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RESEARCH REPORT

Endoscopy and Procedures

The clinical utility and safety of rectal suction biopsy in children, a single center report

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1 | INTRODUCTION

Rectal suction biopsy (RSB), which dates to the mid-20th century, has been essential in the diagnosis of gastrointestinal pathology, particularly Hirschsprung's disease (HD). While the technique itself has remained unchanged, the tools have evolved. The Noblett gun was the first device designed for bedside RSBs and featured a reusable blade.[1] The more recent RBi2 system introduced a disposable blade to address concerns about blade dullness over time.[2]

RSB remains the gold standard for HD diagnosis.[3] Compared to endoscopic and surgical sampling, RSB is minimally invasive, highly accurate, and does not require general anesthesia. It is particularly suited for preterm infants and those with cardiopulmonary disease.[4] While rare, serious adverse events like bowel perforation and significant rectal bleeding have been reported.[5]

The clinical safety and efficacy of RSBs at our institution was suspected to differ from limited data currently available in the literature. The aim of this study was to provide additional clinical data regarding the safety and utility of RSB in children.

2 | METHODS

We performed a single institution retrospective review of all patients <21 years of age who underwent RSB from April 2013 to June 2023. Medical records and histopathologic records were reviewed to extract the following data: demographics, specimen adequacy, patient weight at time of biopsy, biopsy results, procedural adverse events, occurrence of repeat biopsy if required, surgical procedures performed and clinical outcome. Adverse events and severity were defined according to the American Society for Gastrointestinal Endoscopy (ASGE) adverse event lexicon and criteria. Additionally, incidents that required telephone consultation and management, but did not meet ASGE adverse criteria were also captured.

2.1 | Biopsy technique

All RSBs were performed by the pediatric gastroenterology or general surgery fellow and/or attending. At our institution, the RBi2 Suction Rectal Biopsy System (Aus Systems) has been preferentially used since 2013. The patient, without bowel prep, was positioned supine or lateral per provider preference. After

assembly, the nurse confirmed appropriate construction by applying suction to the catheter and ensuring a constant negative pressure could be maintained before the procedure was performed. The technique included insertion of the RSB device into the anus to approximately 2–3 cm proximal from the dentate line and angled either posteriorly or laterally. 150 mmHg suction was then applied, and the blade was deployed by pushing the device trigger. While there was no prespecified number of biopsy specimens or passes, the standard approach at our institution is to perform the number of passes necessary to obtain two biopsy specimens which are placed in separate formalin containers before delivery to pathology.

2.2 | Pathology

Tissue samples underwent standard processing techniques. Hematoxylin and eosin staining, as well as calretinin staining were performed. All slides were reviewed by a pathologist with subspecialty training in pediatrics. A specimen was considered inadequate if there was insufficient mucosa, squamous/transitional mucosa present, inadequate depth, or too small to process. HD was diagnosed by the absence of ganglion cells in an adequate specimen. Supportive criteria including the presence of hypertrophic nerve bundles or trunks in the myenteric and submucosal plexus in children less than 1 year of age and negative calretinin activity were also identified.

2.3 | Statistical analysis

Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data tools provided by UT Southwestern Medical Center. REDCap is a secure, web-based application designed to support data retrieval for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources. Continuous variables, such as patient demographics, were presented as the median with interquartile range and categorical variables, including clinical characteristics, as a numerical value and percentages.

2.4 | Ethics statement

This study was approved by the UT Southwestern institutional review board and supported by the UT Southwestern Academic Information System (CTSA NIH Grant UL1-RR024982) and the REDCap project.

3 | RESULTS

A total of 414 unique RSB procedures were included in the analysis. Patient demographics and data are summarized in Table 1. A diagnosis of HD was made in 19 patients, with evidence provided by RSB in 12 cases (2.9%) and alternative diagnostic modalities, including full thickness biopsy (FTB), required for the remaining seven patients. Of all RSB procedures, 82.6% (342) resulted in a conclusive biopsy specimen. A total of 31 (7.5%) unique RSB failed to provide any adequate sample, while 40 (9.6%) samples were insufficient for evaluating HD and 1 (0.2%) sample was missing after

TABLE 1 Patient demographics and audit results.

Demographics	
Female	187 (45%)
Median weight at biopsy (kg)	9.3 (IQR: 5.8–16)
Median age at time of biopsy (months)	12.7 (IQR: 4.4–50)
Total no. of procedures	414
Race	
White	269 (65%)
Black or African American	108 (26.1%)
American Indian or Alaska Native	5 (1.2%)
Native Hawaiian or Pacific islander	1 (0.2%)
Other	27 (6.5%)
Ethnicity	
Hispanic or Latino	109 (26.3%)
Not Hispanic or Latino	305 (73.7%)
Procedure	
Total no. of procedures yielding a specimen	413 (99%)
Total no. of procedures with at least one conclusive biopsy	342 (82.6%)
Mean no. of biopsies per procedure	1.96 (0–4)
Diagnosis of Hirschsprung disease via RSB (%)	12 (2.9%)
Significant adverse event	21 (5.1%)
Bleeding	18 (4.3%)
Mild	15 (3.6%)
Moderate	2 (0.5%)
Severe	1 (0.2%)
Capsule retention	3 (0.7%)
Mild	1 (0.2%)
Severe	2 (0.5%)

Abbreviations: IQR, interquartile range; RSB, rectal suction biopsy.

processing. The most common reason for specimen inadequacy was the presence of squamous or transitional mucosa (58%), followed by insufficient biopsy depth (44%). Additional follow-up diagnostic testing was necessary for 19% (77 patients), including FTB ($n = 32$), repeat RSB ($n = 14$), contrast enema ($n = 6$), or anorectal manometry ($n = 31$). Adverse events occurred in 5.1% (21 patients) following RSB. As illustrated in Table 1, intraprocedural or post-procedural bleeding was the most frequent adverse event. Among these, five required an endoscopic or surgical procedure for bleeding control, and one patient needed blood transfusion and intensive care unit (ICU) admission. The RSB gun capsule was retained in the rectum in three patients (14% of adverse events), with two requiring surgical intervention. Minor incidents, including bleeding, pain, or fever that required telephone management but did not meet criteria for an adverse event, occurred in 3.1% (13 patients).

4 | DISCUSSION

RSB is a valuable diagnostic tool utilized by gastroenterologists and surgeons to evaluate HD. To date, we have conducted the largest review of RSB procedures at a single institution. Historically, inadequate sample collection has been the most frequent challenge associated with RSBs, a finding consistent with the cohort of patients. Specimen adequacy rate (73%–100%) has varied significantly in the literature.[6] Friemacher et al.[7] performed a systematic review regarding RSB and they reported 89.9% of adequate tissue samples in suction biopsies for the diagnosis of HD from 14,053 samples. In this review, 99.7% (413 procedures) successfully obtained a specimen, with 82.6% (342/414) of cases yielding at least one conclusive biopsy. In 2023, Vervloet et al.[8] reported that nonsurgical biopsies were more prone to yield more inconclusive results, often due to biopsy technique and pathologist evaluation. This study concluded most indeterminate results were due to the presence of squamous or transitional mucosa, suggesting rectal biopsies were likely taken too distally.

The minimally invasive nature of RSB allows for few potential adverse events; however, major morbidity from RSB occurs in up to 2% of patients.[9] Regardless of the technique used for biopsy, significant bleeding, and/or perforation from the site are rare but serious adverse events that have been historically identified.[9] Interestingly, while significant bleeding was not reported with the Rbi2 device until Corbett et al.,[1] bleeding requiring transfusion remains the most common adverse event of RSB, with an occurrence rate of 0.53%.[7] Corbett documented three cases (1.6%) of persistent rectal bleeding following RSB with the Rbi2 gun. This investigation identified 18 bleeding events (4.3%), most of which were classified as mild to moderate, with one severe case. The severe case involved an infant presenting with rectal bleeding and a hemoglobin of 6.1, requiring a blood transfusion, ICU admission for monitoring, and surgical oversewing of two biopsy sites identified on anoscopy. Going forward, an important consideration to help minimize bleeding complications is to document the biopsy location and characterize the biopsy sample.

A notable, previously unreported adverse event identified in this study, involved the retention of a biopsy capsule (Figure 1). Three cases were observed where the single-use sterile capsule could not be retracted from the rectum following deployment during RSB; one mild case was resolved with air and manipulation, while two severe cases required surgical intervention, though none of the patients needed ICU admission or transfusion. The gastroenterologists involved reported no procedural errors or deviations from standard technique. It is suspected that equipment-related issues may have contributed to the three malfunctions. Specifically, we believe the tissue may have become lodged between the device's plate and the cutting board, hindering full retraction. Despite our use of a standard protocol, including the recommended suction pressure, other potential factors could include increased suction force, improper positioning, or patient compliance.

There are several important limitations to consider with this study. This retrospective study relies on data from a single institution, which may limit the generalizability of the findings to other healthcare centers. Although a standardized practice of obtaining biopsies was followed during the study period, with more than 20 gastroenterologists performing RSB, variations in biopsy techniques among operators were not specifically examined. Additionally, while the overall cohort size is substantial, the small number of adverse events,

FIGURE 1 Retention of sterile single use rectal biopsy capsule.

such as retained biopsy capsules, restricts the ability to draw definitive conclusions about these occurrences.

5 | CONCLUSION

The bleeding rate and proportion of inconclusive biopsies observed at our institution over the past 10 years are slightly higher than those reported in previous studies. While further multicenter studies are needed to confirm and expand on these findings, these results suggest proper training and continuous quality monitoring are crucial at centers performing RSBs, given that adverse events and inadequate specimen collection occur at nonnegligible rates.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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