis. The above mentioned tools were used as the gold standard for evaluating the apendicititis in females.

Given the prospective cohort study nature of this study, with specific follow-up protocol defined for surveillance of patients with apendicititis in 120 patients who underwent the screening in the department of radiology. To minimize bias in the cases of discrepancy, pathology report diagnosis was used as final diagnosis, because

pathologists were not aware of study and didn't have results of any imaging done preoperatively. Patients those who were not diagnosed with appendicitis were either seen in follow up clinic or called to ensure that no cases of the appendicitis were missed. The performance of clinical practice guideline was assessed using the primary outcome measures of the rates of the missed appendicitis (false negatives), negative appendectomy (false positives), CT use, and the rates of appendicitis in each risk group. Significance was considered at P<.05. Sensitivity, specificity, negative predictive values and positive predictive values of each imaging the pathway for diagnosis of appendicitis were determined by using the contingency tables, and 95.0% confidence intervals were calculated.

In our study the personal history in the majority of patients was abdominal pain followed by Greater than 13 hours of the abdominal pain, nausea & Anorexia with 100.0, 80.08%, 80.8% and 78.3% respectively while abdominal tenderness, rebound and guarding were mainly seen in physical examination of the studied patients. White cells counts (≥10,000/µl) were in 72.5% and Polymorphonuclear Leukocytes was in 82.5% in laboratory tests. **Santillanes G et al[15], Lipsett Sc et al[19]** and **Wilson EB et al[14]** in their respective study showed the similar outcome as in present study.

In present study Alvarado score shows the low risk of the appendicitis in 53.3% followed by high risk in 27.5% and intermediate risk in 19.2% and our study was in accordance with **Santillanes G et al[15]** who reported low risk of the appendicitis in 61.3% followed by high risk in 19.1% and intermediate risk in 35.0%.

Alvarado score can be used as the objective mean of sorting patients according to the risk so that unnecessary ultrasound could be avoided at the extreme of Alvarado score. Ultrasound and the Alvarado scoring system is the diagnostic tool that leads to an early diagnosis and rapid surgical treatment of acute appendicitis.

In our study it was observed that that appendicitis was diagnosed in 49 patients out of 120 with RLQ Positive (41), RLQ Equivocal (5), RLQ negative (3) in USG findings while RLQ Positive (42), RLQ Equivocal (6), RLQ negative (1) in CT findings while No-Appendicitis (n=71). Similar findings were depicted by **Santillanes G et al[15]** in their study. **Wilson BE et al[14]** also found the similar results with appendicitis in 50 out of 99 patients and without appendicitis were 49 out of 99.

In our study the sensitivity of USG was 72.88% while that of CT it was 83.76%, specificity (USG-87.29% and CT-92.19%), Accuracy (USG-84.19% and CT-91.69%). **Wilson BE et al** reported the PPV of CT was 92%, and the negative predictive value was 94%. In contrast, the use of US resulted in 75 equivocal tests, with no negative test results. The positive predictive value of US was 71%, and the negative predictive value was not calculable because of a lack of negative test results. **Russelle WS et al[18]** depicted in their study that Computed tomography was obtained in 61 patients (45.5%) and had a sensitivity of 100% and a specificity of 86.7%. Sixty-three (47.0%) of these patients underwent US with a sensitivity of 63.9% and specificity of 92.6%. **Santillanes G et al[15]** also observed the similar results as in present study and reported Ninety six (50%) patients with the final diagnosis of appendicitis had US studies & 69 (36.0%) had CT scans. In their center, US had the high specificity (99.0%) but the low sensitivity (47.0%). US had the 4.0% false positive and a 20.0% false negative rate. CT had the specificity of 98.0% and the sensitivity of 91.0%, with a 5.0% false positive and 5.0% false negative rate.

Introduction of clinical practice guideline reduced the number of CT scans done for females with appendicitis, but it was difficult to calculate exactly what numbers of CTs were avoided. In a recent study by Ramarajan et al[7], their protocol was considered to have avoided the CT if US was ordered and was not followed by the CT. If one also made the same assumption, use of clinical practice guidelines could have saved 144 CTs in population of 475 patients.

Comparison of Ultrasonography and CT in Suspected Appendicitis

1. Accuracy of USG ranges from 71.0%-97.0% while that of CT 93.0%-98.0%
2. Sensitivity of USG (85.0%-90.0%) and CT (87.0%-100.0%)
3. Specificity of USG (47.0%-96.0%) and CT (95.0%-99.0%)
4. Approximate cost of USG very less as compared to CT scan
5. Advantages of USG are that it is easily available, on-invasive, no radiation, rapid, no preparation needed.
6. Advantages of CT scan are More accurate, better identification of phlegmon and abscess, may complement USG when results are sub-optimal and better ability to diagnose normal appendix
7. Disadvantages of USG are that it is operator dependent, not as accurate as CT and cannot rule-out appendicitis if negative appendix is not apparent
8. Disadvantages of CT scan are that it has radiation exposure, cost is high, patient's discomfort if contrast media used

Limitations of the study

The small sample size in both our pre-implementation and post-implementation groups makes generalizability of our findings challenging and made subset analysis of sensitivity/specificity of US and clinical variables used to diagnose appendicitis difficult. Some of the physicians were free to deviate from guidelines based on the clinical judgment, and some patients did have the imaging not recommended by the guidelines. We made multiple attempts to contact patients who were discharged home. However, some phone numbers provided were incorrect or disconnected, and were unable to contact some patients.

Strengths of the study

The results were in accordance with protocol of the study. Tools and procedures used were precise and very much effective

Recommendations

A large sample size study with more focus on Clinical Practice Guideline for the Diagnosis of Appendicitis to reduce the usage of computed tomography is required. We recommend increased awareness regarding to the potential dangers associated with radiation-induced malignancy from CT utilization.

CONCLUSION

Ultrasound and Alvarado score is an accurate combination that leads to an early diagnosis and rapid surgical treatment of acute appendicitis. Implementation of the clinical evaluation pathway emphasizing clinical examination, early pediatric surgeon involvement, and selective utilization of US as the initial advanced imaging modality for the assessment of abdominal pain relating to for appendicitis resulted in the marked decrease in reliance on CT scan without the loss of diagnostic accuracy.

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