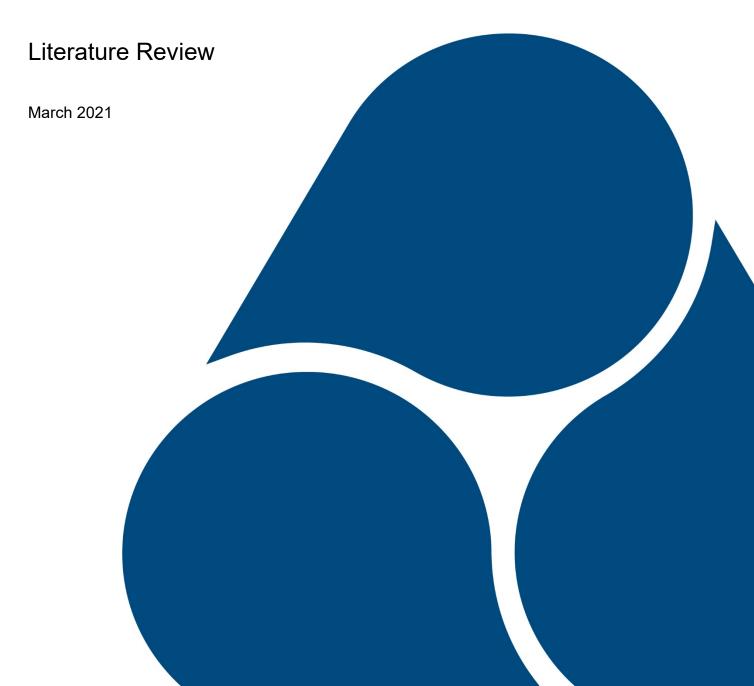


What is the harm associated with small magnet ingestions in both paediatric and mature consumer populations?



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Executive summary

Small magnets are a unique category of foreign body ingestion events which pose several unique challenges to their management. The attractive nature of small magnets can often prevent their natural progression through the gastrointestinal (GI) tract, requiring medical intervention to remove. Small magnet ingestion events are associated with magnet specific injuries, which often result from the compression (or twisting in the case of the bowel) of soft tissue between two attracting magnets. This compression or rearrangement of tissue can result in reduced blood flow to the affected areas, potentially resulting in tissue death and potential perforation of the GI tract. These injuries can cause severe health risks and may be fatal. Cases studies considered in this rapid literature review for small magnet ingestion events identified 102 case-reports which fell within the paediatric population and 3 cases for the mature population. This is likely due to foreign body ingestion events in the mature population primarily being food-related, such as the ingestion of fish or other animal bones. It is likely therefore that the paediatric population disproportionately composes the majority of small magnet ingestion cases. Of the 102 paediatric cases identified here, 80% were categorised as high harm either due to magnet specific injuries or a requirement for invasive surgery, with a single instance of patient mortality. The most frequent injuries to patients included bowel perforation (38 cases) and fistula formation (35 cases). 75% of paediatric patients in the cases considered here required invasive surgery. Increased risk of harm does not seem to correlate to an increased number of magnets ingested, rather an increased delay between ingestion and medical intervention. A majority of small magnet cases involved the ingestion of spherical small magnets. It is not possible to identify whether this is due to increased ease of ingestion or whether these products are more prevalent on the market resulting in increased consumer exposure.

The findings of this literature review must be qualified under the following caveats:

- A potential reporting bias for events requiring surgical intervention. Case reports are either authored by or targeted towards medical/surgical practitioners, which may result in an under-reporting of cases which required monitoring only (and therefore an under-reporting of lesser harm events).
- As these results are composed of global examples from a limited pool of case literature, they should not be used as a measure of incidence rate for small magnet ingestions. This review additionally should not be used to contextualise magnetic foreign body ingestion rates to other categories of foreign body events.
- This literature review was conducted as part of a national incident response into the harms of small magnets managed by the Office for Product Safety & Standards (OPSS). Due to the time sensitive nature of our evidence gathering process, this literature review is not an exhaustive review of literature concerning small magnets ingestion events.
- Single/multicentre reviews which measured incidence, but not patient outcome have not been included in this review. As previously stated, the purpose of this literature review is to identify the harms associated with small magnet ingestions rather than their frequency.

Introduction

Foreign body (FB) ingestion in the paediatric population is a common event, with most instances occurring between 6 months and 3 years of age (1). In the majority (80%–90%) of cases, FBs in the gastrointestinal (GI) tract are passed naturally without the requirement for medical intervention, with a further 10%–20% of FBs removed endoscopically (2), and 1% via open surgery (3) (4). However, ingestion cases involving small rare-earth magnets (SREMs) can dramatically affect the requirement for surgical intervention. In one study of 74 United States (US) cases of small magnet ingestion, surgery was required in 69.7% of cases where treatment was reported (5).

Rare-earth magnets created from alloys of neodymium iron boron or samarium cobalt can be up to 5-20 times stronger than traditional iron magnets despite frequently being less than 6 mm in diameter (6) (7) (8). The United States Consumer Product Safety Commission (CPSC) first issued warnings regarding the use of small magnets in children's toys in 2006, with the voluntary recall of several toy products following 33 cases of magnet ingestion and one case of death in the paediatric population (9) (10). In 2007, the CPSC issued a health warning regarding the possibility of high-powered magnets detaching from children's toys, such as building sets, causing injuries and death (11).

These magnets can continue to be found in a range of consumer products, including entertainment products designed for adults. In 2008, magnet sets composed of typically between 125-224 spherical, cylindrical or cuboid rare-earth magnets were introduced to the market (12). One of the primary manufacturers of these magnets (known as Buckyballs or Buckycubes) was subject to a 2010 product recall in the United States due to the sale of high-powered magnets to consumers under the age of 14, contrary to US federal toy standard F963-08 (13). Post-product recall, these products have been marketed as adult desk-toys (14), however despite marketing towards an adult consumer base, Roo et al. notes that 50.7% of the magnets causing injury to the paediatric patients identified were from products intended for use by adults.

In 2012, the CPSC filed administrative complaints against Zen Magnets and Maxfield & Oberton, major manufacturers of SREMs in order to prohibit their sale in the US (15) (16). However, in 2016 a US court case ruled that "proper use of Zen Magnets and Neoballs creates no exposure to danger whatsoever", and that the manufacturers did not "design, manufacture, or market SREMs as a plaything for children under 14 years of age" (17). Since this ruling, SREMs have continued to be marketed as adult entertainment products in the United States.

In the United Kingdom, the first regulations introduced to specifically target magnets in children's toys were The Magnetic Toys (Safety) Regulations 2008, which set out the requirement for magnetic toys to be accompanied by a warning (18). These Regulations were revoked in 2009 with the implementation of British Standard EN 71-1:2005+A8:2009, later superseded by the introduction of British Standard BS EN 71-1:2011+A3:2014 in 2011 (replaced with BS EN 71-1:2014+A1:2018 in 2014), which sets the requirement that loose as-received magnet(s) and magnetic component(s) shall have a magnetic flux index less than 50 kG²mm² (19). This limit was upheld throughout the introduction of BS EN 71-1:2011+A3:2014 and BS EN

71-1:2014+A1:2018 in 2011 and 2014 respectively (20) (21). This limit is not required if, when tested, the magnets do not fit into a small parts cylinder testing device (as defined in section 8.2 of Standard BS EN 71-1:2014+A1:2018).

Global incidences of SREM ingestion are increasing (6) (22) (23), with several studies documenting an increase in the number of incidents involving multiple magnets (22) (24). Strickland et al. notes that within a study of cases presenting to a large US paediatric hospital, ingestion events involving multiple SREMs increased by a factor of 8.40 for cases presented in 2010-2012 vs. cases in 2002-2009 (22). Buckyballs (or Buckyball-like spherical/cuboid magnetic products) have seen an increase in ingestion cases involving this specific product type (25), with a 9-fold increase in cases reported in 2017-2018 compared to 2013-2014 reported by Wang et al (24). Due to the small size of the magnets (typically < 1 cm (6)) and the large number of loose magnets (often between 125-224) included per product, it is possible that this product type may present a greater hazard once ingested. As noted by Roo et al. previously, SREM ingestions are a special type of FB ingestion with a higher likelihood for requiring surgical intervention. This is likely due to the specific nature of the magnetic bodies and the unique mechanisms of injury that these present.

When a single SREM is swallowed, it is likely to pass through the GI tract uneventfully (24) (26). However, when two or more magnets become separated along their course in the GI tract, these magnets pose the unique danger of being able to attract each other through different loops of bowel, arresting their movement, and potentially causing mural pressure necrosis (22; 26). This can result in subsequent small bowel obstruction or perforation, volvulus, fistula formation, intraabdominal sepsis, and death (9; 26). There has been an increase in the reported number of cases of paediatric magnet-related injuries (27). This increase is likely in part due to the increased relative strength of SREMs, couple with an increased potential for multiple magnets to be ingested due to their small size and high number of loose magnets per product.

The Office for Product Safety & Standards (OPSS) is the UK's national regulatory body for consumer products. SREMs and understanding their potential risk for harm constitute part of a national incident response into small magnets being managed by OPSS, with increasing reporting of SREM ingestion events (6) (21) (22). This rapid literature review was conducted to support this incident response into SREM ingestion events. It has been identified that the severity of harm associated with these ingestion events is a gap in OPSS knowledge and an area of key required research. Crucially, this does not distinguish between a mature or a paediatric consumer population. To inform our risk assessment, which requires clarification of the types of injury that could occur, severity of associated injuries, and success of any required medical intervention, this literature review shall address the following research question:

What is the harm associated with small magnet ingestions in both paediatric and mature consumer populations, and what is the likelihood of required surgical intervention?

Methodology

The aims of this literature review shall be met by analysing available patient casestudy information relating to medical intervention or observation in both mature and paediatric consumer populations. Harm will be assessed utilising a rating scale built upon a categorisation method identified in a recent CPSC briefing package (28). These CPSC categories describe six scenarios of magnet ingestion and the associated magnet specific injuries (MSIs), treatments, and outcomes, detailed below:

Category 1. Ingestion of a <u>single</u> magnet that passes through the GI tract uneventfully, but that can be monitored during passage, using one or more serial x-ray images.

Category 2. Ingestion of <u>two or more</u> joined magnets that pass through the GI tract uneventfully, but that can be monitored using one or more serial x-ray images by health care professionals who are aware of the GI magnet injury potential.

Category 3. Ingestion of two or more magnets that are identified by x-ray imaging and that are removed from the stomach or small intestine via endoscopy shortly after ingestion and prior to causing any serious internal injuries.

Category 4. Ingestion of two or more magnets that presents when the patient has had nonspecific GI symptoms for some time, indicating serious internal injury has started; health care professionals, who have a good understanding of the magnet ingestion hazard, immediately recognize this as an urgent situation requiring surgical intervention to remove magnets and repair any damage.

Category 5. In more severe cases, patients who ingested two or more magnets, present after first becoming symptomatic, when serious internal injury has started, but where the urgency of the situation is not recognized immediately by caregivers and/or health care professionals.

Category 6. In the worst-case scenarios, ingestion of small NIB magnet spheres results in a patient's death, either at home, or shortly after being brought to a hospital. The few known magnet ingestion-related fatalities suggest volvulus injuries present a particularly serious acute risk of death, especially when intervention is delayed because magnet ingestion is not considered and/or nonspecific GI symptoms are not recognized as an urgent, rapidly escalating situation by caregivers and/or healthcare professionals.

Building upon these criteria to apply these ingestion scenarios to cases of harm, the following classification criteria shall be applied to identified case studies:

Table 1 - Categories of harm following small magnet(s) ingestion

Category 1	Category 2	Category 3	Category 4	Category 5	Category 6
Single Magnet	Multiple magnets or metallic components	Single <u>or</u> Multiple magnets or metallic components	Multiple magnets or metallic components	Multiple magnets or metallic components	
No MSIs	No MSIs	No MSIs	Immediate medical observation/di agnosis	Delayed medical observation/di agnosis	Patient mortality as a direct result of MSIs
No surgical intervention	No surgical intervention	Endoscopic intervention only	Surgical intervention including and beyond endoscopic	Surgical intervention including and beyond endoscopic	

"Delayed" in this context identifies events where medical intervention or observation begins post 24-hours from the time (estimated or confirmed) of the initial magnet ingestion. Instances of surgical intervention beyond endoscopy where no MSIs or general GI symptoms are present are still considered to fall within categories 4 or 5 (depending on time of intervention) for the purposes of harm. This is due to the more invasive nature of these procedures, requiring longer periods of recovery and hospital stay. This differs from the original CPSC rating scale as a "gap" was identified in the categorisation of harm regarding asymptomatic patients requiring open surgery to remove ingested FBs. Using the original categorisation scale, these would fall somewhere between categories 3 and 4/5 due to removal prior to serious injuries but possessing a lack of general GI symptoms. This inclusion in these categories addresses this analysis gap, ensuring a patient-focused view of harm is taken by the review.

For the purposes of identifying "high harm" events, these will be classified as ingestion scenarios between categories 4-6. These categories were selected as patients within these ranges will experience increased risk of MSIs, present a requirement for more invasive surgical procedures (such as enterectomy or open laparotomy), or in the most extreme cases result in patient mortality. Categories 1-3 are unlikely to result in high harm to individuals due to either early less-invasive medical intervention (laparoscopic removal) or the natural, uneventful passing of the magnets. The data shall be separated into two populations for paediatric and mature case studies, where paediatric cases define any individual below the age of 18-years old and mature any individual of the age 18-years old and above.

This review acknowledges one of the limitations of the literature review may be a potential reporting bias for events requiring surgical intervention. As this literature review's aim is not to identify all global cases of magnet ingestion, but rather identify indicative outcomes to support the wider evidence gathering process, this bias will not compromise the integrity of the future review.

For the purposes of this rapid review, databases which provide access to peerreviewed journal articles have been selected for the purposes of evidence collection. Alternative databases hosting information such as injury data or specific product information (such as the product safety database or external regulatory databases such as RAPEX) have been excluded, as these databases are currently under evidential review by colleagues within the wider scope of the rapid evidence gathering process. Databases were selected based on the ability of OPSS to readily access scientific literature via current institutional subscriptions. As such, it should be noted that this approach likely excludes an unknown quantity of relevant case literature from other databases. However, within the constraints of our wider approach to rapidly building an evidence base on the issue of SREMs as part of a live incident response, this was deemed an appropriate compromise.

For this purpose, criteria for database selection were chosen outlined below:

- Full text material is available online either via free access or existing subscription-based access
- Literature should be available from at least 2008 up to the present day
- Databases should provide access to peer-reviewed scientific sources

Based on these criteria, two databases were selected for evidence collection: PubMed (including PubMed Central (PMC)) and ScienceDirect. As 2008 saw the first introduction of UK regulations setting specific requirements for magnetic toy products (The Magnetic Toys (Safety) Regulations 2008), the timeframe selected for evidence collection from these databases was set from 2008 to 2021.

This rapid literature review is conducted at pace to identify the harms associated with small magnet ingestions. As such, the following criteria have been selected to ensure evidence included in this review best aims to answer the proposed research question:

- Identify evidence of small magnet ingestions in the paediatric and mature populations
- Identify cases of magnet ingestion requiring surgical intervention in both the paediatric and mature populations, and the nature of this intervention
- Identify cases of successful surgical intervention in the event of magnet ingestion
- Identify cases of patient mortality in incidents related to small magnet ingestion
- Identify long-term health effects post-magnet ingestion in both the paediatric and mature patient population
- Identify evidence relating to magnet shape and the severity of harm
- Identify evidence relating to number of magnets ingested and severity of harm

To identify relevant case studies based on the above criteria, the following search terminology will be conducted:

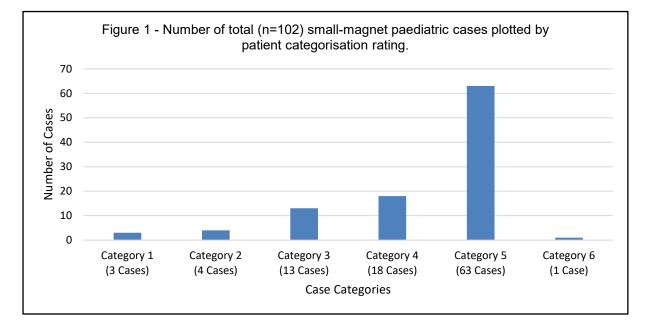
Table 2 - Search criteria for identifying small magnet case studies

Search Criteria
(paediatric* OR pediatric* OR child*) AND magnet* AND ingest*
(paediatric* OR pediatric* OR child*) AND magnet* AND ingest* AND toy*
(paediatric* OR pediatric* OR child*) AND magnet* AND ingest* AND (bead* OR ball*)
(paediatric* OR pediatric* OR child*) AND magnet* AND ingest* AND disc*
(paediatric* OR pediatric* OR child*) AND magnet* AND ingest* AND multiple
magnet* AND ingest*
magnet* AND ingest* AND toy*
magnet* AND ingest* AND (bead* OR ball*)
magnet* AND ingest* AND disc*
magnet* AND ingest* AND multiple

This review has not discussed all available literature on the topic of small magnets but has selected for relevant medical case studies which identify patient examples on an individual basis. Literature pertaining to the subject of small magnets but not fitting the criteria for inclusion in this rapid literature review will be noted and bookmarked for potential future discussion if required.

Case study analysis

In total, 102 (annex I) case studies have been identified in the paediatric population and 3 case studies (annex II) in the mature population. This vast difference in the number of cases identified is likely due to the nature of adult FB ingestions. Foreign body ingestion is most common in children aged between 6 months and 6 years (29), with children under five-years old making up 75% of foreign body ingestion cases (30). Adult foreign body ingestion on the other hand is accidental in 95% of cases, primarily arising as a result of food-related impactation (31). Some of the most common adult foreign body ingestions include bones (8–40%) and fish bones (9–45%) (32; 33). Fung and Shanmugam note that non-accidental ingestion of foreign bodies rarely occurs in adults, however this should be recognized as a risk factor in those with psychiatric illnesses or learning difficulties (34). Indeed, out of the three mature cases identified two individuals presented with pre-existing learning difficulties (34; 35). Due to the small sample size however, it is not possible to draw any definite conclusions between instances of small-magnet ingestion and increased risk to mature patients with pre-existing psychiatric illnesses or learning difficulties.



Of the 102 paediatric cases identified, 82 case reports (or 80%) fell within event categories 4-6 and are therefore defined as high-harm events. Figure 1 demonstrates the stark increase in cases falling within category 5 (63 cases) compared to category 4 (18 cases). One of the primary reasons for this difference was the definition of "delayed intervention". A key factor in this delay (defined as any treatment/observation occurring 24-hours post-ingestion) was whether the ingestion was witnessed by parents of caregivers in the first instance. In case studies where small-magnet ingestion was unwitnessed, patients were presented for medical intervention only once symptomatic, often resulting in a lag between ingestion and treatment. Of these 82 high-harm cases, 72 (or 88%) were identified to possess magnet specific injuries (table 1). The most common of these were instances of bowel perforation and fistula formation in 38 and 35 patients respectively. These magnet specific injuries arise as a result of the unique attractive nature of small

magnets (22; 26). Multiple ingested magnets may attract each other through bowel or gastric walls, compressing the tissue between them (36). This compression results in restricted blood flow to the affected tissues (ischemia), which can result in a number of complications. These can range from death of the tissue due to the induced ischemia (pressure necrosis), to bowel perforation and fistula formation (an abnormal connection between two epithelial surfaces) (37). Attraction between the bowel wall may additionally result in shifting of the bowel, causing abnormal twisting of the intestine (volvulus) which may result in ischemia to the entire affected loop of bowel.

Of note, all 63 cases classified as Category 5 events presented with MSIs in patients. This is likely due to the nature of category 5 events including the majority of unwitnessed ingestion events compared to categories 1-4. By the nature of these unwitnessed events, intervention is typically sought once the patient has already become symptomatic, which indicates serious internal injury may have already started. Comparatively, cases identified as category 4 demonstrated MSIs in 9 (50%) of these instances.

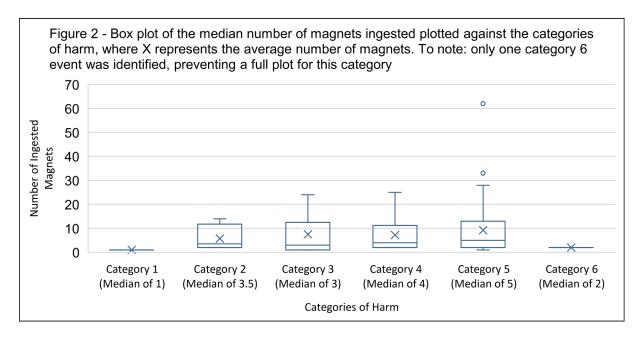
Magnet Specific Injury (MSI)	Number of Unique Instances
Bowel Perforation	38
Gastric Perforation	4
Fistula Formation	35
Pressure Necrosis	7
Volvulus	3
Other MSI	10
No injury listed	29

Table 3 - Unique MSIs experienced by paediatric patients identified (n=102).

To identify whether the harm was correlated with the number of magnets ingested, the median number of magnets for each category was calculated (table 2). Utilising the interquartile range as a measure of range variance, these values were then plotted on a box plot (figure 2) to identify whether a positive correlation could be identified between the number of magnets and instances of high harm. While categories 4 and 5 do present a higher median number of magnets that categories 2 and 3 (category 1 is by definition a single magnet), due to the variance in the number of magnets ingested within these ranges it is not possible to support a direct correlation between increasing numbers of ingested magnets and increasing categories of harm. It is clear that just two magnets can cause life threatening injuries which may result in patient mortality (38). Indeed, even instances of single magnets swallowed alongside additional metallic objects have the capability to induce pressure related MSIs (39; 40).

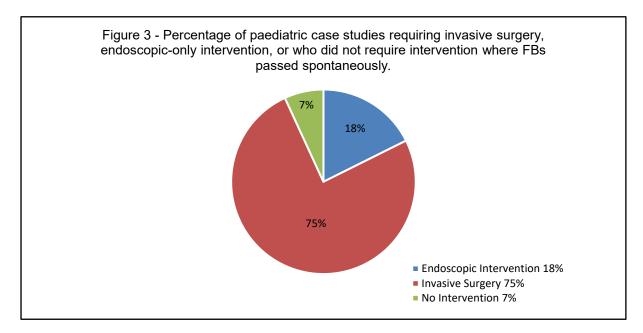
Table 4 - Median number of magnets involved in paediatric ingestion events for each identified category of harm. The interquartile range is a demonstration of variance for number of magnets swallowed within each category.

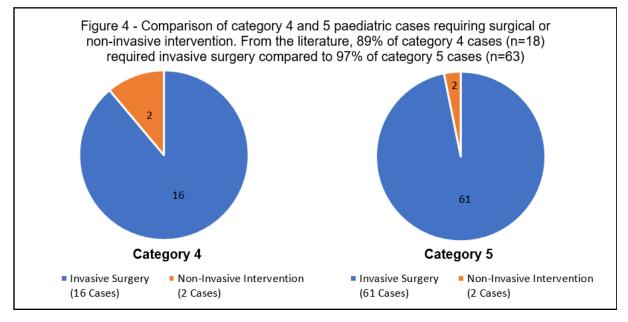
Event Ranking	Median No. Magnets	Interquartile Range
Category 1	1	0
Category 2	3.5	5.25
Category 3	3	9
Category 4	4	7.75
Category 5	5	11
Category 6	2	0



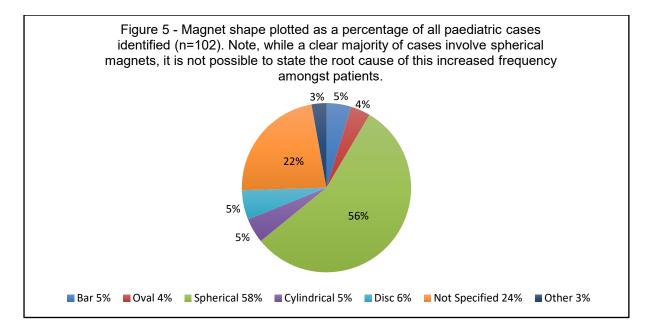
The attractive forces between small magnets poses the additional medical challenge that the ingested object may not progress through the GI tract spontaneously (41). In these instances, the ingested FBs must be removed via medical intervention utilising either endoscopic or invasive techniques (invasive defined as the creation of any artificial incision into the body) to prevent or minimise any MSIs (40). Where the magnets are identified as progressing through the GI tract, it is likely (in the event of multiple ingested magnets) that these magnets are linked together and may pass naturally without risk of obstruction (42). Where natural progression is not identified however, immediate intervention should be administered to remove the ingested magnets (43). Figure 3 identifies that in 75% of identified cases in this review, invasive surgery was required. These cases often present examples where endoscopic intervention is not possible, either due to the magnets being located in a region of the body outside of endoscopic reach or magnet strength preventing separation via forceps. Comparison of categories 4 and 5 (figure 4) does not identify any immediate differences in the pattern of patients who required surgical

intervention, however it must be noted that the sample size identified for category 5 (63 patients) heavily outweighs those identified within category 4 (18 patients).





While much of the literature does not comment on the specific nature of the magnet ingested, a majority of the cases (78 of 102) report on the shape of the object ingested. Of these, 56% of cases (59 patients) were reported to have ingested spherical magnets. A further research question remains as to whether this is due to any potential increased ease of ingestion of spherical magnets when compared to magnets of alternative shapes, or whether this is due to the noted prevalence of spherical magnets on the marketplace increasing consumer exposure to these products (12).



Within the paediatric case studies identified, 14.3% (11 cases) of patients who underwent invasive surgical intervention experienced post-surgical morbidities. These morbidities are composed of a wide range of post-surgical complications, with no clear correlation between any one morbidity and small magnet ingestions. Of these morbidities, it is suspected there is a bias towards reporting complications of a surgical rather than a psychological nature. What is unavailable from the evidence collected is information on the potential long-term effects on a patient's physical and mental health several years post-surgery/ingestion event. As the case reports identified primarily document the surgical intervention and the rationale behind this, it is unlikely these reports cover the entire patient journey post-surgical outcome.

Conclusion

Small magnets (both iron-based and SREMs) present a unique category of foreign body ingestions. Previous studies have noted that small magnet cases are often associated with a far greater requirement for surgical intervention compared to nonmagnetic foreign body ingestions (5). This is an observation supported by those cases identified in the literature here, with a requirement for surgical (the creation of an artificial incision into the body) intervention in 75% of paediatric cases identified within this sample of 102 patients. However, a vast majority of the authors of the literature identified are either medical or surgical practitioners, resulting in a likely reporting bias for cases requiring surgical intervention. While this may be the case, the mechanisms which result in MSIs to patients remain constant throughout the literature, with the most frequent injuries found to be experienced by patients being bowel perforation and fistula formation as a result of soft tissue compression via magnets. It is these MSIs which elevate the potential harm presented by small magnet ingestions compared to other foreign bodies. Comparisons of the number of magnets vs. the associated categories of harm do not identify a clear pattern of increasing harm alongside increasing number of ingested magnets. Indeed, it is the case that the single category 6 report (resulting in patient mortality) involved only two magnets. It is likely that this lack of immediate correlation is due to the fact that only a minimum of two magnets are required for the potential formation of MSIs. The literature suggests there exists a potential positive correlation between the increased likelihood of harm and the length of time until medical intervention is administered. Category 5 paediatric patients (cases where medical intervention is >24 hours from the confirmed or suspected time of small magnet ingestion) experienced MSIs in all 63 cases. This is likely as these patients typically present only once symptomatic and injuries are in progress, as a recurring cause for delay to intervention is unwitnessed small magnet ingestion. Comparatively, only 50% of category 4 cases where medical intervention is <24-hours from ingestion resulted in MSIs to patients. While this literature review aims to identify the harm of small magnet ingestion cases in both the paediatric and mature populations, there is a stark contrast in the amount of available evidence documenting these cases. As only three mature cases have been identified, it is not possible to draw specific conclusions from this data due to the limited sample size. It is worth noting however, that this difference is likely due to the alternative nature of adult foreign body ingestions, primarily composed of foodrelated impactations. It is possible that small magnets may present a larger risk to mature individuals with existing learning difficulties or psychiatric disorders, however this would require specific research.

The evidence presented here suggests small magnets pose a greater risk of harm to the paediatric population compared to mature individuals. Of the paediatric case studies identified, 80% of these are classified as high-harm cases either due to the formation of MSIs or the requirement for surgical intervention. Small magnets pose several unique challenges compared to other foreign bodies, primarily being the increased risk of lack of spontaneous progression through the GI tract and the formation of tissue compression or contortion related injuries. Evidence suggests that harm is more often associated with the length of time between medical intervention and initial ingestion event when compared to the number of magnets ingested. While this study has set out to identify the nature of the harm experienced by patients of small magnet ingestion events, further questions remain as to the nature of the magnetic products involved. As the identified case studies are likely to possess a strong reporting bias and are not selected for any one region in particular, these cases are not reflective of global incidence rates of small magnet ingestion. In conclusion, small magnets, if and when ingested, can cause injuries that constitute high harm. The degree of harm that they can cause is influenced by the time taken to make a medical intervention; immediate medical intervention or monitoring should be sought to reduce the risk of developing harm.

Table 5 – Annex I: Paediatric case studies

Case	Category	Region	No. Magnets	Magnet Shape	Invasive Surgery	Surgery Type	Magnet Specific Injuries	Post-Operative Morbidities
1 (44)	4	FRA	2	Spherical	Yes	Gastrotomy	None listed	None listed
2 (44)	4	FRA	12	Spherical	Yes	Laparotomy/ Gastrotomy	None listed	None listed
3 (44)	4	FRA	5	Spherical	Yes	Laparotomy/Colotomy	None listed	None listed
4 (45)	4	BHR	11	Spherical	No	N/A	None listed	None listed
5 (46)	4	EGY	7	Bullet	Yes	Bowel resection/ Anastomosis	Fistula formation	None listed
6 (47)	5	BHR	20	Spherical	Yes	Enterotomy	Fistula formation	None listed
7 (48)	4	CZE	2	Oval	Yes	Appendectomy	None listed	None listed
8 (48)	4	CZE	2	Spherical	Yes	Appendectomy	None listed	None listed
9 (49)	5	PAK	11	Spherical	Yes	Laparotomy	Bowel perforation	Subacute intestinal obstruction 11-days post- operative
10 (6)	5	QAT	26	Spherical	Yes	Enterotomy/ Gastrotomy	Bowel perforation, pressure necrosis	Bowel obstruction 6- months post-operative
11 (6)	5	QAT	5	Spherical	Yes	Enterotomy	Bowel perforation	None listed
12 (50)	3	USA	2	Spherical	No	N/A	None listed	None listed

13 (51)	5	USA	13	Not specified	No	N/A	Fistula formation	None listed
14 (52)	5	GRC	14	Cone	Yes	Enterotomy	Fistula formation	None listed
15 (53)	5	ITA	2	Cylindrical	Yes	Enterotomy	Fistula formation	None listed
16 (54)	5	GRC	2	Spherical	Yes	Laparotomy	Bowel obstruction, Fistula formation	None listed
17 (55)	5	GBR	Not stated	Not specified	Yes	Appendectomy Laparotomy	Bowel perforation, Fistula formation	None listed
18 (56)	5	HKG	2	Spherical	Yes	Laparotomy	Bowel obstruction, bowel pressure necrosis	None listed
19 (56)	4	HKG	5	Spherical	Yes	Enterotomy	None listed	None listed
20 (57)	4	KOR	5	Spherical	Yes	Laparotomy, Bowel resection	Bowel perforation, Fistula formation	None listed
21 (57)	4	KOR	2	Disc	Yes	Laparotomy, Bowel resection	Bowel herniation, fistula formation	None listed
22 (57)	5	KOR	3	Cylindrical	Yes	Laparotomy	Bowel perforation, Gastric perforation, Fistula formation	None listed
23 (58)	5	BRA	2	Cuboid	Yes	Laparotomy	Fistula formation	None listed
24 (59)	5	JPN	3	Not specified	Yes	Laparotomy	Fistula formation	None listed

25 (60)	5	USA	3	Disc	Yes	Laparotomy	Fistula formation, Volvulus	None listed
26 (61)	5	USA	3	Spherical	No	Endoscopy	Bowel perforation	None listed
27 (62)	4	HRV	25	Spherical	Yes	Laparotomy, Bowel resection	Fistula formation	None listed
28 (63)	5	GBR	10	Spherical	Yes	Laparotomy	Bowel obstruction, Bowel perforation	None listed
29 (39)	5	GBR	2	Spherical/ Cylindrical	Yes	Laparotomy	Bowel perforation	Minor wound infection
30 (39)	5	GBR	1	Not specified	Yes	Laparotomy	Fistula formation	None listed
31 (39)	5	GBR	5	Cylindrical	Yes	Laparotomy/ Enterotomy	Bowel obstruction	None listed
32 (64)	5	TUR	Not stated	Not specified	Yes	Laparotomy	Bowel perforation	None listed
33 (65)	5	MYS	15	Spherical	Yes	Laparotomy	Bowel pressure necrosis	None listed
34 (66)	4	KSA	22	Cylindrical	Yes	Laparotomy	None listed	None listed
35 (66)	5	KSA	4	Not specified	Yes	Laparotomy	Bowel perforation	None listed
36 (66)	4	KSA	2	Oval	Yes	Laparotomy	Bowel perforation	None listed

37 (67)	5	USA	2	Oval	Yes	Anastomosis/Bowel resection	Bowel wall ischaemia	None listed
38 (68)	5	TUR	10	Disc	Yes	Laparotomy	Bowel perforation	None listed
39 (69)	5	CHN	12	Spherical	Yes	Laparotomy, Bowel resection	Bowel perforation	None listed
40 (70)	3	CHN	9	Spherical	No	N/A	None listed	None listed
41 (71)	5	USA	11	Spherical	Yes	Laparotomy	Bowel perforation	None listed
42 (72)	4	CAN	3	Spherical	Yes	Enterotomy	Bowel perforation	None listed
43 (73)	5	ITA	2	Disc	Yes	Bowel resection	Fistula formation	None listed
44 (40)	5	USA	7	Spherical	Yes	Minilaparotomy, bowel resection	Fistula formation	None listed
45 (40)	4	USA	16	Spherical	Yes	Laparotomy, enterotomy	Bowel perforation	None listed
46 (40)	4	USA	3	Spherical	Yes	Minilaparotomy, enterotomy	None listed	None listed
47 (40)*	5	USA	1	Spherical	Yes	lleocecectomy, bowel resection	Bowel pressure necrosis	None listed
48 (74)	5	IND	5	Spherical	Yes	Laparotomy, bowel resection	Bowel perforation	None listed

49 (75)	5	TUR	20	Spherical	Yes	Laparotomy	Bowel perforation	None listed
50 (76)	5	GBR	16	Spherical	Yes	Open exploratory surgery, anastomosis/bowel resection	Bowel perforation, Fistula formation	lleus, wound infection
51 (77)	5	PAK	7	Not specified	Yes	Anastomosis/bowel resection	Bowel pressure necrosis	Re-operative procedure for burst abdomen 5 days post-op, unable to tolerate feeds
52 (78)	5	ECU	6	Spherical	Yes	Laparotomy, bowel resection	Bowel perforation, Fistula formation	None listed
53 (79)	5	GBR	Not stated	Not specified	Yes	Laparotomy, appendicectomy	Fistula formation	Manage food fear and behavioural difficulties surrounding feeding
54 (80)	3	USA	10	Spherical	No	N/A	None listed	None listed
55 (81)	3	USA	6	Spherical	No	N/A	None listed	None listed
56 (42)	1	USA	1	Not specified	No	N/A	None listed	None listed
57 (42)	1	USA	1	Spherical	No	N/A	None listed	None listed
58 (42)	3	USA	24	Spherical	No	N/A	None listed	None listed
59 (42)	2	USA	14	Spherical	No	N/A	None listed	None listed

60 (42)	5	USA	17	Spherical	Yes	Laparotomy, bowel resection	Bowel perforation, gastric perforation	None listed
61 (42)	4	USA	3	Spherical	Yes	Enterotomy	Bowel perforation	None listed
62 (82)	5	USA	Not stated	Not specified	Yes	Laparotomy, bowel resection	Bowel perforation	None listed
63 (82)	5	USA	4	Not specified	Yes	Laparotomy, bowel resection	Bowel perforation	Multiple intra-abdominal abscesses
64 (82)	5	USA	2	Not specified	Yes	Laparotomy	Bowel perforation	None listed
65 (82)	5	USA	2	Not specified	Yes	Laparotomy	Bowel perforation, fistula formation	lleus <1-week post- operative
66 (82)	3	USA	1	Not specified	No	N/A	None listed	None listed
67 (82)	3	USA	1	Not specified	No	N/A	None listed	None listed
68 (82)	3	USA	1	Spherical	No	N/A	None listed	None listed
69 (83)	1	USA	1	Not specified	No	N/A	None listed	None listed
70 (84)	5	KOR	6	Spherical	Yes	Laparoscopic removal	Fistula formation	None listed
71 (84)	5	KOR	7	Spherical	Yes	Laparoscopic removal	Fistula formation	None listed

72 (84)	5	KOR	12	Bar/Spherical	Yes	Enterotomy/ Minilaparotomy	Bowel perforation	Recurrent event occurred
73 (84)	5	KOR	2	Bar	Yes	Enterotomy/ Minilaparotomy	Bowel perforation	None listed
74 (84)	5	KOR	2	Spherical	Yes	Laparoscopic removal, Gastric resection, Bowel resection	Fistula formation	None listed
75 (84)	5	KOR	2	Spherical	Yes	Laparoscopic removal, anastomosis/Bowel resection	Bowel wall edema and hematoma	None listed
76 (84)	2	KOR	2	Not specified	No	N/A	None listed	None listed
77 (84)	2	KOR	5	Not specified	No	N/A	None listed	None listed
78 (84)	2	KOR	2	Not specified	No	N/A	None listed	None listed
79 (38)	6	POL	2	Spherical	No	N/A	Patient mortality due to intestinal volvulus	N/A
80 (85)	5	USA	18	Bar/Spherical	Yes	Laparotomy	Bowel perforation, volvulus	None listed
81 (86)	3	IND	1	Disc	No	N/A	None listed	None listed
82 (87)	5		Not stated	Bar	Yes	Not specified	Bowel perforation, pressure necrosis	None listed

83 (88)	5	USA	4	Not specified	Yes	Laparotomy, bowel resection	Bowel ulceration, gastric ulceration	Poor gastric motility post- operatively until post-op day 9
84 (89)	5	UK	10	Spherical	Yes	Laparotomy, bowel resection	Fistula formation, pressure necrosis	None listed
85 (89)	5	UK	2	Not specified	Yes	Hemicolectomy	Fistula formation	None listed
86 (90)	4	USA	3	Disc	No	N/A	Gastric perforation, bowel perforation	None listed
87 (91)	5	AUS	7	Not specified	Yes	Laparotomy	Fistula formation, bowel perforation	None listed
88 (92)	5	GRC	2	Not specified	Yes	Laparotomy, bowel resection	Bowel perforation	None listed
89 (93)	3	USA	2	Spherical	No	N/A	None listed	None listed
90 (43)	5	KSA	13	Spherical	Yes	Laparotomy, enterotomy	Fistula formation	None listed
91 (94)	5	ROU	28	Spherical	Yes	Laparotomy, bowel resection	Fistula formation	None listed
92 (95)	5	USA	19	Spherical	Yes	Laparotomy, gastrotomy	Fistula formation, bowel perforation	None listed
93 (96)	5	SGP	62	Spherical	Yes	Laparotomy	Fistula formation, bowel perforation	None listed
94 (97)	5	USA	33	Spherical	Yes	Laparotomy	Bowel perforation	None listed

95 (98)	5	IND	Not stated	Spherical	Yes	Laparotomy, bowel resection	Fistula formation, gastric perforation	None listed
96 (99)	3	TWN	23	Spherical	No	N/A	None listed	None listed
97 (100)	3	MEX	15	Oval	No	N/A	None listed	None listed
98 (101)	5	DNK	15	Bar/spherical	Yes	Laparotomy	Fistula formation	Re-admitted on 5 th post-op day for re-laparotomy
99 (102)	5	USA	4	Spherical	Yes	Laparotomy	Bowel perforation	None listed
100 (103)	5	GBR	5	Spherical	Yes	Laparotomy, bowel resection	Fistula formation	None listed
101 (41)	5	BRA	2	Not stated	Yes	Laparoscopy, enterectomy	Fistula formation	None listed
102 (104)	3	CAN	3	Spherical	No	N/A	None listed	None listed

Table 6 – Annex II: Mature case studies

Case	Category	Region	No. Magnets	Magnet Shape	Open Surgery	Surgery Type	Magnet Specific Injuries	Post-Operative Morbidities
1 (40)	5	USA	27	Spherical	Yes	Gastrotomy, duodenotomy	Bowel perforation, gastric perforation	None listed
2 (34)	5	GBR	6	Bar/spherical	Yes	Laparotomy	Fistula formation	None listed
3 (35)	5	KOR	19	Cylindrical	Yes	Laparotomy, bowel resection	Fistula formation, pressure necrosis	None listed

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