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Efficacy of adhesive strapping on umbilical hernia in children: a systematic review and meta-analysis of cohort studies

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ABSTRACT

Background Although adhesive strapping (AS) for pediatric umbilical hernia (UH), which was once obsolete, has been reconsidered as a common practice in Japan, its efficacy is still unclear. This study aimed to evaluate its efficacy by reviewing related articles.

Methods A comprehensive literature search of PubMed, Cochrane, Google Scholar, and Igaku Chuo Zasshi via Ichushi-Web was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. Cohort studies reporting on the UH closure rate after AS compared with observation-only management were included.

Results A total of 10 cohort studies were included, and the overall UH closure rate was not statistically significant (p=0.31, risk ratio (RR)=0.76, 95% confidence interval (CI) 0.45 to 1.28). However, there were significant differences in the UH closure rate at the age of 6 months (p<0.01, RR=0.55, 95% CI 0.41 to 0.75) and the efficacy of preventing protruding umbilici with redundant skin (p=0.049, RR=0.16, 95% CI 0.03 to 0.99).

Conclusions Although the efficacy of AS on UH compared with observation-only management did not differ in terms of the UH closure rate, the application of AS may be effective for faster UH closure and the prevention of protruding umbilici. However, due to the high heterogeneity of the study, further large-scale studies, particularly randomized controlled trials, are warranted to reach a conclusion.

PROSPERO registration number CRD42022314417.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The present treatment of pediatric umbilical hernia is observation, although adhesive strapping was conducted decades ago.
⇒ In Japan, adhesive strapping is regarded as a basic treatment due to the accumulation of retrospective and prospective studies.
⇒ There is no comprehensive review comparing the efficacy of adhesive strapping and observation-only treatment.

WHAT THIS STUDY ADDS

⇒ We found that there was no significant difference in the overall closure rate of pediatric umbilical hernia.
⇒ We found that the application of adhesive strapping may be effective for faster umbilical hernia closure and the prevention of protruding umbilici.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ There is insufficient number of studies focusing on the efficacy of adhesive strapping on pediatric umbilical hernia, and thus further studies, including randomized controlled studies, are warranted to reach a conclusion.
⇒ Adhesive strapping could be considered an alternative treatment option for cosmetic purposes.

INTRODUCTION

Pediatric umbilical hernia (UH) is a common disease that occurs in 10%–20% of newborns.[1] Despite its high prevalence, 80% of patients with UH are expected to heal spontaneously before reaching 1 year of age and 90% before 2 years of age without any treatment.[2]

Since the mid-20th century, adhesive strapping (AS), which involves strapping the abdomen with adhesive tape to keep the UH reduced, has been considered a useful method, and several studies and case reports regarding this maneuver have been published.[3–8] However, as studies on its usage became limited, its efficacy was doubted and AS became obsolete.[9–12] Therefore, in most countries, children are under observation for UH until the age of 2 years. Surgical repair is considered when UH persists beyond that age.[13]

In Japan, AS has been recently reconsidered a standard procedure. This is because some studies have revealed that AS accelerates healing and suppresses umbilical protrusion after hernia closure.[2 14–18] However, its efficacy is still unclear because there are no randomized controlled trials; several cohort studies have investigated the strategy. Therefore, this systematic review and meta-analysis aims to reveal the efficacy of AS for UH compared

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with observation-only management by analyzing previous cohort studies.

Herein, the primary outcome was the change in the UH closure rate. The secondary outcomes were the closure rate at 6 months of age, among patients with a large hernia, among mature or premature infants, and the rate of children with umbilical protrusion with redundant skin at the end of the observation period. We examined the closure rates with data in recent studies and reviewed the complications of AS.

METHODS

We performed a systematic review and meta-analysis of the related literature according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (online supplemental file 1) to conduct this meta-analysis of cohort studies, which was registered on PROSPERO (registration number CRD42022314417).

Search strategy of the literature

First, databases including PubMed, Cochrane, Google Scholar, and Igaku Chuo Zasshi via Ichushi-Web (a Japanese medical abstract database) were searched independently by two investigators (TS and KT). The search included studies published before March 8, 2022, without any limitation on publication year. The search terms "umbilical hernia" and "strapping" were used in PubMed and Cochrane, and "umbilical hernia," "strapping," and "pediatric" were used in Google Scholar. We used equivalent words in Japanese when searching Ichushi-Web. Second, relevant articles were identified through a manual search of secondary sources, including references to initially identified studies and a search of reviews and commentaries. The search was limited to cohort studies in children, and all cohort studies that reported on the closure rate of UH after AS in comparison with that after observation-only management were eligible for inclusion. The other inclusion criterion was an observation period of at least up to 1 year of age. If the observation period was not mentioned, the authors evaluated whether the period was acceptable. Japanese articles without an English abstract were excluded.

Eligibility was assessed by two investigators (TS and KT) following a three-stage procedure: title screening, abstract screening, and whole article screening. The Newcastle-Ottawa Quality Assessment (NOS) was used to access the quality of the included studies. In the NOS, 9 scores can be maximally awarded by adding up to 4 scores for selection criteria, 2 scores for comparability, and 3 scores for the outcome. We defined age as the most important factor and the size of the UH defect as the second most important factor for comparability. We designated scores of 0–3, 4–6, and 7–9 as low-quality, moderate-quality, and high-quality studies, respectively. Any differences in the procedure were resolved by consensus (TS and KT).

Data extraction

The following data were extracted from the included studies: publication year, country, period of intervention, number of patients who underwent AS and observation-only management as a control arm, sex, proportion of large and small UH, proportion of premature and mature infants, age at which AS was first applied, observation period, inclusion and exclusion criteria, AS procedure, study outcome, UH closure rate at the end of the study and age of 6 months, UH closure rate in large hernias, UH closure rate among premature or mature infants with hernia, overall AS duration, age when the UH was cured, incidence of protrusion of umbilicus with redundant skin, and complications.

Statistical analysis

All analyses except that for publication bias were implemented using EZR (V.1.54; Saitama Medical Center, Jichi Medical University, Saitama, Japan). We chose risk ratios (RRs) and 95% confidence interval (CIs) as the main outcome indices. If not reported in the primary studies, RRs and other associated variance components were calculated from the original data. Forest plots were produced to visualize the assessment of the RRs across studies. I^2 values were used to evaluate the heterogeneity across studies. Values of 0%–25% represented minimal heterogeneity, 26%–75% represented moderate heterogeneity, and >75% represented substantial heterogeneity. Summary estimates of the RRs were performed using Mantel-Haenszel random-effects models. Publication bias was assessed by inspection of the funnel plots for asymmetry with Begg's and Egger's tests using the metafor package of R software (R Foundation).[19]

RESULTS

Study selection

In total, 129 studies were identified through database searching and manual searching (figure 1). After removing duplicates, two reviewers identified eligible articles independently by title and abstract screening. Studies that did not meet our inclusion criteria were removed, and 12 studies were assessed for eligibility. After excluding articles with no English abstract and insufficient data, finally, 10 studies were included in our analysis (figure 1).

Study characteristics and quality assessment

The general characteristics of the included studies are shown in tables 1 and 2. The 10 included studies were cohort studies: 4 articles from Europe, Australia, and the USA were published in the mid-20th century, and 6 articles from Japan were published after 2000. AS was commenced before the age of 1 year in all cases, particularly during the first 6 months of life. The observation periods were at least 12 months. The qualities of the eligible studies were assessed using the NOS, which suggested that they were of high quality: a score of 7 in five studies and a score of 8 in five studies (online supplemental file 2).

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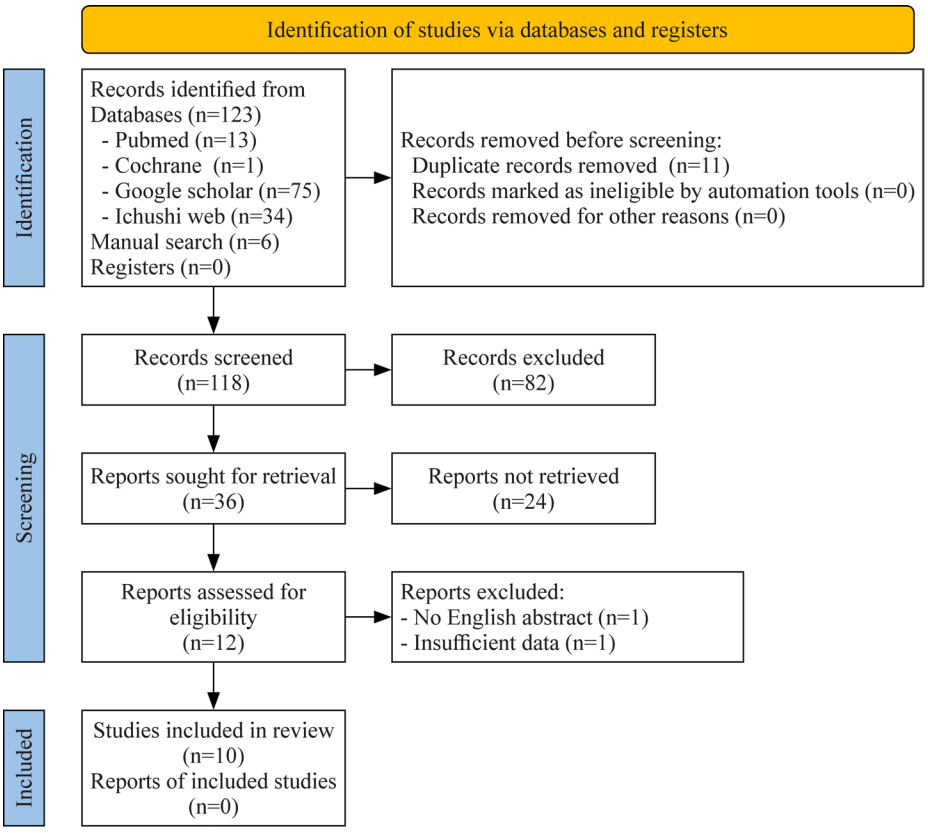

Figure 1 Flow chart of the selection of eligible studies.

AS procedure

Regarding the initiation age, eight studies mostly applied AS within the first 6 months.[2 5 9 14 16 17 20 21] One study did not mention it clearly, but the author probably applied it to patients of less than 6 months.[10] Infants less than 1 year old were included in a study.[11] There were several differences in the procedures of the included studies (table 2). First, in the studies before 2000, an elastic plaster or tape was directly applied after the hernia was reduced. However, in the latest studies after 2000, a cotton ball or a plug was inserted on the umbilicus, and subsequently plaster was placed in all studies except one.[14] Second, the frequency of changing AS varied in studies. In four studies, AS was changed weekly, in two studies every 2–3 weeks, in one study every 4 weeks, and two studies did not determine the specific period except when a plaster became dirty or peeled off and the frequency was not mentioned. Third, AS was changed by doctors or nurses in two studies and was changed by guardians at home in three studies. The other five studies did not mention who changed AS. Two studies reported that 7.8% and 12.6% of patients discontinued AS due to skin trouble.[16 21] One study excluded two patients who could not continue AS.[5] The overall duration of AS was reported in four studies.[2 11 14 21] The shortest duration was reported to be 11 days[2] and the longest was 10 months.[14] The average duration was mentioned in three studies: 2 months in two studies[14 21] and 49 days in the other.[2]

Efficacy of the intervention

Overall UH closure in the AS group and observation group

The meta-analysis comparing AS and observation-only management was conducted on 10 cohort studies (table 3). We compared unsuccessful UH closure rates of each group to calculate the RR, and there was no statistical significance between the two groups as per the forest plot shown in figure 2 (p=0.31, RR=0.76, 95% CI 0.45 to 1.28; heterogeneity was found: p<0.01, I^2=71%).

UH closure rate at 6 months of age

Five studies compared the UH closure rate at the age of 6 months (table 3).[2 5 9 14 17] The closure rates of UH were consistently higher in the AS group in four studies, and the meta-analysis showed a significant difference between the AS group and the observation group, as presented in the forest plot (p<0.01, RR=0.55, 95% CI 0.41 to 0.75; moderate heterogeneity was found: p=0.03, I^2=63%) (figure 3A).

Efficacy of AS on UH closure among large hernias

Four studies evaluated the efficacy of AS on large hernias (table 3).[5 9 10 20] The definitions of large hernia varied; the defect diameter was >5 mm in two studies[5 20] and >10 mm in another study.[10] The other study defined a large hernia as an hernia with an orifice that permits passage of a fingertip.[9] Therefore, this analysis was performed with four studies that had different definitions. Three studies[5 9 20] revealed a higher cure rate in the AS group

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Table 1 Characteristics of the cohort studies included in the analysis

Authors	Publication year	Study design	Country	Number of patients (AS/C)	Sex (M/F)	Hernia size (large/small)	Premature infants/mature infants	Age at which strapping was first applied (mean)	Observation period
Haworth[5]	1956	Cohort	UK	51/49	AS: 34/17 CL: 32/17	AS: 13/38 C: 12/37	NR	1 month: 1 1–2 months: 40 3–6 months: 8 >6 months: 2	By the age of 12 months
Karlström[9]	1961	Cohort	Sweden	56/68	NR	AS*: 22/34 C*: 18/50	NR	1–2 months	By the age of 12 months
Halpern[10]	1962	Cohort	USA	29/118	Total: 62/85	AS†: 18/11 C†: 25/93	NR	NR	NR
Angel-Lord[11]	1971	Cohort	Australia	87/78	AS: 58/29 C: 35/43	NR	AS‡: 27/60 C‡: 11/67	<12 months	12 months
Oshio *et al*[2]	2002	Cohort	Japan	102/24	AS: 57/45 C: 17/7	NR	NR	25 days–4 months (59.9±18.9 days)	Up to 27 months
Kanada *et al*[14]	2006	Cohort	Japan	32/32	AS: 19/13 C: 21/11	NR	NR	1–4 months (2.1 months)	By the age of 2 years
Hiraoka[20]	2014	Cohort	Japan	54/7	NR	AS: 48/6 C: 2/5	NR	Mostly <4 months	Up to 18 months
Hayashida *et al*[21]	2017	Cohort	Japan	89/27	AS: 45/44 C: 15/12	NR	NR	0.29±0.33 months	NR
Kurobe *et al*[16]	2021	Cohort	Japan	87/30	AS: 42/45 C: 19/11	NR	AS§: 45/42 C§: 0/30	1–3 months in mature infants (2 months) 1.5–5 months in premature infants (2.8 months)	Up to 39 months
Kitano *et al*[17]	2021	Multi-institutional cohort	Japan	97/31	AS: 58/41 (2 infants dropped) C: 15/16	AS: 1.2±1.1 cm^2 C: 1.8±1.0 cm^2	NR	≤6 months	By the age of 24 months

*Large hernias were defined as those with the orifice permitting the passage of a fingertip.
†Large hernias were defined as those with the orifice larger than 1 cm.
‡The definition was not mentioned.
§Premature infants were defined as those treated in the neonatal intensive care unit due to either a gestational age of <33 weeks or birth weight <2500 g.
AS, adhesive strapping; C, control; F, female; M, male; NR, not reported.

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Table 2 Criteria for AS, the procedure, and the outcome of the studies included

Authors	Inclusion criteria	Exclusion criteria	AS procedure	Outcomes
Haworth[5]	Only true umbilical hernia.	Babies whose hernias had previously been kept efficiently reduced. Supraumbilical hernia, linea alba hernia, babies with cutis navel, Asian, hypothyroidism, and general muscular hypotonia. Infants felt excessive discomfort or soreness of the skin during application of AS (2 cases).	The skin was first painted with tincture of benzoin. Using two pieces of nonelastic plaster (2 inches) and threading a tongue cut in one through a hole cut in the other. The assistant reduced the hernia by pinching the skin into a vertical fold over the hernia and the plasters were pulled tight. Another plaster (3 inches) was applied over the plasters. Strapping was kept for 4 weeks. Strapping was renewed for a further 2 weeks and continued (maximum 8 weeks).	Efficacy of AS at age 12 months. Efficacy depending on the size of protrusion and defect size. Relation between efficacy and the age at which AS was applied. Complications.
Karlström[9]	Umbilical hernia treated during a 2.5-year period.	Hernia of which healing had not taken place at the time of the investigation. Patients who had not been kept under sufficiently strict observation.	Hernia was restored and the skin was drawn tightly together into a longitudinal fold over the umbilical ring and held in this position with an approximately 5 cm wide elastic plaster band, which extended as far as the axillary line. The plaster was changed by the author or by nurses before it fell off or when it had begun to loosen at the edges. Only when the skin was extremely irritated was it allowed to rest for a few days before a new plaster was applied.	Efficacy of AS by the age of 4 months, 6 months, and 1 year according to the size of the hernia defect.
Halpern[10]	Every infant who attended the author's clinic within the time limit (1950s) and had an umbilical hernia.	NR.	AS was applied in deference to parental insistence. Elastic tape was used. Return visits were scheduled for every 2 weeks during the first 6 months of life, every month during the remainder of the first year, every 3 months during the second year, and every 6 months thereafter.	Efficacy of AS according to the size of protrusion and defect size.
Angel-Lord[11]	Congenital umbilical hernia. Baby's age must initially be ≤12 months. There must be a visual and palpable protrusion. There must be a palpable gap in the linea alba. The hernia must be digitally reducible.	Paraumbilical hernia, Asian, and children with any apparent chronic illness.	A single piece of zinc oxide plaster (nonelastic) 2–3 inches wide was applied across the abdomen from flank to flank. The protrusion was reduced by digital pressure only and there was not folding of skin across the hernia site. Children were observed every 3 or 4 weeks for at least 12 months. Strapping was renewed by the author or the baby health center sister when it became too dirty or water-logged or peeled from the edges, without a definite time set for renewal.	Efficacy of AS.
Oshio *et al*[2]	Umbilical hernia treated at institute A (control group) and those at B (AS). Birth weight over 1500 g. Children aged ≤6 months.	NR.	A cotton ball was placed after hernia reduction. Skin was drawn tightly over the umbilicus and then elastic bandage (5×12 cm) was placed over the umbilicus. The bandage was renewed every week. When skin had severe inflammation, new bandage was applied after a few days of rest period.	Efficacy of AS and the duration until the hernia was healed.
Kanada *et al*[14]	Infants aged <6 months and followed up to age 2 years. AS group included babies who visited from October 2000 to January 2005. Control group included babies who visited before December 2002.	NR.	After hernia reduction, a bandage was placed after skin was drawn tightly over the umbilicus. The bandage was renewed by guardians every 2–3 days at home.	Efficacy of AS and the duration until the hernia was healed.

Continued

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Table 2 Continued

Authors	Inclusion criteria	Exclusion criteria	AS procedure	Outcomes
Hiraoka[20]	Infants treated by AS for a 3-year period from September 2010.	Babies who dropped from follow-up visit.	A resin plug was placed on the umbilicus and a plaster (10×6 cm) was placed. The plaster was renewed every week. If protrusion was not observed twice in a row, another plaster was renewed for 1 week and treatment was completed.	Frequency of umbilical hernia. Efficacy of AS according to the defect size.
Hayashida *et al*[21]	Babies referred from April 2011 to December 2015.	Babies who had a coexisting disease that required surgery, those transferred to another hospital, and those who were lost to follow-up.	After hernia reduction, a cotton ball matching the size of the hernia orifice was inserted and fixed in place using elastic adhesive plaster.	Efficacy of AS. Comparison between success group and failure group in AS group. The effect of AS on the difficulty of surgery and operation time among infants whose treatment failed.
Kurobe *et al*[16]	Control group included infants observed from January 2006 to December 2008. AS group included infants treated from January 2010 to December 2014.	NR.	After hernia reduction, a small sponge was inserted and the fold of skin from two sides was brought together, forming a single crease. Covering the sponge, an elastic adhesive tape was placed. The tape was renewed every week by guardians.	Efficacy of AS. Complication and limitation of AS.
Kitano *et al*[17]	Babies aged ≤6 months at the first visit from 2012 to 2015.	Infants with trisomy 21, hypothyroidism, muscle disease, congenital heart disease, hypospadias, spina bifida, meningocele, and mucopolysaccharidosis. Birth weight <1500 g.	After hernia reduction, a small gauze or cotton wool matching the size of the hernia was inserted. Then, the fold of skin from two sides was brought together to cover the plug. An elastic adhesive plaster was placed. A transparent waterproof film dressing was placed over the plaster. The tape was renewed every week by guardians.	Efficacy of AS.

AS, adhesive strapping; NR, not reported.

than in the observation group, except one.[10] According to the forest plot, however, there was no significant difference between the two groups (p=0.33, RR=0.70, 95% CI 0.33 to 1.44; moderate heterogeneity was found: p=0.08, I^2=55%) (figure 3B). When analyzing two studies[5 20] that defined hernias >5 mm in diameter as large hernias, there was also no significant difference (p=0.15, RR=0.46, 95% CI 0.16 to 1.31; moderate heterogeneity was found: p=0.21, I^2=35%).

Efficacy of AS among mature and premature infants

Only one study reported the efficacy of AS based on maturity.[16] Among premature infants, the UH closure rate after AS was 80%. In the study, there were no premature infants who underwent observation. Among mature infants, the closure rates with and without AS were reported as 85.7% and 90.0%, respectively.

Efficacy for prevention of umbilical protrusion with redundant skin

Three studies evaluated the efficacy of AS in the prevention of umbilical protrusion (table 3).[14 16 20] These studies defined the condition in which the fascial defect was closed but the umbilicus protruded, with excess skin as umbilical protrusion with redundant skin. According to the forest plot, there was a significant difference between the AS and the observation group in preventing umbilical protrusion (p=0.049, RR=0.16, 95% CI 0.03 to 0.99; heterogeneity was moderate: p=0.18, I^2=41%) (figure 3C).

Efficacy of AS among recent studies

Six studies were published after 2000, which were all from Japan[2 14 16 17 20 21] (table 3). There was no significant difference between the two groups in the rate of unsuccessful closure (p=0.11, RR=0.58, 95% CI 0.29 to 1.13; heterogeneity was found: p=0. 10, I^2=45%) (figure 3D).

AS-related complications

Six studies reported complications due to AS, and the incidence rates were between 1.1% and 41.2% (table 3). The most common complication of AS was skin irritation, which caused discontinuation of AS when it was severe. However, the majority of patients were tolerant and they were able to complete AS after a short refraining period. Apart from skin complications, one case of strangulation was reported and we counted it as unsuccessful.[10]

Publication bias

Visual inspection of the funnel plot of the primary outcome revealed some asymmetry (online supplemental file 2). However, Begg's test and Egger's test did suggest

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Table 3 Summary of outcomes of the studies included

Authors	Cured n/N (%)	Cured at age 6 months n/N (%)	Cured large hernia (≥6 mm) n/N (%)	Cure rate in premature infants n/N (%)	Cure rate in mature infants n/N (%)	Overall AS duration (mean)	Age cured (mean)	Protrusion with redundant skin n/N (%)	Complication n/N (%)
Haworth[5]	AS: 44/51 (86.0) C: 36/49 (73.5)	AS: 36/51 (70.6) C: 23/49 (46.9)	AS: 8/13 (61.5) C: 5/12 (41.7)	NR	NR	NR	NR	NR	AS: 13/51 (25.5) C: NR
Karlström[9]	AS: 53/56 (94.6) C: 63/68 (92.6)	AS: 45/56 (80.4) C: 53/68 (77.9)	AS*: 19/22 (86.4) C*: 13/18 (72.2)	NR	NR	NR	NR	NR	NR
Halpern[10]	AS: 13/29 (44.8) C: 89/118 (75.4)	NR	AS†: 7/18 (38.9) C†: 14/25 (56.0)	NR	NR	NR	NR	NR	NR
Angel-Lord[11]	AS: 73/87 (83.9) C: 62/78 (79.4)	NR	NR	NR	NR	1–8 months	NR	NR	AS: 1/87 (1.1) C: 1/78 (1.3)
Oshio *et al*[2]	AS: 102/102 (100) C: 19/24 (79.2)	AS: 102/102 (100) C: 11/24 (45.8)	NR	NR	NR	11–123 days (49.1±29.9 days)	AS: 107.9±29.6 days C: 7.6±5.3 months	NR	NR
Kanada *et al*[14]	AS: 28/32 (87.5) C: 25/32 (78.1)	AS: 22/32 (68.8) C: 10/32 (31.3)	NR	NR	NR	0–10 months (2.1 months)	AS: 5.1 months C: 9.0 months	AS: 3/32 (9.4) C: 6/32 (18.8)	NR
Hiraoka[20]	AS: 49/54 (90.7) C: 6/7 (85.7)	NR	AS: 43/48 (89.6) C: 1/2 (50)	NR	NR	NR	AS: NR C: 5–10 months	AS: 0/54 (0) C: 1/7 (14.3)	AS: 5/54 (9.3) C: NR
Hayashida *et al*[21]	AS: 71/89 (79.8) C: 15/27 (55.6)	NR	NR	NR	NR	2.43±2.3 months	NR	NR	AS: 22/89 (24.7) C: NR
Kurobe *et al*[16]	AS: 72/87 (82.8) C: 27/30 (90.0)	NR	NR	AS: 36/45 (80) C: 0/0 (0)	AS: 36/42 (85.7) C: 27/30 (90.0)	NR	Mature in AS: 3–6 months (3.9) Premature in AS: 3–7 months (4.7)‡ C: 4–31 months (13.5)	AS: 0/87 (0) C: 3/30 (10)	AS: NR C: NR
Kitano *et al*[17]	AS: 96/97 (99.0) C: 31/31 (100)	AS: 84/97 (86.6) C: 24/31 (77.4)	NR	NR	NR	NR	NR	NR	AS: 40/97 (41.2) C: NR

*Large hernias were defined as those with the orifice permitting the passage of a fingertip.
†Large hernias were defined as those with the orifice larger than 1 cm.
‡Premature infants were defined as those treated in the neonatal intensive care unit due to either a gestational age of <33 weeks or birth weight <2500 g.
AS, adhesive strapping; C, control; NR, not reported.

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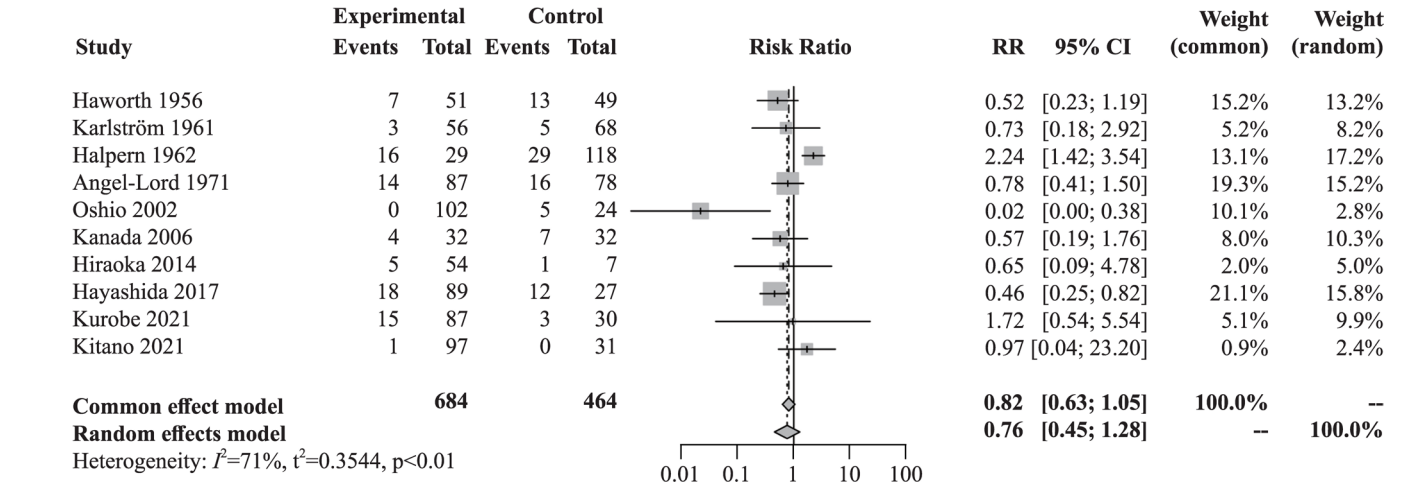

Figure 2 Forest plot showing the analysis for the overall unsuccessful UH closure comparing the AS group and observation-only group. Events: unsuccessful UH closure. AS, adhesive strapping; RR, risk ratio; UH, umbilical hernia.

any significant publication bias (Begg's test: τ=0.111, p=0.728; Egger's test: t=−1.457, p=0.183). Funnel plots of secondary outcomes were also visualized (online supplemental file 2). However, Begg's and Egger's tests were not conducted because of the small number of included studies.

DISCUSSION

The technique to treat pediatric UH, called adhesive strapping, compression, or binding, has regained popularity in Japan. There are many minor differences in this method (table 2), but the concept is the same: compressing the UH and maintaining it inward. As an example, we provide photos demonstrating how to conduct it at our site in online supplemental file 2.

To our knowledge, our meta-analysis is the first reported study to examine the evidence from cohort studies on the efficacy of AS on UH. Our meta-analysis analyzed information on a total of 684 patients with AS and 464 patients without AS. There was no significant difference in the efficacy of AS on the overall UH closure and that of large hernia compared with observation-only management. Furthermore, the subgroup analysis of recent studies did not show a significant difference.

We believe that the factors that affected our results were the sample sizes and the proportion of large hernias in the included studies. Regarding sample sizes, 80% of patients with UH are expected to heal spontaneously before attaining 1 year of age and 90% before 2 years of age. Therefore, we estimated the closure rates by AS and observation-only management as 95% and 90%, respectively. The necessary sample size is calculated as 475 cases each with α=0.05 and 1−β=0.80. We estimated these sample sizes as 85% and 80%, respectively, and the sample size needed rose to 946 each. The sample sizes of the included studies in our study were mostly less than 100 in each arm. Therefore, we could not exclude the possibility that insufficient sample sizes affected the results.

The proportion of large hernias in each arm should also be considered when interpreting the results. Some studies indicated that the size of the UH did not influence its closure.[18 22–24] For instance, Heifetz *et al*[23] reported that 72 out of 78 patients (92%) with UH >0.5 cm were cured spontaneously within 4 years. Meier *et al*[24] revealed that spontaneous closure of UHs >10 mm in diameter with at least 5 mm protrusion seemed to occur by the age of 14. However, Walker[25] indicated that the diameter of the internal fascial ring was the most relevant parameter to determine whether spontaneous UH closure would be accomplished and that the healing rate differed according to the UH size. In our study, the proportion of large hernias in the AS group was higher in four studies[5 9 10 20] and was not mentioned in five studies. One study reported that the average size of UH in the AS group was smaller than that in the observation group.[17] Although we did not show an advantage of AS for large hernias, there would be several variabilities in this subgroup analysis, such as insufficient patient numbers, differences in the proportion between the two groups, and the definition of "large hernias." From these points of view, randomized controlled trials with strict definitions of large hernias measured by ultrasound are warranted to reach a conclusion.

Although our study did not show the significance of the efficacy of AS on the closure rate, it indicated some possible advantages through secondary outcomes. One of them was the efficacy of earlier UH closure.

As Cresson and Pilling[26] described, there was already some agreement in the 1950s that AS has no advantage after the age of 6 months. While Cresson and Pilling also noted from their experience that AS rarely hastened UH healing,[26] our result corresponded to a previous study that revealed that the treatment duration was shorter in the AS group than in the observation group.[27] Once AS is applied at an earlier age, it accelerates the healing of UH and the duration of UH existence is expected to be shortened. Consequently, it reduces the burden and anxiety

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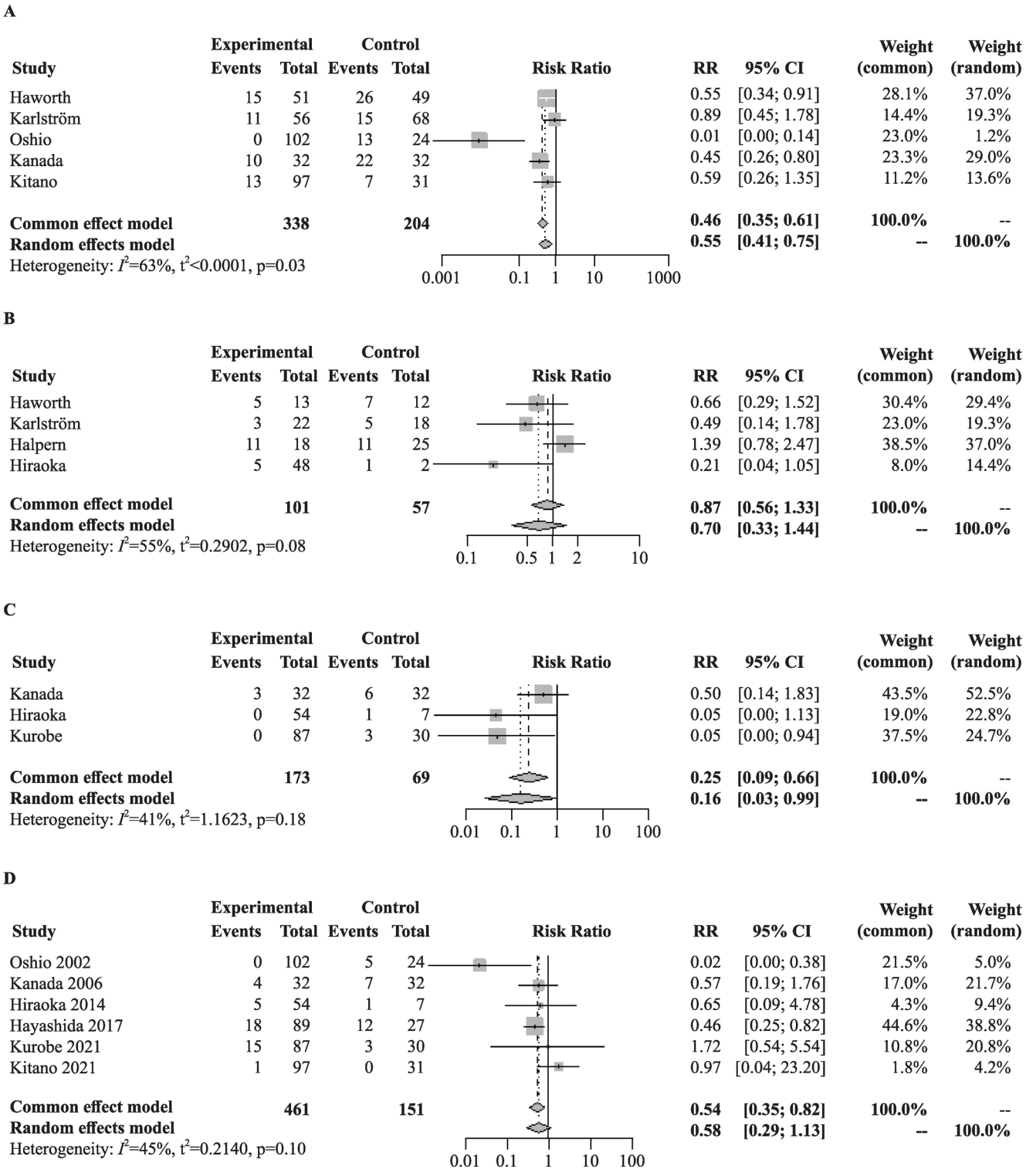

Figure 3 Forest plots of secondary endpoints comparing the AS group and the observation-only group: (A) unsuccessful UH closure at the age of 6 months old, (B) among large UH, (C) event of umbilical protrusion with redundant skin, and (D) among only recent studies. Events: unsuccessful UH closure. AS, adhesive strapping; RR, risk ratio; UH, umbilical hernia.

of parents. Therefore, it is rational that AS was mostly applied within 6 months in recent studies to close UH earlier.[2 14 16 17 20 21] The earliest time of application was less than 1 month of age, 18 days old.[20] However, no study has revealed how early AS could be safely applied and how effective AS would be when applied earlier. Regarding premature infants, it was also uncertain whether the corrected age should be adopted rather than the real age. Factors such as umbilical condition, gestational age, and body weight should likely be considered for AS application.

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Another possible benefit of AS to babies with UH is that AS prevents umbilical protrusion with redundant skin. In most studies, UH closure was defined as the closure of the orifice regardless of the umbilical figure. Therefore, if an umbilical defect is closed spontaneously, patients with protruding umbilicus will undergo umbilicoplasty for cosmetic reasons. According to the included studies, the prevalence of the protruding umbilicus at the end of the study was 0%–9.4% and 10%–18.8% in the AS and observation groups, respectively. This result corresponded to a study that gathered data from multiple institutions through questionnaires; it reported that the prevalence rates of redundant skin among patients who were regarded as cured from UH were 107 of 908 (11.8%) in the AS group and 33 of 146 (22.8%) in the observation-only group.[28] Regarding umbilicoplasty, Hayashida *et al*[21] reported that the operation time of patients who tried AS was shorter than that of patients without AS. The authors also mentioned that the difficulty of umbilicoplasty depended on the existence of redundant skin. Therefore, if AS prevents redundant skin and disfigurement of the umbilicus, it may be beneficial to patients.

Prematurity is regarded as a factor for UH because there is a difference in UH prevalence between mature and premature infants.[3 12] We did not find articles that compared the UH closure rates by maturity, but Kurobe *et al*[16] reported that the closure rates among mature and premature infants who were treated with AS at the end of the study were 85.7% and 80%, respectively. Although they seemed different, it was unclear whether closure rates would change if the corrected age was used.

AS was implemented mainly in the mid-20th century and after the year 2000. Particularly in Japan, AS was reconsidered as a practical treatment for UH because many retrospective studies indicated its positive effects on UH closure. The discontinuation rate of AS was reported to be approximately 10%, and skin irritation due to plasters and tape is one of the determinants in deciding whether to continue AS. Since more skin-friendly plasters and tapes have been developed, we expected that the AS completion rate would rise and increase the successful UH closure rate with a lower complication rate. In our study, however, the comparison of the AS group with the observation group on UH closure among recent studies, all published in Japan, did not show a significant difference.

The most severe complications of UH are strangulation, incarceration, and evisceration, but their occurrence rates are considered low.[13 29] Therefore, based on the prevention of these complications, AS has few advantages for patients. If AS is applied for earlier closure or the prevention of redundant skin, AS-related complications should be taken into consideration. The most common problem was skin irritation or dermatitis from a plaster, which was the most decisive factor regarding AS continuation. However, these skin problems were relatively prevented using skin-friendly plasters and films or by introducing a short refraining period. Other complications reported in Japanese literature were massive bleeding from the umbilical artery, strangulation due to compression, and UH perforation caused by skin ulceration, which were all reported as case reports.[30] One study reported that AS caused delayed UH closure and increased severity, but other articles did not report similar events.[12] Despite the low prevalence, doctors need to explain these possibilities and pay attention to the umbilical condition when changing AS.

This study had several limitations. First, this was a meta-analysis of cohort studies with somewhat different endpoints. While some studies provided the specific period of closure, others adopted whether the UH was closed at a specific age. Second, the sample sizes of each study were probably insufficient to reach a conclusion. Third, each meta-analysis, particularly that of the primary outcome and that of the efficacy at 6 months old, contained moderate heterogeneity. We presumed that this was due to the insufficient sample size of the included studies. Following the protocol, we did not conduct post-hoc subgroup analyses to determine other factors that affected the results. However, when related studies are accumulated, subgroup analyses should be conducted according to differences in follow-up periods, AS procedures such as with or without plugs to reduce UH, and the UH closure rate in the observation group. Next, there was a possibility that we may not have found some old studies. Finally, recent studies were only conducted in Japan; thus, language bias may exist. Therefore, further studies at higher evidence levels are necessary to reach a definitive conclusion.

In conclusion, our study did not clarify the significant difference in the overall efficacy of AS on UH closure. However, there might be advantages to accelerating the closure speed and preventing protruding umbilici with redundant skin. Due to the high heterogeneity of our study, further studies at higher evidence levels are warranted before reaching a definitive conclusion.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This study is a systematic review and meta-analysis and the data were extracted from the original studies. No patients or animals were involved in this study. Therefore, this study did not require ethics approval.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction Par 2-3
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction Par 4
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Search strategy of the literature
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Search strategy of the literature par 1 Figure 1
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Search strategy of the literature Par 1
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Search strategy of the literature Par 1-2
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Search strategy of the literature Par 1-2
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Search strategy of the literature Par 1-2 *Data extraction* Table 1-3
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Table 2
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	*Search strategy of the*

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
			literature Par 2
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Statistical analysis
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Search strategy of the literature Par 2
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Statistical analysis
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Statistical analysis
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Study selection Fig. 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Fig. 1
Study characteristics	17	Cite each included study and present its characteristics.	Table 1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Supplementary table 1
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Table 1-3
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Throughout results
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Throughout results
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Throughout results
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion Par 2
	23b	Discuss any limitations of the evidence included in the review.	Discussion
	23c	Discuss any limitations of the review processes used.	Discussion
	23d	Discuss implications of the results for practice, policy, and future research.	Discussion
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Method par 1
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Method par 1
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Author Disclosure Statement
Competing interests	26	Declare any competing interests of review authors.	Author Disclosure Statement
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Data in the possession of the authors can be available on request Not publicly available

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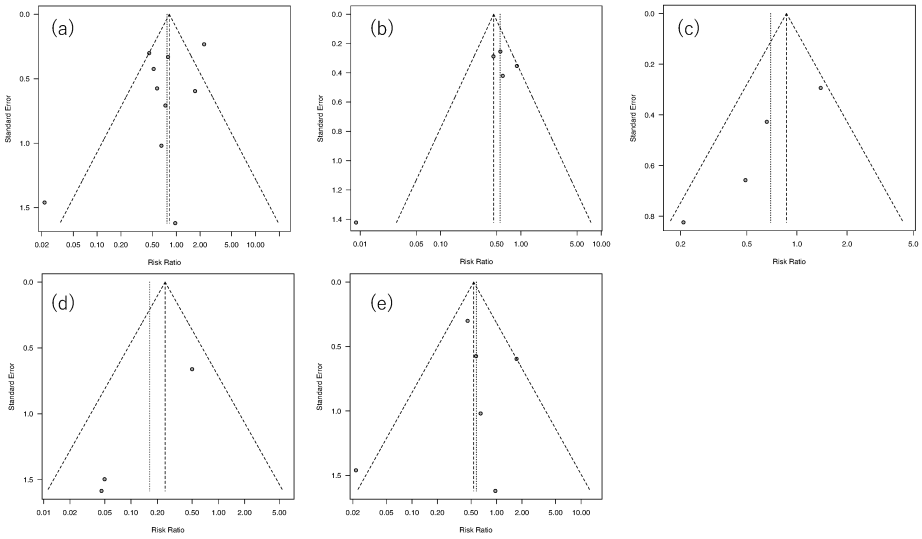
Author	Selection				Comparability	Outcome			Score
	1	2	3	4	5,6	7	8	9	
Haworth	*	*	*	*	*		*	*	7
Karlström	*	*	*	*	*		*	*	7
Halpern	*	*	*	*	*		*	*	7
Angel-Lord	*	*	*	*	*		*	*	7
Oshio	*	*	*	*	*		*	*	7
Kanada	*	*	*	*	*	*	*	*	8
Hiraoka	*	*	*	*	*	*	*	*	8
Hayashida	*	*	*	*	*	*	*	*	8
Kurobe	*	*	*	*	*	*	*	*	8
Kitano	*	*	*	*	*	*	*	*	8

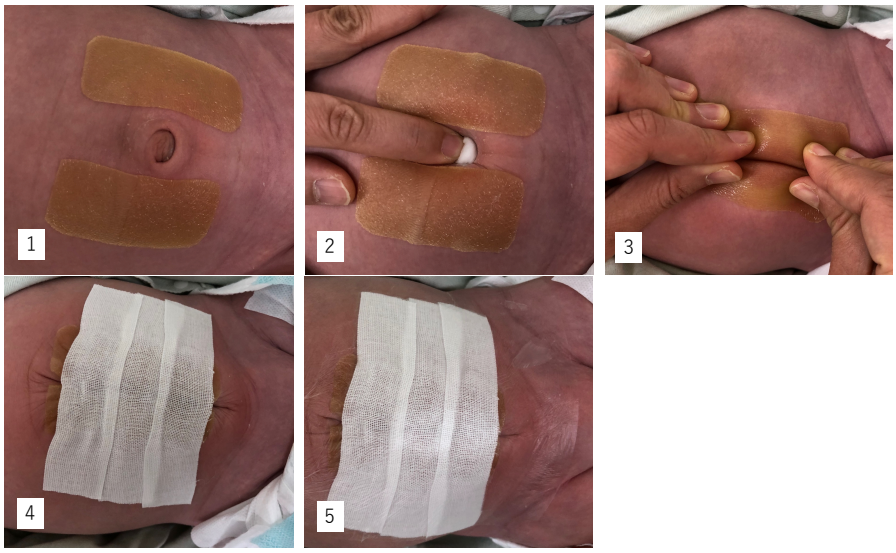
Supplementary Table 1. Quality assessment of studies based on the Newcastle-Ottawa Quality Assessment Scale score.



Funnel plot for analyzing the publication bias.

Supplementary Figure 1(a) Overall UH closure in the AS group and observation. (b) Unsuccessful UH

closure at the age of 6 months old. (c) Among large UH. (d) Event of umbilical protrusion with redundant skin. (e) Among only recent studies.



Supplementary Figure 2. Adhesive strapping was conducted by a pediatric surgeon with a nurse or two pediatric surgeons. (1) A piece of Duoactive™ is placed to protect the skin on each side of the umbilicus. (2) A cotton ball is placed on the umbilicus. (3) The umbilicus is reduced by pinching the skin into a vertical fold over the hernia. (4) Plasters are placed to maintain the reduction. (5) A piece of transparent waterproof film is finally placed over the top. Ten days after the application, AS is removed at home. The umbilicus and skin were examined every two weeks, and the surgeon decided whether next AS cycle was conducted.