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The non-diagnostic ultrasound in appendicitis: is a non-visualized appendix the same as a negative study?

Brian Cohen [a], Jordan Bowling [b], Peter Midulla [a], Edward Shlasko [a], Neil Lester [c], Henrietta Rosenberg [c], Aaron Lipskar [a,*]

[a] Division of Pediatric, General, and Thoracic Surgery, Icahn School of Medicine at Mount Sinai, New York, NY, USA
[b] Department of Surgery, Icahn School of Medicine at Mount Sinai, New York, NY, USA
[c] Department of Radiology, Icahn School of Medicine at Mount Sinai, New York, NY, USA

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ABSTRACT

Purpose: The purpose of this retrospective study was to investigate outcomes in children who underwent a non-diagnostic ultrasound (US) evaluating for appendicitis and to identify predictors of a negative diagnosis.
Methods: An IRB-approved retrospective chart review was performed on patients age 0–18, who underwent an abdominal US evaluating for acute appendicitis from 2004 through 2013. Clinical data and specified outcomes were recorded, and exams were categorized into non-diagnostic studies and further separated into studies where the appendix was non-visualized.
Results: Of the 1383 studies included for analysis, 876 were non-diagnostic for acute appendicitis (63.34%) with 777 specifically because the appendix was non-visualized. Seven hundred forty of the 876 non-diagnostic studies and 671 of the 777 non-visualized studies were ultimately considered true negatives, corresponding to a negative predictive value (NPV) of 84.47 and 86.36%, respectively. In patients with WBC $<7.5 \times 10^9$/L, the NPV of non-diagnostic and non-visualized studies increased to 97.12 and 98.86%, respectively. Patients with WBC $<11.0 \times 10^9$/L have similarly high NPVs of 95.59 and 96.99% (non-diagnostic and non-visualized).
Conclusion: Based on the high NPV of a non-diagnostic US in children without leukocytosis, these patients may safely avoid further diagnostic imaging for the workup of suspected appendicitis.
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Acute appendicitis is the most common abdominal emergency worldwide and appendectomies are the most common emergency surgery in the pediatric population [1]. The foundation of the diagnosis of appendicitis is clinical assessment, however, history and physical examination alone have low sensitivity and specificity [2], and adjunctive imaging studies have become relatively commonplace in the workup of right lower quadrant pain. Even with significant advances in imaging modalities, the question of what imaging, if any, should be used to aid in diagnosis, persists [3,4].

Early diagnosis is critical in preventing perforation, abscess formation, and postoperative complications [5]. This consideration must be weighed against the risks inherent in unnecessary appendectomies, as well as the health and financial costs of excessive imaging. There were early reports advocating that computerized tomography (CT) scan be the gold standard for diagnosis of appendicitis [6], citing the high sensitivity offered by the CT exam vs. other modalities. Due to increasing concern regarding the risk of radiation exposure, there is significant interest both in the media as well as in the surgical literature regarding the avoidance of CT scans. Many tertiary care centers around the country are therefore using ultrasound (US) as the first imaging modality, and there have been studies that proposed US followed by selective CT or magnetic resonance imaging (MRI) when the US study is non-diagnostic [7–9]. Research regarding the negative predictive value (NPV) of a non-diagnostic CT scan has been reported [10], however, there are minimal data regarding the meaning of a non-diagnostic US. The purpose of this study is to investigate outcomes in children who underwent a non-diagnostic US and identify predictors of a negative diagnosis after an equivocal study.

We hypothesized that a non-diagnostic US, especially in conjunction with specific clinical parameters such as the absence of leukocytosis, the absence of obesity, and the study being performed between normal work/fully staffed hours (9 am and 5 pm), are highly predictive of a truly negative appendicitis diagnosis.

1. Methods

1.1. US technique and diagnostic criteria

Following voiding, a linear 12-5 transducer was used (linear 9-3, and/or curvilinear 9-4, 5-2 or 5-1 MHz for obese patients) for evaluation of the right lower quadrant in transverse and sagittal directions using a graded compression technique to search for the appendix. A positive study was reported upon identification of a blind-ending, tubular,

* Corresponding author at: Icahn School of Medicine at Mount Sinai, Division of Pediatric, General, and Thoracic Surgery, 5 East 98th Street, 15th Floor, Box 1259, New York, NY, 10029. Tel.: +1 212 241 1602.
E-mail address: aaron.lipskar@mountsinai.org (A. Lipskar).

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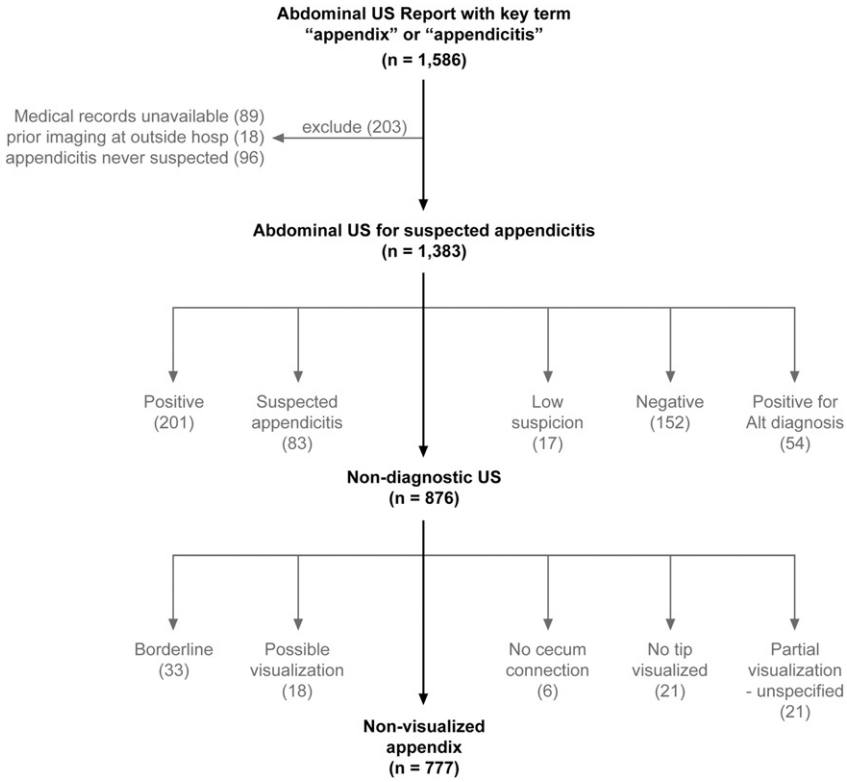


Fig. 1. Breakdown of US result categories—the bold center line represents data on which the majority of analysis was performed.

non-compressible structure in the right lower quadrant measuring >6.5 mm in diameter and showing connection to the cecum. Other signs indicating towards a positive study included appendiceal hyperemia, abnormal echogenicity of surrounding fat, or free fluid in the area. In addition, the pelvis and lower abdominal quadrants were evaluated with the bladder as well distended as possible to identify localized or free fluid collections, an appendix that extends into the pelvis, the right ovary, as well as other pathology. In our institution, a pediatric radiologist and pediatric radiology technologist were both present between the hours of 9 am and 5 pm, whereas an on-call radiology resident performed the studies during "off-hours". We based our analysis on the time of the study instead of directly recording who performed the exams.

1.2. Study design and population

After obtaining approval from the internal review board (IRB # 13-1902-00001-01-PD), we performed a retrospective chart review for all patients, age 0–18, who underwent an abdominal US evaluating for appendicitis between January 2004 and December 2013 in a single tertiary academic medical center. A total of 1586 studies were identified after patients underwent an abdominal US (ordered as either an "US Abdomen Complete" or "US Abdomen Limited") in which the US report mentioned the key terms, "appendix" or "appendicitis". From this group, 203 studies were excluded if the patient's medical records were unavailable for review, if they had prior imaging done at an outside hospital, or if it was deemed that appendicitis was never suspected according to the US report.

1.3. US result definitions

After reviewing the remaining US reports, an additional 54 studies were excluded because the US was conclusive for an alternative diagnosis (intussusception, ovarian cyst, etc.). Studies were then categorized as positive or negative when an ultrasound was conclusive for acute appendicitis. If there were signs indicating towards appendicitis, but the report fell short of calling it a conclusive study (because of a failure to trace the appendix back to the cecum, failure to fully visualize the tip, etc.) the study was categorized as "suspected appendicitis". A similar label of "low suspicion" was used when the US report fell short of a negative study, but still described most of a normal-appearing appendix. The remaining reports were all categorized as non-diagnostic. The non-diagnostic US studies were further broken down into the following categories: borderline (diameter between 6 and 7 mm, conflicting diagnostic criteria, etc.), no connection to the cecum visualized, no tip visualized, partial visualization (unspecified), possible visualization (questionable structure which may represent an appendix or a bowel loop, etc.), and non-visualized (neither a normal nor abnormal appendix was seen). The breakdown of categories is shown in Fig. 1 along with the number of studies that fell into each group. Patient's medical records were reviewed for all non-diagnostic studies.

1.4. Data collection and outcome definitions

For each electronic medical record that was reviewed, the following information was collected: date of birth, date of service, time of service, gender, weight, temperature, and WBC count.

It was also recorded whether the patient had a CT scan, any associated CT findings, whether they went to surgery, any operative findings, whether they had a repeat US, and any associated US findings. For the purposes of this study, multiple ultrasounds were treated as separate data points. If a repeat US was conclusive, it was categorized as such, whereas the original non-diagnostic scan remained as a separate, non-diagnostic data point. Pathological findings were used to record if the patient was ultimately diagnosed with acute appendicitis. If a patient had no CT scan or a negative CT, no surgery or a negative appendectomy, and no conclusive repeat US, then they were presumed to not have acute appendicitis (true negatives). Two patients with non-diagnostic ultrasounds developed appendicitis at future visits (5 months and 4 days and 5 months and 10 days after their equivocal scans); they

Table 1
Stepwise logistic regression: predictors of acute appendicitis after non-diagnostic and non-visualized US.

	Non-diagnostic		Non-visualized	
	p value	Odds ratio (95% CI)	*p* value	Odds ratio (95% CI)
Age <5 years	0.001	4.123 (1.720–9.884)	0.010	3.261 (1.323–8.036)
Female	0.012	1.736 (1.131–2.666)	0.068	n/a[a]
WBC count[b]	<0.0001	1.176 (1.132–1.222)	<0.0001	1.187 (1.138–1.239)

[a] Gender was not found to be significant after a non-visualized study. No odds ratio was calculated as it was not included in the final model.
[b] WBC count was analyzed as a continuous variable to provide insight on both cutoff values (7.5×10^9/L and 11.0×10^9/L) simultaneously.

were counted as being negative for appendicitis at the time of their non-diagnostic scans. Outcomes were also recorded for the group of negative ultrasounds in order to identify how many were true negatives.

1.5. Data categorization and analysis

Patient data were then categorized based on where it fell in relation to defined cutoff points. Limits for age (5 years), weight (90th percentile in weight-for-age), temperature (37.3 °C), and WBC (7.5×10^9/L and analyzed separately, 11.0×10^9/L) were chosen based on previous literature [11–14] according to whether the patients were at an increased risk for having appendicitis (temperature, WBC) or if they were less likely to have a conclusive US study (age, weight). It was also documented if their US was performed between 9 am and 5 pm, and gender was noted for its impact on US reliability [10]. Two different values for WBC were chosen based on data from Schellekens et al., showing the optimum cutoff point for WBCs to be 11.0×10^9/L when using plasma concentrations to diagnose acute appendicitis. Adjusting for a point with maximum sensitivity yielded a lower WBC cutoff of 7.5×10^9/L. Both values were tested for the purposes of this study. Also of note, because BMI information was only sparsely available within our medical records, weight-for-age ≥90th percentile was used as a marker for obesity instead of the BMI for-age-percentile >85% used by Hormann et al. Weight data were categorized based on CDC growth charts [15,16], which did not make the 85th percentile information available.

Statistical analysis was performed using SPSS 20.0.0.

2. Results

2.1. Ultrasound results

A total of 1383 ultrasounds were performed on 1260 patients in order to evaluate for appendicitis. Two hundred one studies were positive (14.53%), 83 studies were suspicious as described in Section 1.3 (6.00%), 17 studies had low-suspicion (1.23%), 152 studies were negative (10.99%) and 54 studies were positive for an alternative diagnosis (3.90%). The remaining 876 studies were non-diagnostic for acute appendicitis (63.34%). This percentage was slightly higher than the 56–61% that was reported in other studies [17,18], although we did see a large difference in proportions for studies performed between 9 am and 5 pm and those performed "off hours". These differences are further considered in our discussion section. Of the non-diagnostic studies, 777 (56.18%) were because the appendix could not be visualized ("non-visualized" category as described in Section 1.3). The 740 of the 876 non-diagnostic studies and the 671 of the 777 non-visualized studies were on patients ultimately considered to be true negatives, corresponding to a NPV of 84.47 and 86.36%, respectively.

For comparison, of the 152 negative studies, 150 of them were on patients who were ultimately considered true negatives, yielding an NPV of 98.68%. This value is consistent with previous literature [19].

Table 2
Negative predictive value (NPV): predictors of acute appendicitis after non-diagnostic and non-visualized ultrasound (US) Studies.

		Number of studies	True negatives	NPV
	Non-diagnostic	876	740	84.47%
	Non-visualized	777	671	86.36%
	Negative US	152	150	98.68%
Non-diagnostic AND…	WBC <7.5×10^9/L	208	202	97.12%
	WBC <11.0×10^9/L	454	434	95.59%
	Age <5 years	100	92	92.00%
	Female	419	366	87.35%
	Temperature <37.3 °C	601	511	85.02%
	9 am–5 pm[a]	383	325	84.86%
	WFA[b] <90th percentile	570	481	84.39%
Non-visualized AND…	WBC <7.5×10^9/L	175	173	98.86%
	WBC <11.0×10^9/L	399	387	96.99%
	Age <5 years	93	85	91.40%
	Female	375	331	88.27%
	Temperature <37.3 °C	527	458	86.91%
	9 am–5 pm[a]	333	288	86.49%
	WFA[b] <90th percentile	495	429	86.67%

[a] US exams performed between the hours of 9 am and 5 pm.
[b] WFA weight-for-age.

2.2. Influences on NPV

Data were further analyzed to determine if age, gender, weight, temperature, WBC count, or the time of day of the study had any impact on the predictive value of an equivocal US. A stepwise logistic regression was run with all independent variables expressed as binary data (temperature < 37 °C vs. temperature ≥ 37 °C, etc.). The only exception was WBC, which was run as a continuous variable to avoid any correlation while analyzing the two cutoff points simultaneously. Analysis was run for all non-diagnostic US studies, and then separately for those where the appendix was non-visualized. Results are listed in Table 1 and show that a low WBC count, gender (female), and age (<5 years) are all predictive of truly being negative for appendicitis among a population with non-diagnostic US. Age and WBC remained significant when looking at only the non-visualized group, whereas gender ($p = 0.068$) did not. Variables not found to be significant predictors were the following: temperature ($p = 0.611, p = 0.437$), time of day of the exam ($p = 0.868, p = 0.955$), and weight ($p = 0.984, p = 0.422$), reported as (p-value for the non-diagnostic group, p-value for the non-visualized group).

US studies were then grouped into the following non-mutually exclusive categories: non-diagnostic studies on patients with WBC count <7.5×10^9 (208), non-diagnostic studies on patients with WBC count <11.0×10^9 (454), non-diagnostic studies on patients less than 5 years old (n = 100), non-diagnostic studies on female patients (419), non-diagnostic studies on patients with a temperature less than 37.3 °C (601), non-diagnostic studies that were performed between 9 am and 5 pm (383), and non-diagnostic studies on patients who weighed less than the 90th percentile for their age (570). Negative predictive values for each of these groups were calculated. This process was then repeated for the subcategory of studies where the appendix was non-visualized and NPVs were again calculated. All results are listed in Table 2 along with the NPV of a non-diagnostic US, a non-visualized US, and a negative US for comparison.

3. Discussion

Despite appendicitis being the most common abdominal emergency in the world [1], its diagnosis remains problematic. The most immediate diagnostic tool has always been a skillfully executed history and physical exam. Unfortunately, clinical variations in presenting symptoms, difficulties interpreting the history and physical, non-specific signs and symptoms, and competing differential diagnoses all limit the efficacy

of clinical reasoning [5]. A number of scoring systems have been developed to support the clinical diagnosis of appendicitis, including the widely used Alvarado score [13]. Basing a score on signs, symptoms, and laboratory findings, the goal is to apply a systemized approach that improves diagnostic judgment. Multiple studies, however, have found scoring systems fall short of their goal to reduce negative appendectomies without increasing the risk of perforation, when compared to sound clinical judgment [20,21]. These limitations of clinical assessment, combined with the risks of perforation, abscess formation, and postoperative complications associated with a delayed diagnosis [5], have promoted the increasing use of imaging studies in order to aid in the diagnosis of acute appendicitis.

The higher sensitivity of a CT scan compared to other imaging modalities, in addition to its ability to establish alternative diagnoses and differentiate between perforated and non-perforated appendices, has caused some to make a case for the increased use of CT in the diagnosis of appendicitis [6,22,23]. CT has improved on many of the limitations of using US to diagnose appendicitis. Namely, that US is very operator dependent, has difficulty visualizing a retrocecal appendix, and presents a unique set of technical problems during examination (because of excess gas, patient obesity, guarding, etc.) [18].

More recently, however, concern has increased over the risks of radiation exposure, specifically in relation to an increased incidence of leukemia and brain tumors in children who have undergone CT exams [24]. Although absolute risk for the relatively rare cancers remains small, many have stressed a cautious approach to avoid unnecessary exposure [25,26]. Research has supported the utility of limited CT use only after an US is non-diagnostic [7,8]. By implementing a staged US and CT protocol when working up right lower quadrant pain, providers can achieve diagnostic accuracy for appendicitis while reducing exposure to ionizing radiation.

A lack of literature elucidating the true meaning of a non-diagnostic US, however, suggests the possibility that many children still undergo unnecessary CT scans. A recent study from the Stanford Emergency Department has shown that children with equivocal US may be amenable to observation [27], but the study is limited by using CT as their primary end-point rather than the positive or negative outcome of appendicitis. Our study is the first that we know of, to date, to look at the relationship of a non-diagnostic US and the primary outcome of the presence or absence of appendicitis. Our results show that under the right clinical conditions, a non-diagnostic, and more specifically, a non-visualized US study can be just as good as a negative study. Particularly, in patients with a WBC $<7.5 \times 10^9$/L, a non-visualized appendix has an NPV of 98.86%, exceeding the NPV of a negative US study when leukocytosis is not taken into account (98.68%). Identifying patients with a higher WBC cutoff of 11.0×10^9/L, the NPV of a non-visualized appendix remains high at 96.99%. NPV for WBC $<7.5 \times 10^9$/L (and 11.0×10^9/L) plus a non-diagnostic US was still impressively high at 97.12% (and 95.59%). Analyzing non-visualized appendices separately from the more broadly defined non-diagnostic US resulted in an increase in NPV in almost every subcategory (the only exception being in children <5 years old), however none of these changes in NPV were deemed significant using a t-test between percentages. Based on these data, observation, either in the hospital or at home with proper instructions for follow-up, without treatment for pain or antibiotics, and a low threshold for repeat imaging (with either US, low-dose CT, MRI, or diagnostic laparoscopy) may be an acceptable course of action in select patient populations with non-diagnostic US.

Of the 106 studies with non-visualized appendices on patients who were found to be positive for appendicitis, 55 were on patients who ultimately had a positive CT and 40 never had a CT. Another 10 had equivocal CT studies and 1 had a negative CT. Looking at patients with non-diagnostic US, of the 136 who were positive for appendicitis, 71 had a positive CT whereas 54 never had CT. No additional equivocal or negative CT studies were performed that were not counted within the non-visualized group.

Surprisingly, having a weight-for-age <90th percentile did not affect the NPV of a non-diagnostic study. It was thought that because weight influences the reliability of an US exam [12], we might have found more true negative cases being reported as non-diagnostic. While we did not adhere strictly to the definitions of obesity set forth by Hormann et al. [12], using weight-for-age instead of BMI, we did use a stricter cutoff of 90th percentile instead of the 85th percentile, which one would believe would exaggerated any findings. Despite the fact that weight may have hindered the physical performance of an US exam, it is possible that counteracting effects of obesity were present which were not taken into account.

Similarly, we expected the time of day of the US to affect which studies were non-diagnostic, based on the presence of a pediatric radiologist and pediatric radiology technologist. Looking further into the data, we found that although there was no significant change in the NPV between 5 pm and 9 am, there was an increase in the incidence of non-diagnostic studies. While our overall rate of non-diagnostic studies was 63.34%, studies performed from 9 am to 5 pm yielded a rate of 314/582 (53.95%) with studies performed "off-hours" producing a rate of 562/747 (75.23%). Similarly, the rate of non-visualized appendices went from 269/582 (46.22%) to 508/747 (68.01%). Both of these represent significant differences in percentages ($p < 0.001$). This increase in the rate of non-diagnostic findings may warrant further study, though it was still interesting to see that even with a higher number of non-diagnostic exams, the percentage of true negatives was consistent.

The limitations of performing a retrospective chart review must be considered. Specifically, patients who presented with acute appendicitis at a different institution after being discharged with an equivocal US would have been incorrectly categorized as "true negatives" in our analysis. Further studies that incorporate a follow-up protocol such as a phone questionnaire to confirm an actual negative diagnosis would help eliminate such uncertainty. Also, a lack of uniformity in the language of US reports used to categorize US findings was seen. The "positive", "negative", "suspicious for appendicitis", "low suspicion", and "non-diagnostic" groupings were all created for the purposes of this study based on the text of the US report. While the language was often specific and lent itself very easily to the defined categories, occasional ambiguity demanded interpretation. Further prospective studies that utilize a protocol to crosscheck all data and have more conformity within the US reports would diminish the possibility for inconsistencies.

In conclusion, the high NPV of a non-visualized appendix on US in patients with WBC $<7.5 \times 10^9$/L or 11.0×10^9/L (98.86 and 96.99%, respectively) suggests that patients fitting this profile may safely avoid further diagnostic imaging for the workup of suspected appendicitis. Furthermore, non-diagnostic US in patients with the same WBC cutoffs (7.5×10^9/L and 11.0×10^9/L) are similarly predictive of a truly negative diagnosis (NPV = 97.12 and 95.59%). This study is a valuable enhancement in the understanding of a non-diagnostic US and suggests that a certain population of children with non-diagnostic studies can be simply observed. Validation of this data with a prospective study will help in avoiding unnecessary imaging and its associated risks.

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