



Cautionary tales in the use of magnets for the treatment of long gap esophageal atresia

Hester F. Shieh^{a,b}, Russell W. Jennings^a, Michael A. Manfredi^c, Peter D. Ngo^c, Benjamin Zendejas^a, Thomas E. Hamilton^{a,*}

^a Department of Surgery, Boston Children's Hospital, 300 Longwood Ave, Boston, MA 02115, United States

^b Department of Surgery, Johns Hopkins All Children's Hospital, 501 6th Ave S, Saint Petersburg, FL 33701, United States

^c Department of Gastroenterology, Boston Children's Hospital, 300 Longwood Ave, Boston, MA 02115, United States



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ABSTRACT

Background: The use of magnets for the treatment of long gap esophageal atresia or “magnamosis” is associated with increased incidence of anastomotic strictures; however, little has been reported on other complications that may provide insight into refining selection criteria for appropriate use.

Methods: A single institution, retrospective review identified three cases referred for treatment after attempted magnamosis with significant complications. Their presentation, imaging, management, and outcomes were reviewed.

Results: All three patients had prior cervical or thoracic surgery to close a tracheoesophageal fistula prior to magnamosis, creating scar tissue that can prevent magnet induced esophageal movement, leading to either magnets not attracting enough or erosion into surrounding structures. Two patients had a reported four centimeter esophageal gap prior to attempted magnamosis, both failing to achieve esophageal anastomosis, suggesting that these gaps were either measured on tension with variability in gap measurement technique, or that the esophageal segments were fixed in position from scar tissue and unable to elongate. One patient had severe tracheobronchomalacia requiring tracheostomy, with improvement in his airway after eventual tracheobronchopexies, highlighting that magnamosis does not address comorbidities often associated with this patient population.

Conclusions: We propose the following inclusion criteria and considerations for magnamosis: an esophageal gap truly less than four centimeters off tension with standardized measurement across centers, cautious use with a history of prior thoracic or cervical esophageal surgery, no associated tracheobronchomalacia or great vessel anomaly that would benefit from concurrent repair, and ideally to be used in centers equipped to manage potential complications.

Level of evidence: Level IV treatment study.

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1. Introduction

The use of magnets for the treatment of long gap esophageal atresia (LGEA) was first described in 1975 by Hendren and Hale [1]. Recently, a renewed interest in magnetic compression for esophageal anastomosis or “magnamosis” has resurfaced. In 2017, the U.S. Food and Drug Administration approved the use of the Flourish™ Pediatric Esophageal Atresia device (Cook Medical Inc., Bloomington, IN) under the Humanitarian Device Exemption (HDE). The device is indicated for the treatment of pediatric patients up to one year of age, with esophageal atresia (EA) without a

tracheoesophageal fistula (TEF) or for whom a TEF has been closed as a result of a prior procedure, with the caveat that the gap between the upper and lower pouches of the esophagus must be less than 4 cm apart [2].

Although it is appealing to be able to treat LGEA with purely endoscopic means, there is concern that the magnet approach leads to very high anastomotic stricture rates, with the resulting need for increased endoscopic dilations and anesthetic events [3]. Furthermore, within the last year, our Esophageal and Airway Treatment (EAT) referral center has treated three children who had undergone failed attempts at esophageal magnamosis at the referring hospitals with significant complications. Our goal is to share these cases as cautionary tales for others considering the magnet route for the treatment of LGEA, and offer suggestions to refine the selection criteria for appropriate use of magnamosis based on insight gained from treating these children.

Abbreviations: LGEA, long gap esophageal atresia; EA, esophageal atresia; TEF, tracheoesophageal fistula; TBM, tracheobronchomalacia; ALTE, apparent life-threatening event; GVA, great vessel anomaly.

* Corresponding author.

E-mail address: thomas.hamilton@childrens.harvard.edu (T.E. Hamilton).

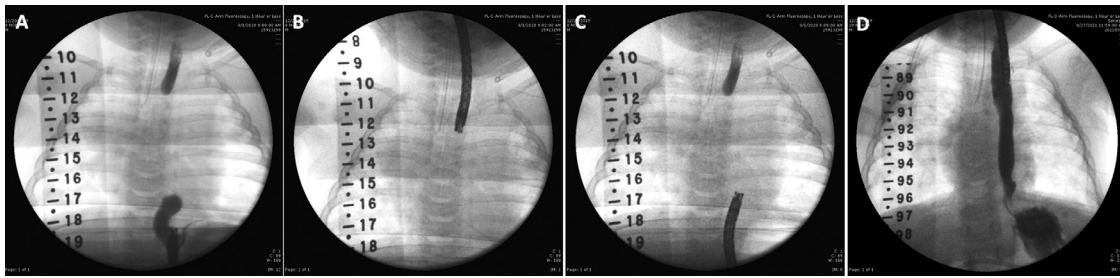


Fig. 1. Case #1. (A) Gapogram off tension with a 5 cm esophageal gap. (B) Upper esophageal pouch on tension and (C) lower esophageal pouch on tension with a 4 cm esophageal gap. (D) Postoperative fluoroscopic contrast study at latest follow up (twenty months of age).

2. Methods

We retrospectively reviewed the medical records of patients with LGEA treated at Boston Children's Hospital by our multidisciplinary EAT referral center, after attempted esophageal magnamosis with the Flourish™ Pediatric Esophageal Atresia device (Cook Medical Inc., Bloomington, IN) at the referring hospitals, between 2020 and 2021. Institutional review board approval and parental permission were obtained. We reviewed the clinical presentation, imaging, treatment, operative course, and outcome of each patient at the referring hospitals and after transfer to our institution.

3. Case series

3.1. Case #1

This is a former premature male (30 weeks [w] and 2 days [d] gestation), birth weight 1.1 kg, with prenatal suspicion of EA, which was confirmed postnatally to be type B with a proximal TEF. He underwent an open gastrostomy shortly after birth, then division of the TEF through a left neck dissection at three months of age. A gapogram demonstrated a 4 cm gap (unclear if on or off tension) and he underwent attempted esophageal magnamosis at five months of age. The device required repositioning within 24 h for displacement of the gastric magnet, and then ultimately failed with no progress in closing the gap and was removed. A month later, a hybrid procedure was attempted with a left thoracotomy to mobilize the esophageal pouches prior to magnamosis. Again, there was no progress and the magnets were removed shortly after placement. From a respiratory perspective, he had chronic lung disease, intubated at birth until four months of age, then extubated and stable on low flow nasal cannula.

At eight months of age, he was transferred to our institution for surgical management. Diagnostic evaluation demonstrated an immobile left vocal cord, no significant tracheobronchomalacia (TBM), and an esophageal gap of 5 cm off tension and 4 cm on tension (Fig. 1A, C). He underwent a very challenging redo left thoracotomy with extensive lysis of adhesions to mobilize both esophageal pouches which were encased in fibrous scar. Given his chronic lung disease and difficulty tolerating the operation from a respiratory perspective, we elected to place his esophageal pouches on internal traction to avoid the potentially prolonged intubation associated with external traction. He recovered from this, extubated in the interim, and returned to the operating room a month later for delayed primary esophageal anastomosis. He was kept intubated, chemically paralyzed, and with thoracic spine flexion for three days postoperatively owing to tension on the anastomosis. His esophagram demonstrated no leak. He was discharged home at one year of age on low flow nasal cannula and tolerating gastrojejunal tube feeds. He developed an esophageal stricture refractory to endoscopic dilations and returned at 14 months of age for an uncomplicated esophageal stricture resection with end to end

anastomosis. Postoperatively, he underwent serial endoscopic dilations, with his last endoscopy at twenty months of age not requiring dilation (Fig. 1D). He is transitioning from jejunal to gastric tube feeds and working on oral feeding therapy.

3.2. Case #2

This is a former premature male (35w5d gestation), birth weight 1.9 kg, with prenatal suspicion of EA, which was confirmed postnatally to be type B with a proximal TEF. He underwent a laparoscopic gastrostomy shortly after birth, then division of the proximal TEF through a right neck dissection at three weeks of age. Subsequently, he had a gastric perforation secondary to a red rubber catheter that was placed through the gastrostomy site to dilate the lower esophageal pouch, requiring laparoscopic repair. He then developed an enterocutaneous fistula and sepsis, and underwent a laparotomy for repair of a small bowel perforation. He recovered from these events, and a gapogram demonstrated a 4 cm gap (unclear if on or off tension), after which he underwent attempted esophageal magnamosis at six months of age. The device required two repositionings within a week for magnet displacement, then was complicated by erosion of the gastric magnet into the right lower lobe of the lung, requiring reoperation and thoracoscopic removal of the magnets. Traction sutures were placed on the two ends of the esophagus.

He was transferred to our institution at eight months of age for surgical management. Diagnostic evaluation demonstrated no significant TBM, and an esophageal gap of 4 cm off tension and 3 cm gap on tension (Fig. 2A, C). He underwent right thoracotomy, extensive lysis of adhesions with partial pulmonary decortication, mobilization of both esophageal pouches, and placement on external traction (Foker process). He had a two week traction process before returning to the operating room for esophageal anastomosis. He was paralyzed and flexed for a week postoperatively owing to tension on the anastomosis, and an esophagram demonstrated no leak. He developed acute gangrenous cholecystitis and underwent a cholecystectomy. He was discharged home at ten months of age on room air and tolerating gastrojejunal tube feeds. His esophageal anastomosis was dilated once postoperatively, with the last surveillance endoscopy at fourteen months of age not requiring dilation (Fig. 2D). He is transitioning from jejunal to gastric tube feeds and progressing on oral feeding therapy.

3.3. Case #3

This is a twin male, term pregnancy, 2.1 kg at birth, with a postnatal diagnosis of type C EA/TEF. On day of life one, he underwent right thoracotomy with TEF ligation, internal traction of both esophageal pouches, and a gastrostomy. This was complicated by an upper esophageal pouch leak, requiring reoperation and repair on postoperative day four. Related to his leak, he developed thoracic spine T2-3 osteomyelitis and bacteremia, for which he

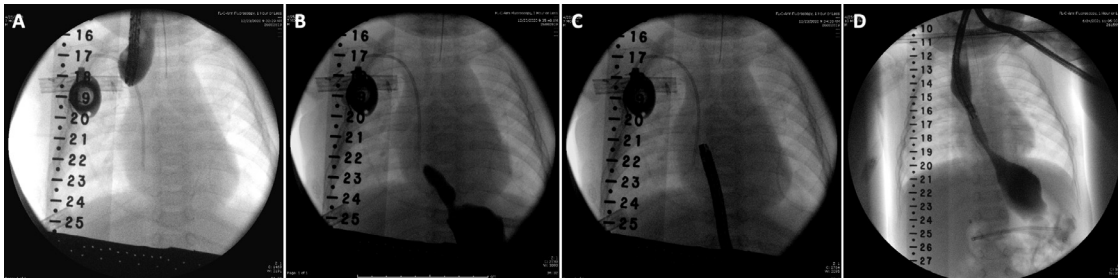


Fig. 2. Case #2. Gapogram with (A) upper esophageal pouch off tension and (B) lower esophageal pouch off tension with a 4 cm esophageal gap. (C) Lower esophageal pouch on tension with a 3 cm esophageal gap. (D) Postoperative fluoroscopic contrast study at latest follow up (fourteen months of age).

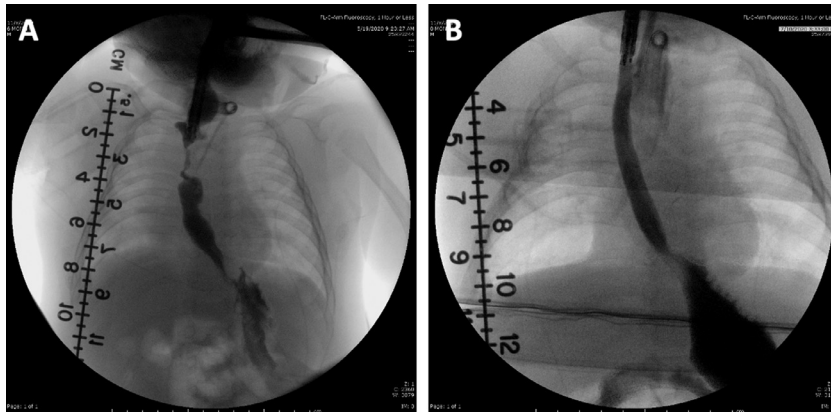


Fig. 3. Case #3. (A) Fluoroscopic contrast study with long segment refractory esophageal stricture after two magnamosis attempts at the referring hospital. (B) Postoperative fluoroscopic contrast study at latest follow up (eight months of age).

was treated with an extended course of antibiotics. At two months of age, a gapogram demonstrated a 2 cm gap and he underwent esophageal magnamosis for anastomosis. He developed a complete anastomotic stricture and a second esophageal magnamosis was attempted, but he subsequently developed an esophageal stricture refractory to dilations. During his first few months of life, he also struggled with respiratory issues, with multiple failed extubations, need for positive pressure support, and apparent life threatening events (ALTEs) requiring resuscitation. He was diagnosed with severe TBM and eventually underwent a tracheostomy, but still with ongoing desaturation episodes and difficulty ventilating.

At six months of age, he was transferred to our institution for esophageal and airway evaluation. Diagnostic evaluation demonstrated severe TBM of the entire trachea and proximal mainstem bronchi, as well as a 2.5 cm long refractory esophageal stricture (Fig. 3A). He underwent a right neck dissection and redo right thoracotomy with extensive lysis of adhesions to fully mobilize the esophagus, which had essentially pulled apart at the anastomosis with a scar band in between. There was significant inflammation in the posterior mediastinum from his prior leak and anterior intrusion of the T3 vertebral body with heterotopic bone and scar impinging the esophagus, which was partially resected by our orthopedic colleagues to create more working room and less posterior airway intrusion. A tracheal diverticulum at the prior TEF repair site was resected and closed with a transverse tracheoplasty. Given the already long operation and his tenuous respiratory status throughout, we elected to stage the additional airway and esophageal work, and placed both esophageal pouches on internal traction.

He returned to the operating room a week later for the next stage of his operation. The esophagus was again mobilized through a redo right neck dissection and right thoracotomy. To support the airway, posterior cervical and thoracic tracheopexy, as well as bilateral mainstem bronchopexy, were performed under direct

bronchoscopic guidance with autologous tissue pledgets to the anterior longitudinal ligament of the spine. The upper and lower esophageal pouches were then placed on external traction (Foker process). He underwent serial bedside traction adjustments for about a week prior to return to the operating room for esophageal anastomosis. Given that the anastomosis was challenging and on tension, he was paralyzed and flexed for a week postoperatively. He underwent an esophagram that demonstrated no leak and was advanced to full gastrojejunal tube feeds. He was able to wean off the ventilator to tracheostomy collar and was placed back on nocturnal ventilation to facilitate weight gain. His esophageal anastomosis was wide open on endoscopy one month post anastomosis and did not require dilation (Fig. 3B). He was then transferred back to his home institution at eight months of age for ventilator weaning.

4. Discussion

LGEA describes a technically challenging subset of EA cases, in which a primary anastomosis of the two ends of the esophagus cannot be performed under acceptable tension by the operating surgeon. There is little consensus on its definition, evaluation, management, and approach to treatment. Delayed primary anastomosis and tension based esophageal growth induction techniques have been used to preserve the native esophagus [4]. Magnamosis was originally used for intestinal anastomoses, but more recently has been used for esophageal anastomoses as a minimally invasive endoscopic option that preserves the native esophagus and theoretically avoids thoracotomy [2]. However, it has been reported that this strategy results in increased anastomotic strictures requiring endoscopic or surgical intervention [3]. There has been little reported in the literature on other complications. We present three cases with significant complications following magnamosis,

and lessons learned that may guide future refinement of patient selection criteria for use of this technique.

4.1. *Lesson #1: Prior surgery such as TEF repair creates scar tissue that can prevent magnet induced movement of the esophagus*

Magnamosis has been approved for pediatric patients with EA and no TEF or for whom a TEF has been closed in a prior procedure. All three of these cases had a TEF that had been closed prior to attempted magnamosis, two through neck dissections and one through a thoracotomy. Two of the cases were complicated by an esophageal pouch leak or gastric perforation requiring reoperation with prolonged infection. These prior neck or chest operations create scar tissue and when the magnets are placed in a reoperative field, the scar tissue may limit the esophagus from moving freely, potentially leading to either magnets not attracting or erosion of the magnets into surrounding structures. A history of esophageal or gastric leak and infection creates even more inflammation and fibrosis, and it may be worth reconsidering the use of magnets in this setting. In all these cases, magnamosis was attempted at least two months after the prior neck or chest operation. It may be better in type B or C patients to attempt magnamosis either shortly after or potentially even at the same time as TEF repair, such that there is less scarring in order to allow maximal mobility of the esophageal pouches. This approach would of course carry increased risk of leak from the TEF repair site if not properly repaired. One additional risk of attempting magnamosis if the esophageal segments are not sufficiently mobile is the formation of a mucosal tube when the magnets separate the muscular layers, but the highly mobile mucosa is stretched and forms an anastomosis, which can result in a recalcitrant stricture as seen in the third case.

4.2. *Lesson #2: A 4 cm gap on tension is not the same as a 4 cm gap off tension*

Measurement of gap length varies widely across the literature. A gapogram is an intraluminal contrast study of the upper and lower esophageal pouches that is used to define the luminal lengths and distance between the two lumens, as well as look for other anomalies such as a proximal TEF or congenital esophageal stricture. Gaps measured using dilators or a flexible endoscope can vary depending on the amount of forward pressure or tension applied by the operator, with inconsistent and potentially misleading results, as a gap off tension can be artificially shortened on tension, as illustrated in Figs. 1 and 2 [4]. If the gap between the esophageal ends is too long, the magnets placed in the upper and lower esophageal pouches cannot attract with sufficient force to elongate the esophageal segments and connect to create a compression anastomosis, thus the measurement of the gap is critical for selection criteria. The first two cases were reported to have a 4 cm gap prior to magnamosis, both at the upper limit for use of the device as defined by the FDA, with both failing to make progress and achieve magnetic anastomosis, suggesting that either these gaps may have been measured on some tension, or that the esophageal ends were fixed in position from scar tissue and unable to elongate. Particularly at the upper limit of selection criteria, it is even more critical that the gap is measured off tension with no undue pressure. Magnets exert an attraction proportional to the square of the distance between the magnets, so doubling the distance will drop the force between them by a factor of four. It may be worthwhile to provide more strict standardized guidelines for gap measurement in the indications for use of this device. In addition, when there is scar tissue from prior operations or leaks that limit the mobility of the esophageal pouches, there may be a decreased chance of achieving an esophageal anastomosis with

magnets, and the 4 cm gap indication may need to be reconsidered in this setting and possibly shortened to account for the magnets having to attract enough to overcome the tissue resistance to elongation and growth. However, if the device is used appropriately in the intended method as described by the manufacturer, these patients could still be candidates for magnamosis, highlighting the importance of provider education on measuring the gap without excess tension. In cases with scar tissue from prior operations or when the esophageal gap is longer than 4 cm, a hybrid approach could be considered, in which esophageal mobilization and alignment (thoracoscopic or via thoracotomy) and placement of the magnets is done in the same setting. However, one must not forget the high anastomotic stricture rates associated with the current 10 French magnet size.

4.3. *Lesson #3: Magnamosis does not address associated comorbidities such as TBM that often coexist in EA patients*

Nearly half of EA patients have associated tracheobronchial anomalies such as TBM, which should always be evaluated preoperatively by dynamic airway tracheobronchoscopy, and if severe, may warrant surgical correction at the time of EA repair [4]. The third case had associated severe TBM, with the child struggling from a respiratory perspective since birth, who continued to have ALTEs despite a tracheostomy. We eventually did cervical and thoracic posterior tracheobronchopexies with significant improvement in his airway, and he was able to wean to tracheostomy collar before discharge. Given the complexity of this patient population with associated comorbidities, a complete multidisciplinary esophageal and airway evaluation is best to treat the patient as a whole. Although magnamosis may be a nonoperative way to achieve an esophageal anastomosis, it may not be the best approach for patients who have other issues such as TBM, a recurrent TEF or a great vessel anomaly (GVA) that would benefit from an operation to concurrently fix all associated issues.

In conclusion, the management and treatment of LGEA continue to evolve, with institutional approach often based on local expertise. Magnamosis is one option that has been shown to be safe and feasible in a small cohort, although associated with an essentially guaranteed stricture owing to current magnet size. We describe the complications from three attempted magnamosis cases that are cautionary tales to remind us that “the force is not always with you.” When considering the magnamosis approach, it is important to think about standardization of gap length measurement off tension and the optimal gap as selection criteria, consideration of scar tissue in a reoperative field and the optimal timing of magnamosis relative to a prior operation, and comorbidities such as severe TBM that may warrant an operation over a non operative approach. The use of magnets in poorly selected patients may ultimately lead to many more operations to address complications, as opposed to one or two definitive operations up front. LGEA is typically more complex than just a gap in the esophagus and may require a center of expertise to understand the nuances and optimize the outcomes of the children afflicted with anomalies of the esophagus, airway, and major blood vessels. As demonstrated in these cases, esophageal preservation via traction induced growth is possible after prior failed attempts at esophageal repair. Nonetheless, our work has clearly shown that Foker process outcomes are significantly better if patients are referred to us without prior failed attempts [5,6]. Hence, referral to or consultation with a center of expertise with management of patients with complex esophageal and airway issues should be considered early in the evaluation of such a child, particularly if the local expertise and resources are not available to manage potential complications from a magnamosis approach.

Although it is possible that the magnet device may be further modified, such as a larger magnet, to address the stricture complication, it is important that we refine patient selection criteria to optimize the likelihood of success. We propose the following selection criteria and considerations:

- Patients with esophageal gaps that are truly less than 4 cm off tension, with standardization of gap measurement technique across centers.
- Cautious use with a history of prior thoracic or cervical esophageal surgery.
- No associated TBM or GVA that would benefit from concurrent repair.
- Ideally to be used in centers that are equipped to manage the potential complications from a magnamosis approach.

5. Reviewer comments

Reviewer #1: This manuscript depicts three cases that had failed magnet treatment for esophageal atresia and suggestions to refine the selection criteria for appropriate use of magnamosis based on insight gained from treating these children. This is a well written manuscript with some important points. A few recommendations listed below:

Recommendations:

(1) should rephrase the conclusion "no history of prior thoracic or cervical esophageal surgery" as a selection criteria for magnet placement would recommend rather than stating these patients are not candidates for magnets, would highlight that there is a decreased chance of anastomosis but are still candidates for surgical repair when used appropriately. It is important to note that undue pressure should not be placed on the magnet catheters and that the device should only be used in the intended method as described by the manufacturer. Rephrased to "cautious use with a history of prior thoracic or cervical esophageal surgery". Other points added to discussion.

(2) only to be used in centers equipped to manage potential complications although I think this is ideal, is not possible to con-

trol which institutions can place the magnets so may be more beneficial to soften the wording (such as is best to do in centers that can manage the complications) and stress the education process for physicians placing them (again to be done in the appropriate fashion without excess tension placed on the catheters). Rephrased to "ideally to be used in centers equipped to manage potential complications". Other points added to discussion.

Reviewer #2: The authors perform a single institution, retrospective review of 3 cases in which magnamosis was attempted for long gap EA.

The authors hypothesize why the magnamosis failed in these 3 patients and then provide recommended inclusion criteria for future EA patients being considered for magnamosis.

- (1) No history of prior thoracic or cervical esophageal surgery.
- (2) Esophageal gaps of 4 cm or less as measured off tension.
- (3) No associated tracheobronchomalacia or great vessel anomaly.

(4) Only performed in centers equipped to handle complications associated with magnamosis use. The paper is well written, and the Figures are clear. Although with 3 patients, it is difficult to make conclusive recommendations regarding inclusion criteria, the four the authors propose seem reasonable. In the discussion the authors state "These prior neck or chest operations create scar tissue and when the magnets are placed in the reoperative field, the scar tissue limits the esophagus from moving freely, leading to either magnets not attracting or erosion of the magnets into the surrounding structures". While this is a reasonable hypothesis, there is no way to be certain that this is the mechanism for failure of the magnamosis. Please tone down this statement unless you have conclusive evidence to support this definitive statement.

Statement toned down.

Reviewer #3: Clearly written. Good review of complicated esophageal atresia repairs following attempted magnamosis.

6. STROBE statement checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4	
Objectives	3	State specific objectives, including any prespecified hypotheses	4	
Methods				
Study design	4	Present key elements of study design early in the paper	4,5	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow up, and data collection	4,5	
Participants	6	(a) <i>Cohort study</i> Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow up	4,5	
		<i>Case control study</i> Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls		
		<i>Cross sectional study</i> Give the eligibility criteria, and the sources and methods of selection of participants		
		(b) <i>Cohort study</i> For matched studies, give matching criteria and number of exposed and unexposed		
		<i>Case control study</i> For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4,5	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4,5	

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	Item No.	Recommendation	Page No.	Relevant text from manuscript
Bias	9	Describe any efforts to address potential sources of bias	4,5	
Study size	10	Explain how the study size was arrived at	4,5	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4,5	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> If applicable, explain how loss to follow up was addressed <i>Case control study</i> If applicable, explain how matching of cases and controls was addressed <i>Cross sectional study</i> If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	n/a n/a n/a n/a n/a	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow up, and analysed (b) Give reasons for non participation at each stage (c) Consider use of a flow diagram	5–9 n/a n/a	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> Summarize follow up time (eg, average and total amount)	5–9 n/a n/a	
Outcome data	15*	<i>Cohort study</i> Report numbers of outcome events or summary measures over time <i>Case control study</i> Report numbers in each exposure category, or summary measures of exposure <i>Cross sectional study</i> Report numbers of outcome events or summary measures	5–9 n/a n/a	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a n/a n/a	
Other analyses	17	Report other analyses done eg analyses of subgroups and interactions, and sensitivity analyses	n/a	
Discussion				
Key results	18	Summarize key results with reference to study objectives	9–13	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9–13	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9–13	
Generalisability	21	Discuss the generalisability (external validity) of the study results	9–13	
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	n/a	

*Give information separately for cases and controls in case control studies and, if applicable, for exposed and unexposed groups in cohort and cross sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jpedsurg.2021.11.002.

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