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Journal of Obstetrics & Gynecological Research Research Article

Predictive Value of Clinical Factors for Delivery At ≥32 Weeks of Gestation after Cervical Cerclage

Ye Xuping[1#], Yang Yuezhou[2#], Li Jun[1], Chang Kaikai[1] and Xu Huan[1*]

[1]Department of Obstetrics, Obstetrics and Gynecology Hospital affiliated to Fudan University, Shanghai, 200011, China

[2]ShanghaiJiai Genetics and IVF Center, Obstetrics and Gynecology Hospital affiliated to Fudan University, Shanghai, 200011, China

#These authors contributed equally to this paper

***Corresponding author**

Xu Huan, MD. No.419, Fangxie Road, Huangpu district, Shanghai, China, 200011. Fax: 86-21-33180478; Tel: 86-21-63459977; E-mail: yyzu@163.com.

Received: 17 March 2021; **Published**: 30 March 2021

Abstract

Aim: To identify the clinical factors that have predictive value for a gestational age of ≥32 weeks at delivery after cerclage.

Methods: The correlations between 13 clinical factors and the number of days of pregnancy after cerclage, as well as the gestational age at delivery, were retrospectively analyzed. Ridge regression was employed to identify the clinical factors that were predictive of a gestational age of ≥32 weeks at delivery after cerclage.

Results: Eight clinical factors were associated with the number of days of pregnancy after cerclage and the gestational age at delivery ($P<0.05$), while 4 factors were not ($P>0.05$). The cerclage method was weakly associated with the gestational age at delivery ($P=0.034$), but was not significantly associated with the number of days of pregnancy after cerclage ($P=0.054$). Indication for cerclage, cerclage method, and cervical length at 2 weeks postcerclage showed predictive value for gestational age of ≥32 weeks at delivery after cerclage.

Conclusion: A multitude of clinical factors are associated with the number of days of pregnancy after cerclage and the gestational age at delivery. Non-emergency cerclage, Shirodkar cerclage, and a long cervical length at 2 weeks postcerclage increased the chance of delivery at ≥32 weeks of gestation.

Keywords: Cerclage, Clinical Factors, Prediction, Gestational Age at Delivery

Introduction

Preterm birth is the primary cause of neonatal morbidity and mortality. The mortality rate among neonates peaks at 54.8% in those who were born at 25 weeks of gestation, while the rate of minor neonatal morbidity peaks at 81.7% in those who were born at 31 weeks of gestation [1,2]. Meanwhile, it has been reported that the morbidity rate of neonates born after 32 weeks of gestation was significantly reduced [3].

Cervical insufficiency is a major reason for second and third trimester pregnancy loss and preterm delivery [4]. Cerclage reduces the rate of preterm birth of singleton pregnancies, and improves perinatal outcomes in patients with cervical insufficiency [5,6]. However, findings from existing studies are discordant [4-10,12-22]. Jorgensen AL et al. [7] suggested that cerclage might reduce pregnancy loss and neonatal death in singleton pregnancies with a risk of preterm birth. However, larger cohort studies are needed to assess the risk-benefit ratio. A study by Berghella V et al. showed that cerclage did not confer benefits to women with a cervical length of less than 2.5 cm on ultrasound and who had no history of preterm birth ($P=0.29$), but it reduced the rate of preterm birth in a subgroup of women with a cervical length of less than 1 cm (relative risk, 0.68; 95% confidence interval, 0.47–0.98) [8]. Their study also showed that cerclage could reduce the risk of preterm birth in women with a short cervix and a history of preterm birth at less than 32 weeks (relative risk, 0.58; 95% confidence interval, 0.34–0.98) [9]. There is no exact same consensus among the current guidelines regarding the recommendations for the diagnosis and treatment of cervical insufficiency [10]. The discrepancies among the conclusions from different studies may be related to the fact that numerous factors can affect pregnancy outcomes after cerclage. It may also be due to the lack of standardized methods for outcome assessment.

The use of a gestational age of ≥32 weeks at delivery as the main efficacy measure for cerclage is of practical significance. The present study aimed to analyze the correlation between various clinical factors and the number of days of pregnancy after cerclage and the gestational age at delivery. The clinical factors that exhibited predictive value for a gestational age of ≥32 weeks at delivery after cerclage were also evaluated.

Methods

Study design

Between January 2016 and June 2019, 127 patients with singleton pregnancies who received cerclage in the Obstetrics and Gynecology Hospital of Fudan University due to cervical insufficiency and had complete clinical data were included in the study. The correlations of 13 clinical factors (patient's age, patient type, indication for cerclage, gestational age at the time of cerclage, cerclage method, length of cervix before and 2 weeks after cerclage, sum of the lengths of the anterior and posterior lips of the ectocervix before cerclage, type of

cerclage suture, preoperative morphology of the cervix, use of a tocolytic agent, results of a vaginal discharge culture, and pregnancy complications) with the number of days of pregnancy after cerclage and the gestational age at delivery were analyzed. The patients were divided into two groups based on the gestational age of ≥32 weeks or <32 weeks at delivery. The clinical characteristics of the two groups were compared. Ridge regression was employed to identify the clinical factors that had predictive value for delivery at ≥32 weeks of gestation after cervical cerclage.

Data collection

Prophylactic cerclage, ultrasound-indicated cerclage and emergency indications of cervical incompetence in single pregnancy were included in this study [10]. Prophylactic cerclage and ultrasound-indicated cerclage were classified as non-emergency cerclage. Exclusion criteria were as follows: 1. severe fetal malformation; 2. multiple pregnancy; 3. body temperature >38°, white blood cell count >10×109/L, and signs of infection; 4. vaginitis detected in vaginal wet mount; and 5. unreliable follow-up data or lost to follow-up. Patient type referred to inpatient or outpatient based on the location of health card registration.

Preoperative examinations

Transvaginal ultrasound was used to evaluate the length and morphology of the cervix. The bladder was emptied, and the probe was placed in the anterior fornix through the vagina. The image was enlarged so that the cervix occupied 2/3 of the screen, and the cervical length was measured. Three measurements were obtained, and the shortest length was recorded [11]. Additionally, the internal os was observed, wherein a closed internal os was defined as a T-shaped cervix, and an internal os that was not closed was defined as a non–T-shaped cervix. All patients completed examinations that included an electrocardiogram, a biochemistry panel, a vaginal wet mount, and vaginal discharge culture. Patients were advised to reduce the level of activities. Patients with anamniotic sac protruding beyond the external os were requested to adopt a Trendelenberg position to reduce the pressure on the cervix. The fetal conditions, as well as any signs of abdominal pain and vaginal bleeding/fluid-leaking from the patient, were closely monitored.

Selection of cerclage method

The McDonald (M) method was used if the length of the ectocervix was >2 cm, and the Shirodkar (S) method was used if the length of the ectocervix was <2 cm. For a subgroup of patients whose local length of the ectocervix was <2 cm, the "modified S method "was adopted. For patients whose length of the anterior lip of the ectocervix was <2 cm, only the bladder-cervix gap was opened to push the bladder upward so that the lengths of both the anterior and posterior lips of the ectocervix after suture were >2 cm. For patients whose length of the posterior lip of the ectocervix was <2 cm, only the rectum-cervix gap was opened to push the rectum upward so that the lengths of both the anterior and posterior lips of the ectocervix after suture were >2 cm. The "modified S method"was approved by the ethics committee of our hospital. The use of a silk suture or a RS22 cerclage suture was selected randomly by the surgeon prior to performing the procedure.

Postoperative follow-up

The cervical length and the dilation status were examined using transvaginal ultrasound at 2 weeks postcerclage. For patients without other obstetric comorbidities, the cervical cerclage sutures were removed prior to delivery at 37–38 weeks of gestation. A tocolytic agent was given postoperatively only to patients with uterine contractions. Patients with uterine contractions prior to 20 weeks of gestation were given indomethacin oral tablets, and those with uterine contractions after 20 weeks of gestation were given ritodrine hydrochloride, nifedipine, or indomethacin tablets. Patients who were intolerant to ritodrine hydrochloride were givenatosiban.

Statistical analyses

The SPSS software version 23 (IBM) was used. Continuous data that followed a normal distribution were analyzed using Pearson's correlation method, and other correlation analyses were conducted using Spearman's correlation method. Categorical data were expressed as percentages (%) and analyzed using a chi-square test. Numeric data were expressed as mean ± standard deviation ($\bar{X}$±S), andwere analyzed using the t test. Ridge regression analysis was employed to analyze the predictive value of various clinical factors for delivery at ≥32 weeks of gestation after cervical cerclage. The significance level was set at 0.05.

Ethical approval

This study was accepted and approved by the review committee of the Obstetrics and Gynecology Hospital of Fudan University (2019-83).

Results

1. A total of 127 patients who met the enrollment criteria and had complete clinical data were included in this study, as shown in (Figure 1).

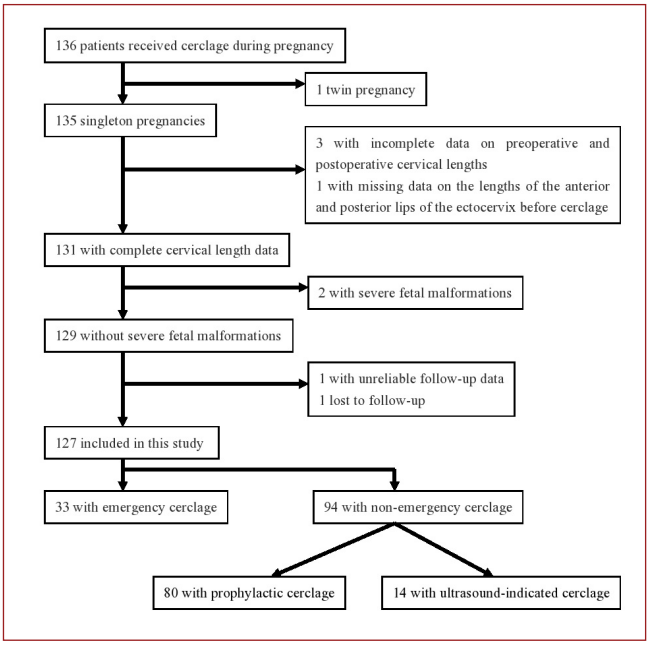

Figure 1: Patient enrollment flowchart

2. The mean age of the patients was 31.76±4.42 years, the mean gestational age at cerclage was 19.09±4.92 weeks, the mean number of days of pregnancy after cerclage was 97.07±64.54 days, the mean gestational age at delivery was 32.95±6.38 weeks, and the mean weight of the neonates was 2300.57±1204.69g. The number of patients as per gestational age at delivery was as follows: ≥37 weeks, 53 (41.73%; 53/127 patients);≥34 weeks, 73 (57.48%; 73/127 patients); ≥32 weeks, 79 (62.20%; 79/127 patients); and ≥28 weeks, 93 (73.23%; 93/127 patients). A total of 107 patients delivered live births and 20 delivered stillbirths or neonates that died during the perinatal period. The gestational age at delivery was <32 weeks (range: 13.86–26.00 weeks) in all of the 20 patients in the latter group. There were 47 patients with

a T-shaped cervix, and 80 patients with a non–T-shaped cervix.

3.Thirteen clinical factors were analyzed in this study, eight of these factors were associated with the number of days of pregnancy after cerclage and the gestational age at delivery (P<0.05), while four of the factors did not correlate significantly with the number of days of pregnancy after cerclage and the gestational age at delivery (P>0.05). The cerclage method was weakly associated with the gestational age at delivery (P=0.034), but was not significantly associated with the number of days of pregnancy after cerclage (P=0.054). The correlations of various clinical factors with the number of days of pregnancy after cerclage and the gestational age at delivery are shown in Table 1. Comparisons between the groups of patients with a gestational age of ≥32 weeks and that of <32 weeks at delivery showed that nine of the 13 clinical factors exhibited differences in mean values or proportions (P<0.05). The group with a gestational age of ≥32 weeks at delivery exhibited significant improvements in neonatal outcomes, including neonatal weight, Apgar score, and NICU admission rate, compared with the group with a gestational age of <32 weeks at delivery (P<0.05), as shown in (Table 2).

Table 1: Correlations of various clinical factors with the number of days of pregnancy after cerclage and the gestational age at delivery

Clinical factors	Number of days of pregnancy after cerclage		Gestational age at delivery	
	Correlation coefficient	P value	Correlation coefficient	P value
Patient's age	0.113	0.205	0.074	0.410
Patient type	-0.054	0.545	-0.055	0.540
Gestational age at cerclage placement	-0.754	0.000	-0.316	0.000
Non-emergency cerclage	0.566	0.000	0.357	0.000
T-shaped cervix	0.507	0.000	0.220	0.013
Preoperative cervical length	0.545	0.000	0.289	0.001
Sum of the lengths of the anterior and posterior lips of the ectocervix before cerclage	0.390	0.000	0.197	0.026
Shirodkar cerclage	0.171	0.054	0.189	0.034
RS22 cerclage suture	-0.097	0.280	-0.017	0.846
Use of a tocolytic agent after cerclage	-0.427	0.000	-0.307	0.000
Cervical length at 2 weeks post-cerclage	0.517	0.000	0.484	0.000
Pregnancy complications	-0.014	0.877	-0.050	0.576
Negative vaginal discharge culture	0.247	0.005	0.226	0.011

Table 2: Comparison of clinical characteristics between the two groups that the gestational age of ≥32 weeks or <32 weeks at delivery

Clinical data	Patients with a gestational age of <32 weeks at delivery	Patients with a gestational age of ≥32 weeks at delivery	T value or chi-square value	P value
Number of patients (n)	48	79		
Patient's age (years)	31.48±4.15	31.92±4.59	0.549	0.584
Proportion of patients with a maternal health card from our hospital (%)	66.67 (32/48)	64.56 (51/79)	0.059	0.809
Gestational age at cerclage placement (weeks)	21.66±4.32	17.52±4.62	-5.007	0.000
Proportion of patients who received emergency cerclage (%)	47.92 (23/48)	12.66 (10/79)	19.300	0.000
Proportion of patients with a T-shaped cervix (%)	18.75 (9/48)	48.10 (38/79)	11.034	0.001
Cervical length at cerclage placement (mm)	15.71±14.58	25.58±9.60	4.602	0.000
Sum of the lengths of the anterior and posterior lips of the ectocervix before cerclage	28.65±15.29	33.71±12.69	2.016	0.046
Proportion of patients who received a Shirodkar cerclage (%)	14.58 (7/48)	44.30 (35/79)	11.916	0.001
Proportion of patients who received a RS22 cerclage suture (%)	33.33 (16/48)	32.91 (26/79)	0.002	0.961
Proportion of patients who received a tocolytic agent after cerclage (%)	37.50 (18/49)	5.06 (4/79)	21.313	0.000
Cervical length at 2 weeks postcerclage (mm)	25.48±3.90	29.03±3.27	4.929	0.000
Proportion of patients with pregnancy complications (%)	52.08 (25/48)	56.96 (45/79)	0.287	0.592
Proportion of patients with a positive vaginal discharge culture (%)	45.83 (22/48)	22.78 (18/79)	7.352	0.007
Number of days of pregnancy after cerclage (day)	27.51±27.64	139.34±38.48	17.556	0.000
Gestational age at delivery (weeks)	25.59±3.48	37.42±2.22	23.398	0.000
Weight of the neonate (g)	927.10±422.44	3135.08±608.79	22.088	0.000
Apgar score of neonates	4.27±3.81	8.71±0.75	10.064	0.000
Proportion of NICU admissions (%)	71.43 (20/28)	10.13 (8/79)	40.210	0.000
Proportion of male infants (%) (boys/girls)	60.42 (29/48)	45.57 (36/79)	2.634	0.105

4. Of the nine clinical factors that might be causally related to a gestational age of ≥32 weeks at delivery after cerclage, eight were included in the ridge regression analysis. The use of a tocolytic agent after cerclage was not included in the regression analysis. Indication for cerclage, cerclage method, and cervical length at two weeks postcerclage showed predictive value for gestational age of ≥32 weeks at delivery after cerclage. The results are summarized in (Table 3).

Table 3: Results of a ridge regression of the clinical factors and a gestational age of ≥32 weeks

Clinical factors	B	SE (B)	Beta	T	Sig
Non-emergency cerclage	0.134	0.055	0.121	2.443	0.016
Gestational age at cerclage placement	-0.009	0.005	-0.091	-1.944	0.054
Shirodkar cerclage	0.198	0.051	0.192	3.892	0.000
T-shaped cervix	0.065	0.050	0.065	1.311	0.193
Preoperative cervical length	0.004	0.002	0.092	1.866	0.065
Sum of the lengths of the anterior and posterior lips of the ectocervix before cerclage	0.001	0.002	0.016	0.318	0.751
Cervical length at 2 weeks postcerclage	0.015	0.004	0.175	3.511	0.001
Negative vaginal discharge culture	0.093	0.052	0.089	1.794	0.075

Discussion

Key Study Results:

The number of days of pregnancy after cerclage and the gestational age at delivery showed positive correlations with preoperative cervical length, sum of the lengths of the anterior and posterior lips of the ectocervix before cerclage, cervical length at 2 weeks postcerclage, a T-shaped cervix, and a negative vaginal bacterial culture, while negative correlations were observed with the gestational age at cerclage placement and emergency cerclage. The S cerclage method was positively associated with the gestational age at delivery. Nine of the 13 clinical factors exhibited differences in mean values or proportions between two groups. Indication and method of cerclage, as well as the cervical length at 2 weeks postcerclage exhibited predictive value for gestational age of ≥32 weeks at delivery after cervical cerclage.

Clinical significance of the study

1. Influence of cerclage indication and gestational age on pregnancy outcomes

Jorgensen AL et al.[7] suggested that the gestational age at cerclage placement was not significantly associated with pregnancy loss and neonatal death, while Gundabattula SR et al.[12] suggested that receiving cerclage after 20 weeks of gestation had a positive correlation with a gestational age of ≥28 weeks at delivery (relative risk, 17.33; P=0.008). Meanwhile, the three guidelines (SOGC, RCOG, ACOG) recommend that patients should receive history-indicated cerclage at 12-14 weeks of gestation [10]. The results of this study suggest: a younger gestational age at cerclage placement and non-emergency cerclage increase the number of days of pregnancy after cerclage, and the gestational age at delivery, in patients with cervical insufficiency and singleton pregnancies. Furthermore, the indication for cerclage is causally related to a gestational age of ≥32 weeks at delivery after cerclage. We believe that pregnant women for whom cerclage is indicated should not delay the procedure to later a gestational age, and that emergency cerclage should be avoided if possible.

2. Influence of preoperative and postoperative cervical lengths on pregnancy outcomes

Studies have shown that that a longer cervix is associated with a lower risk of preterm delivery at less than 35 weeks of gestation (odds ratio, 0.91) [13], and that cervical cerclage reduces the risk of preterm delivery in patients with singleton pregnancies whose cervix is shorter than 25 mm, and who have no history of preterm delivery (relative risk, 0.58, 95% confidence interval, 0.34–0.98). However, cerclage cannot effectively prevent preterm delivery at less than 35 weeks in pregnant women with a cervical length of less than 15 mm [9]. Conversely, Gundabattula SR et al. [12] suggested that cervical length was not associated with a gestational age of ≥28 weeks at delivery (P>0.05). Furthermore, other studies suggested that the risk of premature delivery was higher in patients whose cervical length was further shortened within 2 weeks after cerclage placement compared with those whose cervical length remained unchanged (relative risk, 2.34) [14]. After cerclage, patients in the preterm delivery group showed more extensive cervical shortening (1.40 mm) than did those in the full-term delivery group (0.62 mm) (P=0.008). The risk of premature delivery was increased in pregnant women whose postcerclage cervical length was less than 25 mm at 24–28 weeks of gestation, and those whose proximal cervical length was 0 mm at 24 weeks of gestation [16]. The results of our study suggest: a longer cervical length, both before and 2 weeks after cerclage, is associated with a greater number of days of pregnancy after cerclage and a higher gestational age at delivery. The cervical length at 2 weeks postcerclage exhibits predictive value for a gestational age of ≥32 weeksat delivery. We believe that close monitoring and follow-ups are required for patients with a short cervix, particularly for those with a shortened cervix 2 weeks after cerclage placement. Contingency plans should be in place for accelerating fetal lung maturity in utero and for neonatal resuscitation to respond in a timely manner to a possible early preterm birth.

3. Influence of cerclage height, cerclage method on pregnancy outcomes

Studies have suggested that the cerclage should ideally be placed at a high position, and should be as close as possible to the level of the internal os [17].The higher the cerclage height, the lower the risk of preterm delivery (odds ratio, 0.87). Patients with a cerclage height of less than 14.5 mm exhibit a 70.8% risk of preterm delivery [14]. Odibo A showed that the position of the cerclage placed with the S method was 2.7 mm higher than that with the M method [18]. The gestational age at delivery associated with the S method was 36.3±4.7 weeks, which was greater than that associated with the M method, at32.9±5.9 weeks (P<0.05). The rate of preterm delivery at <33 weeks of gestation was 20% (26/127) with the S method and 42% (19/45) with the M method. However, the results of logistic regression showed no significant difference in the rate of preterm delivery at <33 weeks of gestation between the two cerclage methods. Studies have indicated that compared to the M method, the S

method led to a higher gestational age at delivery, with a higher probability of achieving a gestational age of >32 weeks as well as that of >35 weeks at delivery (P<0.05 for both) [19,20]. However, Rozenberg P et al. concluded that there were no significant differences between the S method and the M method with regard to preoperative and postoperative cervical lengths and the distance between the external os and the cerclage [21]. The probability of delivering at <32 weeks of gestation and that of delivering at <34 weeks of gestation were also not significantly different between the two methods (P>0.05). Melle L suggested that the height of the cerclage was not predictive of the risk of premature delivery after cerclage placement [22]. The three guidelines (SOGC, RCOG, ACOG) state that the S and M cerclage methods are comparable, and the operative approach should be at the surgeon's discretion [10]. The results of this study suggest: although the S cerclage method is more difficult and complicated to perform, it increases the chance of delivery at ≥32 weeks of gestation after cerclage in patients with cervical insufficiency and singleton pregnancies. Therefore, it is necessary to perform cerclage using the S method or the modified S method in patients with an ectocervix length of less than 2cm.

Significance of the Study

This study classified history-indicated and ultrasound-indicated cerclage as non-emergency cerclage. Future studies should involve larger sample sizes and should employ regression analyses on data relating to history-indicated cerclage, ultrasound-indicated cerclage, and emergency cerclage to assess the causal relationships between the clinical factors of patients with different indications for cerclage and the gestational age at delivery. This will guide obstetricians to develop more precise cerclage placement strategies for pregnant women with cervical insufficiency in different conditions. The use of a tocolytic agent after cerclage was shown to correlate negatively with the number of days of pregnancy after cerclage as well as with the gestational age at delivery. Whether this result is due to the fact that the present study only assessed the use of tocolytic agents in patients with uterine contractions, warrants further investigation. In addition, it is necessary to identify the high-risk factors for uterine contractions after cerclage.

Strength and Limitations

The inclusion and exclusion criteria of the study subjects were clearly defined. The clinical factors included in the analysis were comprehensive, and the data were complete. All cerclages were completed by senior obstetric surgeons who had received rigorous training and who also had extensive clinical experience, which lowered the impact of surgical factors on pregnancy outcomes after cerclage. The sample size of this study was not large enough to stratify the clinical factors for further statistical analyses. The subjects included in this study were of the same ethnicity. Whether the results will apply to subjects with different ethnic backgrounds is unclear.

Conclusions

A multitude of clinical factors were associated with the number of days of pregnancy after cerclage and the gestational age at delivery. Patients who delivered at a gestational age of ≥32 weeks and those who delivered at a gestational age of <32 weeks exhibited differences in multiple clinical factors. Non-emergency cerclage, the S cerclage method, and a long cervical length at 2 weeks postcerclage increased the chance of delivery at ≥32 weeks of gestation in patients with cervical insufficiency and singleton pregnancies.

Contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Ye, Yang, Li Chang and Xu. The first draft of the manuscript was written by Ye and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript. Ye: data collection and management, project development, manuscript writing. Yang: data collection, project development, data analysis and manuscript writing/editing. Li: data collection and project development. Chang: data collection and project development. Xu: data collection, project development and management.

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Citation: Ye Xuping, Yang Yuezhou, Li Jun, Chang Kaikai1, Xu Huan. Predictive Value of Clinical Factors for Delivery At ≥32 Weeks of Gestation after Cervical Cerclage. *J Obste & Gyne Res*. 2021, 2: 1-6.