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SYSTEMATIC REVIEW

McDonald versus Shirodkar cerclage technique in the prevention of preterm birth: A systematic review and meta-analysis

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Abstract

Background: Cervical cerclage has been used for decades to reduce preterm birth. The Shirodkar and McDonald cerclage are the most commonly used techniques with no current consensus on the preferred technique.

Objective: To compare the efficacy of the Shirodkar and McDonald cerclage techniques in preventing preterm birth.

Search Strategy: Studies were sourced from six electronic databases and reference lists.

Selection Criteria: Studies including women with a singleton pregnancy, requiring a cervical cerclage, using either the Shirodkar or McDonald technique that ran comparative analyses between the two techniques.

Data Collection and Analysis: The primary outcome was preterm birth before 37 weeks, with analyses at 28, 32, 34 and 35 weeks. Secondary data were also collected on neonatal, maternal and obstetric outcomes.

Main Results: Seventeen papers were included: 16 were retrospective cohort studies and one was a randomised controlled trial. The Shirodkar technique was significantly less likely to result in preterm birth before 37 weeks than the McDonald technique (relative risk [RR] 0.91, 95% CI 0.85–0.98). This finding was supported by a statistically significant reduction in rates of preterm birth before 35, 34 and 32 weeks, PPROM, difference in cervical length, cerclage to delivery interval, and an increase in birthweight in the Shirodkar group. No difference was seen in preterm birth rates <28 weeks, neonatal mortality, chorioamnionitis, cervical laceration or caesarean section rates. The RR for preterm birth prior to 37 weeks was no longer significant when sensitivity analyses were performed removing studies with a serious risk of bias. However, similar analyses removing studies that utilised adjunctive progesterone strengthened the primary outcome (RR 0.83, 95% CI 0.74–0.93).

Conclusion: Shirodkar cerclage reduces the rate of preterm birth prior to 35, 34 and 32 weeks' gestation when compared with McDonald cerclage; however, the overall quality of the studies in this review is low. Further, large, well-designed randomised controlled trials are required to address this important question to optimise care for women who may benefit from cervical cerclage.

KEYWORDS
cerclage, cervical, McDonald, preterm birth, Shirodkar, stitch

This article includes Author Insights, a video abstract available at: https://players.brightcove.net/3806881048001/default_default/index.html?videoId=6320301629112.

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1 | INTRODUCTION

Preterm birth (PTB) is responsible for an estimated 1 million neonatal deaths per year, making it the leading cause of mortality in children under 5 years.[1] Despite increasing international research, PTB remains an unresolved obstetric complication of pregnancy, affecting 5–13% of pregnant women.[2] Children born preterm are at a higher risk of respiratory distress syndrome, intraventricular haemorrhage, necrotising enterocolitis and retinopathy of prematurity.[3] Preterm birth is also associated with increased maternal morbidity with higher rates of obstetric haemorrhage, infection and intensive care unit admission, likely related to increased operative delivery.[4] Additionally, extreme preterm birth, defined as birth before 28 weeks, carries even greater risks for neonatal complications and ongoing societal costs.[5,6]

It has been established in the literature that women with a combination of prior obstetric history and a short mid-trimester cervical length are at a greater risk of extreme PTB.[5] At present, there are few effective strategies to prevent extreme PTB, an issue that is mirrored by the paucity of data on the efficacy of cerclage to prevent extreme PTB as the majority of the research addresses late PTB <37 weeks.[7]

A short cervical length (<25 mm) is a good predictor of PTB, with a 31.2–41.3% risk of PTB if present between 18 and 24 weeks.[8,9] In these women, management options include vaginal progesterone[10] or cervical cerclage.[8,11] Cervical cerclage reduces the risk of preterm birth in women at high-risk of preterm birth and probably reduces risk of perinatal deaths.[12] The two most utilised approaches are the McDonald technique, a simple purse-string suture around the cervix; and the Shirodkar technique, which involves colpotomy and bladder dissection with the aim of a higher suture placement.

There is currently a lack of consensus on the superiority of the McDonald or Shirodkar technique of cervical cerclage and there are no current guidelines or agreement on which technique is recommended. In the absence of emerging therapies to prevent PTB, combined with the increasing rate of PTB worldwide, there is a great need to maximise the effect of the currently available treatments. This review aims to determine whether one of the two surgical techniques provides a greater reduction in preterm birth rates.

1.1 | Aim

To synthesise existing quantitative evidence comparing McDonald with Shirodkar cervical cerclage techniques to determine which is associated with better maternal and neonatal outcomes. This systematic review will answer the following question regarding women requiring elective cervical cerclage in singleton pregnancy: Is there a difference between the McDonald and the Shirodkar cerclage techniques in the prevention of PTB and other significant maternal or neonatal outcomes?

1.2 | Hypothesis

We hypothesise that there will be no significant difference in maternal or neonatal outcomes between the McDonald cervical cerclage technique and the Shirodkar cervical cerclage technique.

2 | METHODS

A protocol paper detailing the methods for this systemic review and meta-analysis has been published previously.[13] Our systematic review protocol was submitted to the International Prospective Register of Systematic Reviews (PROSPERO) on 20 April 2020 and accepted on 6 July 2020 (registration number CRD42020177386). We have presented the data using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement,[14] the Meta-Analyses of Observational Studies checklist (MOOSE)[15] and the Cochrane Handbook for Systematic Reviews of Interventions.[16] Information regarding registration can be accessed from http://www.crd.york.ac.uk/PROSPERO. Patients were not involved in the development of this research.

2.1 | Eligibility criteria

Eligibility of studies included in this systematic review was based on pre-planned inclusion and exclusion criteria applied to each of the following domains: participant, exposure, comparator, study type and outcome.

2.2 | Participants

The review considered all studies that included pregnant women undergoing McDonald or Shirodkar cervical cerclage for prevention of PTB. Studies were excluded if they included women with multiple gestation pregnancies.

2.3 | Intervention

Studies which compared the McDonald and Shirodkar techniques of cervical cerclage as an elective procedure.

2.3.1 | McDonald cerclage

In the McDonald approach, a suture is placed around the cervix in purse-string fashion and securely tied anteriorly.

The McDonald approach requires no dissection into paracervical tissues.[17,18]

2.3.2 | Shirodkar cerclage

The Shirodkar technique involves a transverse anterior colpotomy, dissection of the bladder up to the internal cervical os and a posterior colpotomy with dissection of areola and peritoneum upwards to the internal os. The suture is placed subcutaneously, and the knot tied in the posterior defect and buried under the vaginal epithelium.[17,19,20] Later modifications do not require a posterior colpotomy and place the knot exterior to the vaginal mucosal for ease of removal.[21] While technically more challenging, the rationale of this technique is to allow more proximal placement of cerclage closer to the internal os. A number of other modifications have been reported which simplify the Shirodkar technique by utilising a clamp on the paracervical tissues for more accurate suture needle placement[22] or avoiding a posterior colpotomy and suture burial.[21] For this study, both the original technique described by Shirodkar and the modified techniques have been included.

2.4 | Types of studies

This review accepted randomised control trials, quasi-randomised control trials, non-randomised experimental control trials and cohort studies. All papers included had to compare the interventions, McDonald cerclage and Shirodkar cerclage.

2.5 | Search strategy

Six electronic bibliographic databases were searched for eligible, peer-reviewed literature: MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid), Scopus, CINAHL (EBSCOhost) and Cochrane Library (Wiley). Reference lists of included studies were screened and references in academic textbooks were also reviewed. Where it was not possible to source studies, contact was attempted with the corresponding author. A more detailed database search strategy is described in Appendix S1.

2.6 | Study selection

The titles and abstracts were reviewed using Endnote[23] and Covidence.[24] Studies that did not meet the criteria based on abstracts were excluded (authors A-MA and LM) and full texts of remaining articles were sourced and screened (A-MA and RD). No language restriction was set; all non-English included studies were translated into English. Included studies were critically appraised (by LM and AI) and data extracted using a standardised electronic form (by RD and KPW). At all levels of screening, any discrepancies were moderated by a third senior reviewer (CEP).

2.7 | Data analysis

2.7.1 | Assessment of risk of bias

To facilitate the assessment of possible risk of bias for each study, two independent reviewers (AI and LM) assessed each paper using the Cochrane Collaboration tool for assessing the risk of bias: ROBINS-I for non-randomised studies and RoB 2 randomised studies.[25,26]

2.7.2 | Cochrane GRADE assessment

Quality of evidence for our primary outcome was judged using the GRADE tool by two independent reviewers (A-MA and KPW).[27]

2.8 | Outcomes

2.8.1 | Primary outcome

The primary outcome was PTB <37 weeks' gestation.

2.8.2 | Secondary outcomes

Secondary outcomes included PTB <28, 32, 34 and 35 weeks. Maternal secondary outcomes examined were rates of preterm premature rupture of the membranes (PPROM), chorioamnionitis (clinical or laboratory diagnosis), cervical laceration and stenosis, caesarean section delivery, number of days between cerclage and delivery, intraoperative membrane rupture at time of cerclage, cases requiring repeat cerclage and difference in cervical length before and after cerclage. Neonatal outcomes included birthweight, Apgar score <7 and neonatal mortality, which included mortality up to 1 month post-delivery or neonatal survival (this figure was then inverted to mortality). Thorough definitions of these outcomes are referenced in the protocol paper.[13]

2.9 | Data synthesis

A meta-analysis was performed by pooling studies together using RevMan[28] and Covidence software.[24] The heterogeneity of data was examined using Forest plots and quantified throughout calculation of the I^2-value. An I^2 ≥50% was used to indicate substantial heterogeneity and a random-effects model was used. For all I^2 <50%, a fixed effects model was used. Outcomes with fewer than five studies were analysed using a fixed effects model.[29] For reporting consistency between outcomes, we made the McDonald intervention the reference set for all analyses, standardising the direction of effect across all primary and secondary outcomes.

2.9.1 | Measures of treatment effect

Where applicable, study data were combined and reported using meta-analyses using the standard estimation of: (1) risk ratio (RR) and 95% CI for dichotomous outcome variables, and (2) mean differences (MDs) or standardised mean differences (SMDs) and 95% CI for continuous outcome variables.

2.9.2 | Sensitivity analysis

Sensitivity analysis was conducted on the primary outcomes, PTB <37 weeks' gestation. This was performed by removing studies with an overall high risk of bias to examine their impact on the effect estimate. Where possible, further sensitivity analysis was performed for birth <37 weeks by selecting for indication. Unfortunately, this was only possible for two indication combinations. Another sensitivity analysis was conducted on the primary outcome which removed any paper that was known to include conjunct progesterone.

3 | RESULTS

3.1 | Study selection and characteristics

Searches of databases identified a total of 178 studies, and manual searches identified one additional publication (Figure 1). Seventy-five papers were removed due to duplication, leaving 104 unique papers, of which 46 were excluded at title and abstract review level, and an additional 41 were

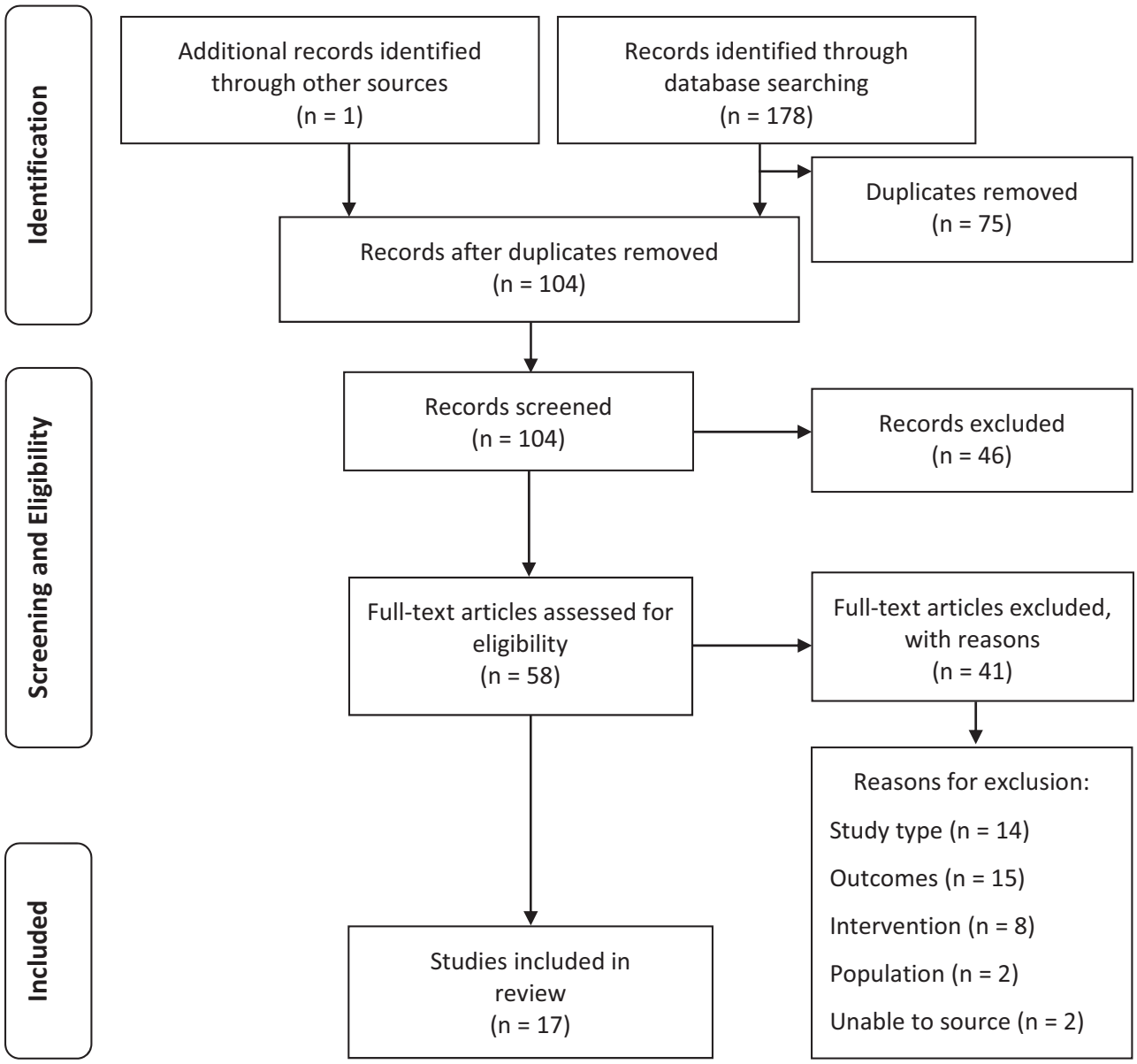

FIGURE 1 PRISMA flow chart of study selection.

excluded at the full text review stage, leaving 17 papers. Of those excluded at full text screening, 14 were inappropriate study designs and two could not be sourced. Of the remaining 23, eight did not compare Shirodkar and McDonald, a further 15 did not report useable outcomes that were comparable to the outcomes of interest in this review, and another two reported on inappropriate populations. This process left a total of 17 studies to be included in the meta-analysis (Figure 1).

A summary of the key characteristics of the included studies is presented in Table 1. The 17 included studies consisted of 2063 participants; of these, 16 studies were retrospective cohort studies and one was a randomised control trial. Of the retrospective studies, one paper[30] utilised data from four separate randomised control trials.[31–34] The sample sizes for the included studies ranged from 25 to 374 and all studies reported quantitative data. Gestational ages (GA) at cerclage insertion were reported specifically for each cerclage type in eight papers ranging from early to late second trimester. Further interventional study data have been extracted in Table S3 including GA at cerclage insertion, antibiotic use, reporting of covariate adjusted or unadjusted results, progesterone use, bed rest, tocolytic use, multiple gestation inclusion, indication for cerclage and birth type.

3.2 | Risk of bias and quality of evidence

Tables S1 and S2 show the level of risk in each of the domains of bias as assessed using Cochranes's risk of bias assessment tools for each of our included study designs. Table S1 summarises the included observational studies risk scores determined using the Cochrane's ROBINS-I. Table S2 summarises the included randomised control trials risk scores using Cochrane's RoB-2.[25,26]

In examining the risk of bias, it was found that the older studies tended to have a higher risk of bias, whereas more recent publications appeared to show a more favourable risk of bias. This is likely due to improved study design and reporting. Of the observational studies, eight papers (47.1%) were judged to be at serious risk of bias, six (35.2%) at moderate risk and two (11.8%) at low risk. Also included was a relatively small ($n = 34$ per arm) randomised control trial (RCT) which was judged to have 'some concerns' (5.9%) regarding bias. The quality of evidence for the primary outcome, birth before 37 weeks, was assessed using GRADE and was ranked as low quality.

3.3 | Birth before 37 weeks

The association between the cervical cerclage technique and the primary outcome of birth <37 weeks is shown in Figure 2. Twelve studies (70.5%) reported data on this outcome. There were significantly lower rates of birth before 37 weeks in the Shirodkar group than in the McDonald group (RR 0.91, 95% CI 0.85–0.98).

When sensitivity analyses were performed, the lower rates of birth prior to 37 weeks were no longer evident, except when studies that utilised progesterone at any time during the same pregnancy (Table 2) were excluded (RR 0.83, 95% CI 0.74–0.93). Removing studies with a serious risk of bias improved the quality of evidence from low to moderate and analyses no longer demonstrated any evidence that one surgical technique was superior to the other (RR 1.01, 95% CI 0.97–1.04). When the primary outcome studies were analysed by risk of bias groups there was no statistical significance between low (RR 0.82, 95% CI 0.63–1.07), moderate (RR 0.90, 95% CI 0.77–1.06) and high (RR 0.87, 95% CI 0.73–1.03).

Sensitivity analyses of the primary outcome were also conducted based on indication for cerclage. When papers which did not include all three indications (history indicated, ultrasound indicated or physical examination indicated) were removed, the primary outcome was no longer significant (RR 0.94, 95% CI 0.83–1.07). A similar non-significant result was also seen with the removal of studies that did not include a short cervix as identified by ultrasound as an indication (RR 0.91, 95% CI 0.82–1.02).

3.4 | Birth prior to 35, 34, 32 and 28 weeks' gestation and the number of days between cerclage and birth

Rates of preterm birth before 35 weeks (RR 0.87, 95% CI 0.79–0.96), 34 weeks (RR 0.86, 95% CI 0.76–0.96) and 32 weeks (RR 0.84, 95% CI 0.76–0.92) were all significantly lower with the Shirodkar than with the McDonald surgical technique. Preterm birth before 28 weeks (RR 0.99, 96% CI 0.95–1.03) was the only one of these outcomes to show no difference between the cerclage techniques. The Shirodkar technique was also associated with a significantly longer interval between cerclage and birth (mean 10.79 days, 95% CI 8.20–13.38; Table 2).

3.5 | Neonatal outcomes (neonatal mortality and birthweight)

There was no difference between the two surgical techniques in neonatal mortality (RR 1.01, 95% CI 0.97–1.04). The birthweight in the Shirodkar group was significantly greater than in the McDonald group (mean difference 348 g, 95% CI 291–405; Table 2).

3.6 | Maternal outcomes (PPROM, chorioamnionitis, cervical laceration, caesarean section and cervical length)

The rate of PPROM was found to be significantly lower in the Shirodkar group than in the McDonald group (RR 0.87, 95% CI 0.77–0.99). The Shirodkar technique group also showed a significantly greater increase in the post-cerclage cervical

TABLE 1 Studies included in the meta-analysis and their reported outcomes.

Study	Study type	Study details	Study period	Group		Outcomes
				Shirodkar (*n*)	McDonald (*n*)	
Peters et al. (1979)[52]	Retrospective cohort	University of Virginia, USA	1957–1977	27	13	Neonatal mortality, chorioamnionitis
Harger (1980)[53]	Retrospective cohort	Magee Women's Hospital, USA	1971–1978	82	169	Preterm birth <37 weeks, cervical laceration
Schwartz et al. (1984)[54]	Retrospective cohort	Edgware General Hospital, England Temple Hospital, USA	1970–1975 1976–1981	67	7	Chorioamnionitis
Cardwell (1988)[55]	Retrospective cohort	Baptist Hospital, USA	1976–1986	80	49	Preterm birth <37 weeks, cervical laceration, chorioamnionitis, caesarean section
Bassaw & Roopnarinesingh (1990)[56]	Retrospective cohort	Mount Hope Women's Hospital, Trinidad	Not reported	49	138	Preterm birth (<37 and <28 weeks)
Marks et al. (1992)[57]	Retrospective cohort	New York University Medical Center and Columbia Presbyterian Medical Center, USA	1973–1986	23	86	Preterm birth <37 weeks
Ayhan et al. (1993)[58]	Retrospective cohort	Hacettepe University School of Medicine, Turkey	1980–1990	51	323	Preterm birth (<37 and <28 weeks), neonatal mortality[a]
Perrotin et al. (2002)[44]	Retrospective cohort	Hospital Bretonneau, France	1996–2001	9	16	Cervical length, neonatal mortality, preterm birth <32 weeks, PPROM, chorioamnionitis
Rozenberg et al. (2003)[45]	Retrospective cohort	Poissy-Saint Germain Hospital Center, France	1998–2001	14	19	Cervical length, preterm birth (<37 and <34 weeks)
Odibo et al. (2007)[59]	Retrospective cohort[b]	Multicentre; USA, UK and The Netherlands	Not reported	127	150	Birthweight, days between cerclage and birth, preterm birth (<28 and <35 weeks), neonatal mortality
Hume et al. (2012)[48]	Retrospective cohort	Mount Sinai Hospital, USA	2005–2010	47	28	Preterm birth (<32 and <35 weeks), PPROM
Heath et al. (2013)[60]	Retrospective cohort	Croydon University Hospital, UK	2008–2012	23	99	Preterm birth <37 weeks, caesarean section
Otsuki et al. (2016)[50]	Randomised control trial	60 tertiary centres of the Japanese Society of Preterm birth prevention, Japan	2004–2011	34	34	Birthweight, preterm birth (<37, <34, <32 and <28 weeks), neonatal mortality
Bartolo et al. (2017)[47]	Retrospective cohort	Llile University Hospital, France	2006–2013	14	24	Birthweight, preterm birth (<37, <28, <35 and <32 weeks), neonatal mortality, PPROM, chorioamnionitis
Wong et al. (2017)[49]	Retrospective cohort	Mackay Memorial Centre, Taiwan	2002–2014	36	24	Birthweight, preterm birth (<37, <34, <32 and <28 weeks), neonatal mortality, PPROM
Cleary et al. (2018)[61]	Retrospective cohort	Trihealth Hospitals, USA	2012–2014	86	20	Preterm birth <35 weeks
Figueroa et al. (2019)[46]	Retrospective cohort	Saint Francis Hospital and Medical Center, USA	2008–2013	47	48	Days between cerclage and birth, birthweight, preterm birth (<37, <35 and <32 weeks), neonatal mortality, PPROM, chorioamnionitis

[a]Reported neonatal mortality to within 1 month postpartum.

[b]From data of four previous RCTs.

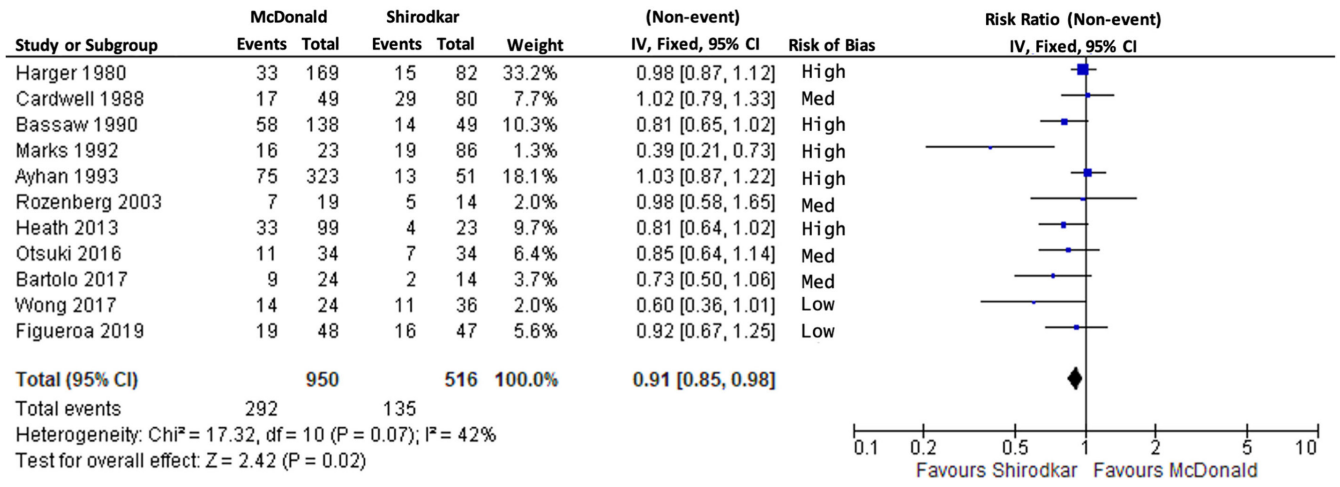

FIGURE 2 Forest plot of preterm birth <37 weeks' outcome.

length (mean difference 5.25 mm, 95% CI 4.68–5.83). There was no difference between the two techniques in the rates of chorioamnionitis (RR 0.96, 95% CI 0.90–1.02), cervical laceration (RR 1.04, 95% CI 0.98–1.10), or caesarean section (RR 1.07, 95% CI 0.94–1.22, Table 2).

4 | DISCUSSION

4.1 | Main findings

The main finding of this systematic review and meta-analysis of all currently available data was that pregnancies requiring a cervical cerclage were less likely to result in preterm birth when the Shirodkar technique of cerclage was utilised compared with the McDonald approach; however, removing studies with serious risk of bias resulted in this improvement no longer remaining significant. Analyses of secondary outcomes did identify statistically significant reductions in rates of preterm birth before 35, 34 and 32 weeks, PPROM, difference in cervical length, cerclage to delivery interval and an increase in birthweight in the Shirodkar group. The greatest improvement in PTB rates was demonstrated at <32 and 34 weeks where there was a three-fold reduction in PTB rates when a Shirodkar cerclage was used rather than the McDonald technique. It was estimated that an additional 28 Shirodkar cerclages (95% CI 18–56) would need to be performed to prevent one birth <32 weeks.[35,36]

It is well established that the risk of spontaneous PTB is increased for women with a short cervix on transvaginal ultrasound.[37–39] Previous studies have shown a correlation between increased cervical length post-cerclage and later gestation at delivery.[40,41] A cerclage height of at least 18 mm (measured from the cerclage to the external os on a mid-sagittal plane on transvaginal ultrasound) has been shown to be associated with a reduction in PTB when compared with cerclages placed closer to the external os.[42] In two publications evaluating the location of cerclage post-surgery, the McDonald cerclage has been shown to fail to achieve this height in the majority of women.[42,43] The Shirodkar approach places the cerclage higher and closer to the internal os and hence is more likely to result in a longer post-cerclage cervical length than those inserted using the McDonald approach. This observation is supported by the studies comparing cervical length post-cerclage,[44,45] where a significant increase in cervical length post-cerclage was demonstrated for the Shirodkar technique compared with the McDonald approach (mean difference 5.25 mm, 95% CI 4.68–5.83).

Respiratory distress syndrome (RDS) was not included in the final analysis, as only one included paper reported on this outcome (REF). In this study, a significant reduction in RDS rates was shown when the Shirodkar technique compared with the McDonald approach. This finding is in keeping with our observation that Shirodkar cerclage was associated with a reduction in early PTB and literature which demonstrating increasing RDS associated with earlier gestations of birth.

In this meta-analysis, the interval between cerclage and birth was significantly longer with the Shirodkar than the McDonald cerclage. This interval has previously been reported by two studies, one of which favoured the Shirodkar cerclage[46] and the other the McDonald approach.[30] It should, however, be noted that in the study that favoured the McDonald cerclage, the McDonald group had a significantly longer cervical length at study entry and less advanced gestational age when compared with the Shirodkar group (20 versus 23 weeks).[30]

Even though the Shirodkar technique requires greater surgical expertise than the McDonald approach, the procedure complication rate is generally low.[12] This review was not able to compare rates of intraoperative rupture of membranes or repeat cerclage due to small numbers. However, there was no difference in the rates of cervical laceration between the two techniques. Furthermore, PPROM, arguably an important technique-related complication, occurs less

TABLE 2 Analysis of secondary outcomes.

Outcome	Favours*	Included studies	Risk ratio	95% CI	I^2 (%)	*P*-value	Events	
							Shirodkar, n_{cases}/n_{total} (%)	McDonald, n_{cases}/n_{total} (%)
Preterm birth <37 weeks	Shirodkar	11	0.91	0.85–0.98	42	0.020	135/516 (26.2)	292/950 (30.7)
Preterm birth <35 weeks	Shirodkar	5	0.87	0.79–0.96	0	0.007	54/255 (21.1)	107/335 (31.9)
Preterm birth <34 weeks	Shirodkar	3	0.86	0.76–0.96	0	0.010	5/84 (6.0)	15/77 (19.4)
Preterm birth <32 weeks	Shirodkar	6	0.84	0.76–0.92	0	<0.001	17/187 (9.1)	46/173 (26.6)
Preterm birth <28 weeks	Neither	6	0.99	0.95–1.03	0	0.550	30/311 (9.6)	83/693 (11.9)
Neonatal mortality	Neither	8	1.01	0.97–1.04	14	0.720	34/345 (1)	70/632 (1.1)
Preterm premature rupture of the membranes	Shirodkar	5	0.87	0.77–0.99	30	0.040	25/153 (16.3)	38/139 (27.3)
Chorioamnionitis	Neither	6	0.96	0.90–1.02	0	0.160	10/244 (4.0)	20/157 (12.7)
Cervical laceration	Neither	2	1.04	0.98–1.10	65	0.190	15/162 (9.3)	23/218 (10.5)
Caesarean section	Neither	2	1.07	0.94–1.22	30	0.320	29/103 (2.8)	23/148 (1.6)

Outcome	Favours*	Included studies	Shirodkar mean	McDonald mean	Mean difference (CI 95%)	I^2 (%)	*P*-value	Events	
								Shirodkar (*n*)	McDonald (*n*)
Birthweight (g)	Shirodkar	5	2921.06	2572.41	348.41 (291.24–405.57)	35	<0.001	258	280
Days between cerclage and birth (days)	Shirodkar	2	133.5	122.71	10.79 (8.20–13.38)	96	<0.001	174	198
Difference in cervical length pre-post-cerclage (mm)	Shirodkar	2	16.27	11.02	5.25 (4.68–5.83)	60	<0.001	23	35

*Favours – Indicates which treatment method is more likely to result in favourable outcomes.

frequently with the Shirodkar technique without a previously reported increase in the caesarean section rate.[44,46–49]

4.2 | Strengths

One of the key strengths of this meta-analysis is the consistency of the results supporting the Shirodkar technique. A further strength is that all data extracted were unadjusted. It is of some concern, though, that most papers did not attempt to adjust data for their significant biases.

4.3 | Limitations

A significant limitation of this meta-analysis is the high risk of bias of many of the included studies. Thirteen of the studies included in this meta-analysis were classified as having a high risk of bias. Further, all papers included were cohort studies, except for one RCT.[50] Of note, the data from this small RCT, while not statistically significant, favoured the Shirodkar technique, highlighting the need to a further well powered RCT. Indication bias was a further limitation, as included papers varied in terms of their indications for cerclage between ultrasound, history and physical examination indicated. Another limitation is that maternal and neonatal morbidity and mortality data were underreported or not reported in the included studies. As a result we were not able to report on some outcomes mentioned in our protocol paper.[13] These included Apgar score, intraoperative membrane rupture, cervical stenosis, repeat cerclage rate and a sub-analysis of preterm birth at <36 weeks' gestation. It should also be noted that although cervical length and neonatal respiratory distress syndrome were presented in this meta-analysis, the sample size for these outcomes was small (Table 2) and these results should be interpreted with caution. It should also be noted that most studies did not report on the type of preterm birth (i.e. spontaneous or iatrogenic), which may be a confounding variable. Another limitation in the meta-analysis is, with one exception, none of the included papers controlled for the effect of surgical experience of different operators. The only study with a single surgeon for all procedures, who was equally experienced in both techniques, reported a statistically significant better outcomes for PTB with the Shirodkar approach.[49]

4.4 | Interpretation

Although this meta-analysis did not report a reduction in PTB <37 weeks' gestation after sensitivity analysis was performed, it does report results that favoured the Shirodkar over the McDonald approach for PTB <35, 34 and 32 weeks' gestation. The overall quality of the studies in the review was low, with the risk of bias rated from between moderate to high. The most comprehensive study to date is a small RCT of 68 participants[50] (RR 0.86, 95% CI 0.85–1.14); although not statistically significant, the data in the study suggest that a higher powered RCT may favour the Shirodkar technique. Until these studies are performed, both surgical techniques should be taught to training obstetricians, as individual circumstances will vary for each woman and the final decision should continue to be left to the discretion of the obstetrician. This is consistent with the current guidelines from the Royal College of Obstetricians and Gynaecologists and the Society of Obstetricians of Gynaecologists of Canada.[51]

4.5 | Conclusion

Regarding preterm birth prior to 37 weeks' gestation, the current literature does not clearly support one surgical technique over another for vaginal cervical cerclage. While the Shirodkar technique achieves greater cerclage post-cerclage, longer interval between time at cerclage insertion to delivery, increased birthweight, a reduction in PPROM and a reduction in PTB rates <35, 34 and 32 weeks when compared with the McDonald approach, the overall quality of studies in this review is low. Further large, well designed randomised controlled trials comparing these techniques are required before firm recommendations can be made regarding the best surgical approach to prevent preterm birth.

AUTHOR CONTRIBUTIONS

LM, AI, KPW, RD, A-MA, JP and CEP led the development of the paper. AM, SL, PM, JP and CEP designed the concept of the review and drafted the paper. CW provided statistical analysis advice and drafting. JP, PM and CEP advised on obstetric care.

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The authors declare they have no competing interests. Completed disclosure of interest forms are available to view online as supporting information.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

ETHICS APPROVAL

None.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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