

Bleeding after suction rectal biopsy with Rbi2: identification of the root cause through a multi-staged approach

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ABSTRACT

Introduction Suction rectal biopsy (SRB) is a key diagnostic tool in Hirschsprung's disease. The original Noblett device has been superseded by modern alternatives including the Rbi2 rectal biopsy gun. We describe a comparison of biopsy results from the Noblett device and the Rbi2 gun and an investigation into significant post-biopsy bleeding episodes with the latter. **Methods** A retrospective review of SRB episodes between 2006 and 2014 was undertaken to audit biopsy success rates. Significant post-procedure bleeding after SRB with the Rbi2 gun prompted further investigations.

Results Biopsies taken with the Noblett gun were more likely to be inadequate (Noblett 82/197 (40%) vs Rbi2 77/438 (18%). After biopsy with the Rbi2 gun, 2 infants suffered from significant bleeding requiring resuscitation, blood product support and multiple theater episodes. As there were no reported cases of bleeding with the Rbi2 gun, a report was made to the Medicines & Healthcare products Regulatory Agency who identified incorrect biopsy technique as a potential contributing factor. A questionnaire of trainees and consultants found unexpected individual variation in SRB technique, with some users applying excessive suction.

Conclusions Significant bleeding occurred after SRB with the Rbi2 gun, excessive suction was thought to be the cause.

INTRODUCTION

Hirschsprung's disease is a congenital bowel condition characterized by aganglionosis.¹ The diagnosis is made by rectal biopsy, taken with either a specific instrument that samples mucosa and submucosa, a "suction rectal biopsy" (SRB) or via a more substantial surgical approach. The "Noblett" gun was the first purpose-made device for SRB which allowed acquisition of partial-thickness biopsies at the bedside.²

A number of SRB devices are now available.^{1,3} The reusable blades in the Noblett gun tended to go blunt, resulting in the need for multiple passes to get suitable samples. The Rbi2 rectal biopsy gun (Aus System Pty Ltd, South Australia) has a disposable blade and is now one of the the most common devices in use.³ The initial audit was undertaken to

Key messages

What is already known about this subject?

- ▶ Suction rectal biopsy (SRB) is a valuable diagnostic tool in infants with symptoms suggestive of Hirschsprung's disease.
- ▶ The Rbi2 device has excellent results.
- ▶ Serious complications of SRB are thankfully rare, but death has been reported.
- ▶ Bleeding is the the most common reported complication of SRB.

What are the new findings?

- ▶ These are the first reported cases of bleeding after SRB with the Rbi2.
- ▶ Investigating the root cause was complex and a multi-staged approach is recommended.
- ▶ Excessive suction was thought to be the cause of bleeding in these patients.

How might it impact on clinical practice in the foreseeable future?

- ▶ Users of the Rbi2 device should follow the manufacturer's instructions carefully.

compare biopsies obtained with the Rbi2 and Noblett guns. During the latter stages of the audit, three patients had significant bleeding following SRB with the Rbi2. Bleeding following SRB is described, but had not been reported after SRB with the Rbi2 device.^{1 4-6} The extended review process that ultimately identified the cause is described.

METHODS

Audit comparing Noblett and Rbi2 guns

A retrospective audit (registered with the hospital audit department) was performed of children under 1 year undergoing SRB between 2006 and 2014. The Noblett gun was used from 2006 to 2007 and the Rbi2 gun from 2008 to 2014. Patients were identified by the histopathology department. Cases in whom complications arose were identified via morbidity and mortality (M&M) reporting and the medical records. The medical records and histopathological reports were



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reviewed; demographic data, biopsy results and the clinical course of the complicated cases were collated. The term “biopsy” represents an individual specimen while a “biopsy episode” is a set of biopsies obtained during a sampling episode.

Biopsy technique

Biopsies were performed or supervised by a registrar level trainee or consultant. The biopsies were taken from the posterior rectal wall at 2 cm, 3 cm and 4 cm from the dentate line using suction from a 10 or 20* mL syringe (*see later in report). The manometer associated with the Rbi2 gun was not used. Rectal washouts, suppositories and enemas were avoided for 24 hours post-procedure.

Investigation

The investigation into the adverse events following rectal biopsy with the Rbi2 gun was multi-staged, and since one event led to the other, it was not planned in advance of the study. Adverse events associated with surgical care are reported to the departmental M&M review process. The initial M&M discussion triggered a detailed review of the cases but did not identify a root cause and the subsequent steps in the investigation evolved as described later.

RESULTS

Audit comparing the Noblett and Rbi2 guns

The pathology laboratory processed 635 biopsies (197 Noblett, 438 Rbi2) from 245 infants during 260 biopsy episodes. Table 1 summarizes the patient demographics and data. Biopsies taken with the Noblett gun were more likely to be inadequate (Noblett 40% vs Rbi2 18%) although the rate of inadequate biopsy episodes was not significantly different. The failing state of repair of the Noblett gun required multiple biopsies in some infants

Table 1 Patient demographics and audit results

Instrument	Noblett	Rbi2
Male:female	57:19	110:74
Mean age at time of biopsy, d (range)	32.5 (2–318)	49 (2–358)
No of biopsies	197	438
No of biopsy episodes	76	184
Mean no of biopsies per episode (range)	2.6 (1–7)	2.4 (1–3)
Inadequate biopsies (%)	82 (41%)	77 (18%)
Inadequate episode rate (%)	10/76 (13%)	14/184 (8%)
Significant complications	1 (bowel perforation)	3 (rectal bleeding)
Hirschsprung's disease (%)	19 (28%)	49 (27%)

Data regarding demographics and details of the biopsies for all of the patients undergoing SRB with the Noblett and Rbi2 devices.

to obtain adequate samples. One patient (1.3%) had a bowel perforation during SRB with the Noblett gun requiring a laparotomy.

Three patients (1.6%) had persistent rectal bleeding following SRB with the Rbi2 gun. In each case, the biopsies were “standard” depth, with no evidence of inadvertent full-thickness biopsy or damage to external vascular structures. None of the patients had abnormal clotting nor did they have Hirschsprung's disease. Two patients required resuscitation (one from respiratory arrest, one from hypovolemic shock), multiple blood products and surgical arrest of bleeding, in one case requiring three trips to the operating theater. The third case presented on day 4 post-biopsy with a significant hemoglobin drop but did not require further treatment though his stool was positive for rotavirus.

M&M review

The departmental M&M process identified the cluster of cases and a detailed case review was initiated. A “root cause” was not identified at this stage. However, the review highlighted poor documentation of biopsy episodes such that detail of the technique for SRB could not be clarified. Outputs from the review included¹ introduction of a procedure care pathway,² increased supervision of trainees and³ a report to the Medicines & Healthcare products Regulatory Agency (MHRA) in case of a device issue.

MHRA report and subsequent survey

An early draft of this manuscript describing the audit and detailed case studies was submitted to the MHRA. This proved to be invaluable: the device manufacturer identified biopsy technique as a potential factor. They considered excessive pressure to be the explanation for what were, in two cases, life-threatening bleeding episodes.

Knowing that the technical detail of the SRB technique was not documented, a short email survey of consultants and trainees was undertaken. This asked simply what size syringe they used for SRB and how far they pulled back the plunger. Eleven responses were received (9/14 trainees, 3/10 consultants); this identified that only four people were using the correct size syringe (10 mL) pulled back to the correct degree (4–6 mL). Two people were using a 20 mL syringe and seven were pulling the plunger further than advised. The biopsy episodes that resulted in bleeding were taken by trainees who used the incorrect technique so the cause was, we believe, identified. An email alert clarifying the correct technique followed promptly, the procedure pathway was introduced and a teaching session was delivered by the company representative a few months later. Use of the manometer was considered at that session but felt unnecessary following clarification of the correction of syringe technique.

Procedure care pathway

A care pathway for SRB was devised which included a standardized consent form, post-procedure monitoring

guidelines and a management pathway for post-procedure bleeding. The pathway required documentation of technique and reasons for deviation where applicable. Since its introduction in 2016, use of the pathway has been audited twice. During the first 4 months, uptake was poor, and an education session followed. At re-audit, the pathway was used for 43 of 45 patients, and the inadequate biopsy episodes rate was 2% (comparable with the initial audit, 1/43 vs 14/184, $p=0.3$). There were three post-procedure bleeding episodes; two were very minor (a little old blood in the nappy) and one resolved with a simple pack.

DISCUSSION

One of the largest series of SRB taken with the Rbi2 gun is reported, and an iatrogenic complication and the pathway taken to identify the root cause are described. The initial aim was to compare adequacy of biopsies obtained with those taken with the Noblett gun: as also shown by Hall *et al*, a greater proportion of adequate biopsies are achieved with the Rbi2 gun.⁵ Significant bleeding has not been reported with the Rbi2 before, even though bleeding requiring transfusion is the most common complication of SRB, occurring at a rate of 0.53%.⁴ The two cases requiring transfusion in this series equates to 1.1% of biopsy episodes (not statistically significant: 2/184 vs 27/5068, $p=0.27$, Fisher's exact test).⁴ As this was a new and worrying complication, there was concern that other infants might be similarly affected and a root cause was sought.

One of the aims of our M&M process was identification of case clusters and another to initiate in-depth review of selected cases. The in-depth review did not identify the cause, but it did highlight inadequate documentation, an issue at the heart of so many claims.⁷ Had documentation of the biopsy episodes been appropriate, the cause may have been revealed at that stage. As it was, the report to the MHRA was pivotal, as was the draft manuscript which described use of both 10 and 20 mL syringes as that was the observation of the trainee who undertook the audit. The device manufacturer immediately raised concerns, without which the subsequent survey would not have been thought of and the root cause would have been missed. This journey is shared as it shows the value of taking those additional steps, even though they may have seemed of little value at the time. There have been no further significant bleeding episodes reported to our M&M process over the past 3 years.

In conclusion, although SRB is considered safe, there is a small risk of serious complications whichever device is used. The manufacturer's instructions must be followed. Perseverance and multistage investigation of adverse events is worthwhile.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants but was not approved by an Ethics Committee or Institutional Board as the data were collected as part of a retrospective audit of practice to evaluate service which does not require such approval in the UK. The audit was registered with the hospital audit department, audit no 3321.

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Data availability statement Data are available on reasonable request. The data are currently stored on a password-protected PC that is in a storage unit. It can be accessed though may take some time as the owner of the storage unit is abroad and not able to travel due to COVID restrictions.

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