After the Recall: Reexamining Multiple Magnet Ingestion at a Large Pediatric Hospital

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Objectives To evaluate the effectiveness of a mandatory product recall on the frequency of multiple mini-magnet ingestion at a large tertiary pediatric hospital, and to examine the morbidity and mortality associated with these ingestions.

Study design In this retrospective chart review, we searched our institution's electronic patient record for patients aged <18 years who had been diagnosed with ingested magnetic foreign bodies between 2002 and 2015, a period that included the mandatory product recall. We compared the frequency and character of ingestions before and after the recall.

Results Comparing the postrecall years (January 1, 2014, to December 31, 2015) with the 2 years immediately preceding the recall year (January 1, 2011, to December 31, 2012) yields an incidence rate ratio of 0.34 (95% CI, 0.18-0.64) for all magnet ingestions and 0.20 (95% CI, 0.08-0.53) for ingestion of multiple magnets. Based on the Fisher exact test, the incidence of both magnet ingestion ($P < .001$) and multiple magnet ingestion ($P < .001$) decreased, and the morbidity associated with magnet ingestion decreased. There were no deaths in either study period.

Conclusion There was a significant decrease in multiple mini-magnet ingestion following a mandatory product recall. This study supports the effectiveness of the recall, which should bolster efforts to keep it in place in jurisdictions where it is being appealed. More broadly, the result provides general evidence of a recall helping decrease further harm from a product that carries a potential hazard. *(J Pediatr 2017;186:78-81).*

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Most developed nations have regulatory authorities tasked with ensuring consumer safety and protection. In the US, this responsibility is granted to the Consumer Product Safety Commission (CPSC), and in Canada, Health Canada serves that role. These agencies must identify new hazards, quantify relative levels of harm, and use their legislated powers to promote public safety.[1,2] Actions may range from requiring simple warning labels to mandating sweeping product recalls with fines for manufacturers who fail to comply.

The consumer protection agencies have various options at their disposal to enforce policy. Among these, a product recall is the strongest, and as such is typically reserved for cases where other approaches are deemed insufficient.[3] Even though intuitively a product recall should result in fewer incidences of harm with a given product, there is scant published evidence to support this hypothesis.[4] Although the literature includes studies examining how many consumers abide by recalls or destroy the consumer products recalled, there is little published work on whether product recalls actually decrease harm.[5] Here we examine the case of multiple mini-magnets, including the threat, the recall, and the impact of the intervention on pediatric morbidity.

Ingestion of high-powered, neodymium-iron-boron magnets (henceforth referred to as magnets) has been shown to be a significant danger to children. Unlike most foreign bodies, or weaker, traditional ferrite magnets, which typically pass through the gastrointestinal tract without incident, these magnets pose a unique hazard owing to their ability to forcefully attract one another across loops of bowel, leading to pressure necrosis of the intervening bowel wall, hollow viscus perforation, and, potentially, death.[6,7]

Starting in 2011, reports began to emerge noting a distinct increase in cases of magnet ingestion coinciding with the introduction of new products marketed as "adult desk toys."[8] These sets typically consist of 125 or 216 small, powerful, spherical magnets that can be linked together to create a wide variety of shapes and patterns. Despite being marketed to adults and bearing clear warning labels on the package, these novelty toys often fall into the hands of children, and they have

CPSC	Consumer Product Safety Commission
ED	Emergency department

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been responsible for significant pediatric morbidity after their launch in late 2009.[9-11] The experience of our large, tertiary care institution was reported in 2013.[12] At that time, an 8-fold increase in multiple magnet ingestions over a 10-year period was reported, with the largest increases seen in 2011 and 2012.

Soon after early data became available, various consumer safety and government organizations across the globe began using regulatory powers to restrict or curtail the availability of these products. In the US, the CPSC used a combination of voluntary and mandatory recalls aimed at individual importers, strong pressure on retailers, and a new rule banning the sale of tiny, powerful magnets.[13] The CPSC's recalls resulted in significant pushback from product manufacturers, with allegations of paternalism and overreach directed at regulators.[14]

In the present study, we investigated the efficacy of the multiple-magnet set recall in Canada. We examined the incidence of injury related to multiple magnet ingestion at our center between 2002 and 2015, a period spanning the years before the introduction of the popular multi-magnet desk toys, product release, enactment of regulatory protections, and 2 subsequent years. We hypothesized that the mandatory product recall, and the associated increased public awareness fueled by media coverage, would result in a significant reduction in multiple magnet ingestions in children seen at our institution.

Methods

We performed a retrospective study of all emergency department (ED) visits between April 1, 2002, and December 31, 2015, to a single urban tertiary care pediatric ED with an average annual volume of approximately 56 000 visits over the study period. Our hospital is 1 of 4 acute-care pediatric hospitals in Ontario, a province of 13.9 million people. It serves as a referral center for all pediatric subspecialties, and is the local hospital for children residing in the surrounding urban neighborhoods.

We identified cases by searching through all ED visits with *International Classification of Diseases, 10th revision* codes corresponding to foreign bodies in the alimentary tract (T18.x). All charts were reviewed to identify patients who met the inclusion criteria, which included age <18 years with suspected or confirmed magnet ingestion based on parent report, diagnostic imaging, or pathology report. Children presenting on multiple occasions with respect to the same ingestion event were abstracted as a single case. We collected data on patient demographic characteristics, type of imaging performed and findings, patient disposition, procedures or operations, and specialist consults.

For magnet ingestions confirmed by concordant history and radiographic, pathological, or surgical findings, we calculated descriptive statistics for patient and magnet factors. To examine whether the Canadian mandatory recall of multiple-magnet sets marketed as adult desk toys may have had an impact on the frequency of injury, we compared data for the 2 years before the mandatory recall (2011-2012) with data for the 2 years after the recall (2014-2015). We used our institution's annually reported number of ED visits to create magnet-related injury rates. Rates for the prerecall and postrecall periods were compared.

The study was approved by the Research Ethics Board of The Hospital for Sick Children.

Table I. Patient demographic data

Characteristics	Value
Alimentary tract magnet ED presentations, n	120
Confirmed magnet ingestions, n (%)	96 (80)
Unconfirmed magnet ingestions, n (%)	24 (20)
Multiple magnet ingestions, n (% of confirmed ingestions)	42 (43.8)
Sex, n (% of confirmed ingestions)	
Male	62 (65)
Female	34 (35)
Age, y, median	4.5
Minimum, y	1.0
Maximum, y	16.9

Results

Between April 1, 2002, and December 31, 2015, 3579 patient visits involving gastrointestinal tract foreign body ingestion were identified. A review of these files identified 120 unique children as meeting our inclusion criteria. In 100 children, magnets were confirmed after removal or by a combination of history of magnet ingestion and detection of a least 1 radio-opaque foreign body on medical imaging. Demographic data for this population are presented in **Table I**.

Comparing the postrecall years (January 1, 2014, to December 31^{t}, 2015) with the 2 years immediately preceding the recall year (January 1, 2011, to December 31, 2012) yields an incidence rate ratio of 0.34 (95% CI, 0.18-0.64) for all magnet ingestions and of 0.20 (95% CI, 0.08-0.53) for multiple magnet ingestions. Analysis using the Fisher exact test showed that the incidence of both magnet ingestions ($P < .001$) and multiple magnet ingestions ($P < .001$) decreased (**Figure**).

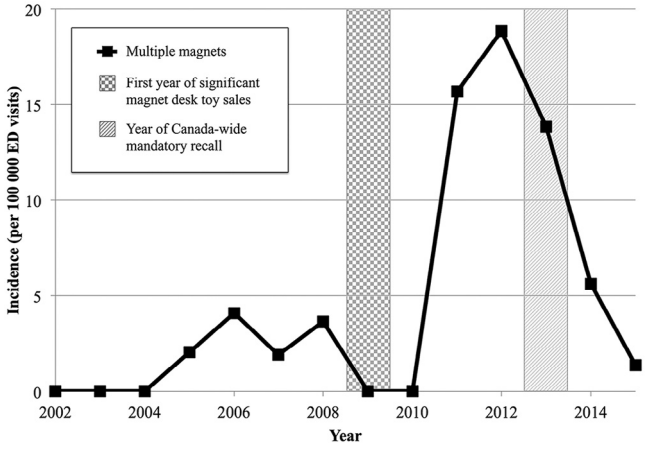

Figure. The frequency (per 100 000 ED visits) of magnet ingestion, 2002-2015.