

Abstract

The aim of this study was to evaluate the efficacy and safety of membrane sweeping in promoting spontaneous labour and reducing formal induction of labour for postmaturity. Based on articles published between 2005 and 2016, 12 electronic databases were searched. Risk ratio (RR) and its 95% confidence interval (CI) were used as pooled statistics. A total of seven studies consisting of 2252 participants were selected for the review and meta-analysis. Results revealed that membrane sweeping is advantageous in promoting spontaneous labour (RR = 1.205, 95% CI: 1.133 - 1.282, $p = <0.001$), and reducing formal induction of labour for postmaturity (RR = 0.523, 95% CI: 0.409 - 0.669, $p = <0.001$). The studies reported several varying outcomes for both maternal and fetal morbidities; meta-analyses were performed where possible on each of these and found there to be no statistically significant differences in outcome between intervention and control groups.

Impact statement

What is already known on this subject?

Research suggests that a pregnancy which exceeds 42 weeks gestation is associated with an increased risk of perinatal morbidity and mortality (Gulmezoglu et al 2012). Consequently, formal induction of labour is usually offered to low-risk pregnant women between 41 and 42 weeks of pregnancy. However, all induction methods carry some degree of risk in terms of associated morbidities and effectiveness (Cunningham 2005, Simpson 2008, Thomas et al 2014), as well as having an impact on NHS resources (Department of Health 2015), and the birth experience of women (Gatward et al 2010). For these reasons it is currently recommended by The National Institute for Health and Care Excellence (NICE 2008)

that women are offered a membrane sweep to promote spontaneous labour prior to arranging formal induction of labour.

What do the results of this study add?

The results from this meta-analysis adds to the body of existing evidence around membrane sweeping. This study clearly demonstrates that membrane sweeping is effective in promoting spontaneous labour and thereby reducing the need for formal induction of labour. However, the results of this review suggest that this effect is significant from 38 weeks gestation, and is not dependent upon the number or timing of membrane sweeps performed.

What are the implications of these findings for clinical practice and/or further research?

There is no evidence supporting any increase in maternal or fetal morbidity suggesting membrane sweeping is safe procedure to offer to all low risk pregnant women. We recommend therefore that there could be a reduction in the gestation at which membrane sweeping is offered from 40 weeks for primiparous women and 41 weeks for multiparous women to 38 weeks onwards for all low risk women without any increased risk of maternal or fetal morbidity. This may result in a decreased risk of requiring formal induction of labour for postmaturity.

Keywords

Term pregnancy, post-term pregnancy, postmaturity, membrane sweeping, membrane stripping, stretch and sweep, meta-analysis, systematic review

Introduction

A pregnancy with a gestation exceeding 42 weeks is associated with an increased risk of perinatal morbidity and mortality. This risk includes increased stillbirth, meconium aspiration, birth injury and hypoxia (Caughey and Musci 2004, Gulmezoglu et al 2012). However, this increase in risk is from a very low initial baseline of pregnancies which exceed this gestation (National Institute for Health and Care Excellence (NICE) 2008), and only a comparatively small proportion of pregnancies are at particular risk from postmaturity. Because it is impossible to precisely identify those pregnancies at risk, arbitrary time limits are introduced, and formal induction of labour is usually offered between 41 and 42 weeks of pregnancy (Gulmezoglu et al 2012).

According to the World Health Organisation (1996) a full term pregnancy is considered as anything from 37 to 42 weeks. The percentage of post-term pregnancies that are induced varies widely between countries (Zeitlin et al 2007). The World Health Organisation Global Survey in 24 countries on Maternal and Perinatal Health sampled 300,000 participants and found that 9.6% of births were induced. African countries have lower rates of induction of labour (lowest: Niger 1.4%) compared with Asian and Latin American countries (highest: Sri Lanka 35.5%) (Vogel et al 2013). Recent statistics show that in the United Kingdom over 25% of all births are medically induced (Hospital Episode Statistics Analysis, Health and Social Care Information Centre 2015). Whilst some labour inductions are carried out due to a potential compromise to the health of either the mother or fetus; the spike in the

overall percentage of inductions of labour between 40 and 42 weeks suggest that the clear majority are undertaken purely due to the pregnancy becoming post-term.

Despite the evidence supporting formal induction of labour in post-term pregnancies to prevent perinatal complications, this needs to be balanced against the well documented potential negative outcomes involved with all formal methods of induction of labour, both in terms of medical risk to mother and fetus (Cunningham 2005; Simpson 2008; Jozwiak et al 2012; Thomas et al 2014), and the impact that induced labour has on the birth experience of women. Gatward et al (2010) suggest that formal induction of labour is associated with less maternal satisfaction with the birth experience, with women perceiving a loss of control, and a lack of confidence in their bodies' ability to birth when spontaneous labour does not begin. Consequently, it is essential that alternatives to formal methods of induction are considered to avoid unnecessary intervention and improve the birth experience.

Cervical membrane sweeping is a relatively simple, and in the UK routine practice clinically indicated in term low risk pregnancies on the recommendation of NICE (2008). The aim is to promote spontaneous labour, and therefore reduce the need for formal induction of labour for postmaturity. The procedure is offered as part of a routine antenatal appointment. Following verbal consent, and the exclusion of contra-indications, the patient is asked to empty her bladder. With the patient lying supine a digital vaginal examination is undertaken, whereby a gloved index finger is gradually advanced into the cervical canal and swept round in either direction several times. The intention is to manually separate the chorioamniotic membranes from the decidua to encourage prostaglandin production leading to cervical ripening. This is believed to initiate the onset of labour and reduce the need for pharmacological or more invasive methods to induce the birth (Rogers 2010).

A body of research has been conducted into the effectiveness of membrane sweeping both to prevent, and in conjunction with formal induction of labour. A Cochrane Review published in 2005 (Boulvain et al 2005), identified new research in 2009, but to date this has not been subsequently used to update their existing original review. The recommendation from NICE (2008) that women are offered a membrane sweep is based largely on the evidence from this Cochrane review. However, the review concluded that routine use of membrane sweeping from 38 weeks of pregnancy onwards does not appear to produce clinically important benefits. When used as a means for induction of labour for post-term pregnancies, membrane sweeping did result in the reduction in the use of more formal methods of induction, but this needs to be balanced against women's discomfort and other adverse effects.

The literature included in that Cochrane review is now over a decade old, and the authors themselves state there were several limitations including substantial heterogeneity between trials, small sample sizes and potential publication bias. In addition, despite membrane sweeping being a routine intervention for post-term pregnancies, a quarter of all pregnant women in the United Kingdom still undergo a formal induction of labour in hospital which raises questions about the efficacy of the procedure. There have been several further primary studies published since the last review; consequently, it is important that an up to date systematic review is undertaken to establish if membrane sweeping is safe and effective in promoting spontaneous labour, and therefore reducing formal induction of labour for postmaturity.

The Centre for Reviews and Dissemination's (CRD 2009) guidance on undertaking a systematic review was used in formulating the review protocol. The review question

was formulated using the PICOS framework and consisted of the main question (1), and two secondary questions (2, 3)

1. Is membrane sweeping at term a safe and effective method of promoting spontaneous labour and reducing the likelihood of a formal induction of labour for postmaturity?
2. Is single or multiple membrane sweeping more effective in reducing the likelihood of a formal induction of labour for postmaturity?
3. How effective is membrane sweeping prior to 40 weeks compared to 40+ weeks of pregnancy in reducing the likelihood of a formal induction of labour for postmaturity?

Materials and Methods

Search Strategy

A comprehensive list of search terms was collated (Table 1). . And used to search 12 databases as well as relevant midwifery journals, reference lists and Google Scholar. Where necessary, authors of studies were contacted for further information.

Inclusion and exclusion criteria

Studies were included if they met the following criteria:

- (1) Term (37-42 weeks) pregnant women with a low-risk, singleton, cephalic pregnancy, with a gestation confirmed by certain LMP and/or first trimester scan, and no contraindications to a vaginal birth;
- (2) Membrane sweep performed on at least one occasion, and at least 72 hours prior to formal induction of labour;

- (3) Studies comparing membrane sweeping with either no intervention, or vaginal examination to assess bishop score only;
- (4) Studies with spontaneous labour, and maternal and fetal morbidity as outcome measures.
- (5) Randomised controlled trials (RCT's) published in the English language between 2005 – 2016.

Studies which did not fulfil the inclusion criteria, were published with insufficient information; non-RCT study design, or duplicates were excluded at this point.

Data extraction and quality assessment

The Critical Appraisal Skills Programme (CASP 2013) checklist for RCT's was used to assess quality as it provided a clear, systematic approach to looking at a study's validity, results and usefulness.

Data extraction was undertaken using a modified data collection form based on the Cochrane Collaborations Effective Practice and Organisation of Care (EPOC) data collection form (Cochrane Collaboration 2013). Modifications to the form were made by referring back to the PICOS chart and aims of this study. This was then piloted on 2 of the included studies and altered where necessary to ensure that all the relevant information was captured to enable the review question to be addressed. . Within the standardised data extraction form, consideration is given to the risk of bias within the studies by utilising the Cochrane Collaboration's Risk of Bias tool (Higgins and Deeks 2011) (Table 3).

The process was also reviewed by an additional researcher at this point to minimise the risk of bias, and one further study was rejected at this point as it did not report the outcome measure separately.

Statistical analysis

The statistical analysis was conducted using the statistical software MedCalc for Windows, version 17 (MedCalc 2017). As the trials varied in the type and detail of statistical information that they provided, this software was used to calculate the Relative Risk (RR), its corresponding 95% Confidence intervals (CI), and p values for all the required outcome data from all seven studies. The heterogeneity between studies was examined using the Cochrane Q test, and the I^2 statistic to identify systematic variation between studies. A p value <0.05 or $I^2 >50\%$ was considered to indicate heterogeneity. A decision was made to use a fixed-effect model for this meta-analysis, as the study population of low risk, term, pregnant women, and the intervention of membrane sweeping were sufficiently similar throughout all the trials to reasonably expect there to be a singular, or common effect size in all included studies.

Results

Eligible studies

The selection process of studies to be included in this systematic review is described in Figure 1. According to the search strategy, a total of 120 articles were identified, of which 86 were excluded because they were not relevant to the present study or

duplicated. These exclusions left 34 articles, of which 24 were excluded from the analyses after assessment against the inclusion/exclusion. After detailed examination, three of remaining ten articles were excluded. Thus, seven articles were finally included in the meta-analysis.

Characteristics of included studies

An overview of the seven included studies is provided in Table 2. There was a total of 2252 participants between the included studies. They were all a mix of primiparous and multiparous women with low-risk pregnancies between 38 and 42 weeks' gestation who underwent at least one membrane sweep to promote the initiation of spontaneous labour.

The studies were published between 2006 and 2014, and were conducted within various health care settings including maternity hospitals, midwifery practices, a medical centre and a university; and in several different countries, which included Denmark, Netherlands, Turkey, Hawaii, Nigeria and Saudi Arabia. Although none of the studies were carried out in the UK, the relative simplicity and standard method of delivering the intervention reported by all the studies meant that the results could be considered easily applicable to any women with a low-risk pregnancy within any health care setting. Two of the studies included a co-intervention, one performed cervical scans to investigate changes in cervical length on all participants (Parlakagumus et al 2014), and the other considered acupuncture as well as membrane sweeping as a method of promoting spontaneous labour (Andersen et al 2013).

The result of quality assessment of the included studies is depicted in Table 3. Other than the relatively low bias level observed in selection and detection bias, the result showed that the overall bias was very low.

Primary Outcomes

Effectiveness of membrane sweeping in promoting spontaneous labour

Meta-analysis of the data demonstrates that membrane sweeping is effective in promoting spontaneous labour (Figure 2), with a pooled relative risk of entering spontaneous labour of 1.205 (CI 1.133 - 1.282). The z-value and its P-value (<0.001) indicates that this is highly statistically significant (Table 4). This relative risk means that on average there is an increase in the likelihood of spontaneous labour of 20.5% in the membrane sweeping groups compared to the control groups (CI 13.3% - 28.2%). The statistical test for heterogeneity was not significant ($p=0.14$). This was confirmed by the I^2 calculation which was calculated at 37.5% indicating a low to moderate risk of heterogeneity.

Five of the studies (De Miranda et al 2006, Yildirim et al 2009, Andersen et al 2013, Ugwu et al 2014, Zamzami and Al Senani 2014) indicated a statistically significant effect of the intervention on the outcome measure, showing that membrane sweeping was associated with an increase in the incidence of spontaneous labour. This effect was significant in studies reporting results from 72 hours up to three weeks post intervention. Rates of 90% and above for the study intervention population were reported in two of the studies (Yildirim et al 2009, Zamzami and Al-Senani 2014). Of the remaining two studies, one reported a small, but not statistically significant increase in spontaneous labour in the study group (Parlakgumus et al

2014), whilst the other (Hill et al 2008) found no difference between the study and control groups.

Effectiveness of membrane sweeping in reducing formal induction of labour

The meta-analysis performed on the five studies (which provided figures for the number of women undergoing formal induction of labour for postmaturity), clearly indicated a reduction in the need for induction when women had received membrane sweeping as an intervention. The forest plot in figure 3 shows that the point estimates are all clearly to the left of the vertical axis, as is the pooled estimate. Table 5 shows a pooled relative risk of requiring induction of 0.523 (CI 0.409 - 0.669) indicating that women in the intervention groups had an average of 47.7% reduction in risk of requiring a formal induction of labour (CI 40.9% - 66.9%). This is quite clearly a significant reduction, which is confirmed by a Z value of -5.155 and associated p value of <0.001. The level of heterogeneity between studies was not statistically significant when considering this outcome with a p value of 0.40 and a very small I² statistic of only 1.78% indicating that the trials were highly homogeneous.

Two of the studies, Andersen (2013) and Yildirim (2009) did not provide results data for the numbers of women undergoing formal induction of labour for postmaturity. The remaining five studies varied in their planned timing for induction of labour between 41 and 42 weeks gestation. Of these five studies, three reported a decrease in the percentage of women within the sweeping group who were induced due to postmaturity. The other two trials (Hill 2008, Parlakgumus 2014) did not report any statistically significant difference between the sweeping and control group.

Safety of membrane sweeping

Meta-analyses were performed on all of the maternal and fetal outcomes reported by at least two of the included studies. The two most commonly reported maternal outcomes were caesarean section and premature rupture of membranes; and the two most commonly reported fetal outcomes were admission to neonatal intensive care (NNU) and fetal distress.

Caesarean section was the only outcome to be reported by all seven studies. The relative risk of requiring a caesarean section is 0.981 (CI 0.791 - 1.217) indicating there was no significant difference between the intervention and control groups. Pre-labour rupture of membranes (PROM) was reported as an outcome in six of the studies. Results indicated that there is an increased risk of PROM in the intervention group, with a pooled relative risk of 1.23, suggesting an average 23% increase in the amount of women experiencing PROM in the membrane sweeping group. However, the confidence intervals for this are relatively wide (0.957 - 1.582) indicating that the effect could lie anywhere between a 4.3% reduction and a 58.2% increase in experiencing PROM. The Z values and associated p values indicate that neither of the outcomes for the two maternal morbidities is statistically significant. The statistical test for heterogeneity is also not significant (Caesarean section $p = 0.69$, PROM $p = 0.80$).

Admission to NNU was reported by five of the studies, and was not statistically significant (RR 1.047 CI 0.568 - 1.930). This is confirmed by a Z value of 0.146 and associated p value of 0.884. In common with the results for maternal morbidities, the test for heterogeneity was not significant.

Four of the studies provided results for the numbers experiencing fetal distress. The meta-analysis of these results indicates a pooled relative risk of 0.67, suggesting that

membrane sweeping reduces the risk of fetal distress by 33%. However, wide confidence intervals of 0.394 - 1.139 alongside a Z value of -1.48 (P = 0.139) indicate that these results are not statistically significant. The statistical test for heterogeneity was not significant (p = 0.0855), but the I² statistic of 54.61% suggests that there is a moderate, but significant level of heterogeneity between the trials. The reason for this may at least partly be attributable to the trial conducted by Zamzami and Al Senani (2014) who reported a significant increase in meconium liquor and fetal distress, however this was in the control group of their study and was atypical of the results of the other included studies.

The remaining results reported by at least 2 of the studies included instrumental deliveries, PPH, labour augmentation, antenatal bleeding and hypertension for maternal outcomes; and Apgar<7 and meconium liquor for fetal outcomes. None of the results from the meta-analysis of these results indicated a statistically significant difference in outcome between the intervention and control groups.

Secondary Outcomes

Effectiveness of single versus multiple membrane sweeping

A subgroup analysis was performed to determine whether there was a different treatment effect observed between the trials performing a single membrane sweep (Yildirim et al 2009, Parlakgumus et al 2014, and Ugwu et al 2014), and those performing more than one membrane sweep (De Miranda et al 2006, Hill et al 2008, Andersen et al 2013, and Zamzami and Al Senani 2014). The results were statistically significant in showing that membrane sweeping is advantageous in

promoting spontaneous labour for both the trials performing single and multiple membrane sweeping, with a pooled relative risk of achieving spontaneous labour of 1.233 (CI 1.133-1.341) and 1.189 (CI 1.094-1.294) respectively. This demonstrates that women receiving a single membrane sweep had on average a 23% increase, and those receiving multiple membrane sweeps had a 19% increase in their chances of entering spontaneous labour. However, the I^2 and p value statistical tests for heterogeneity indicate that there was significant heterogeneity in the trial considering a single membrane sweep ($I^2=69\%$, $p=0.039$); whereas the studies performing multiple membrane sweeping demonstrated a very high level of homogeneity ($I^2=5.93\%$, $p=0.363$).

Effectiveness of membrane sweeping by gestation

The subgroup analysis conducted to determine differences in overall outcome between trials performing membrane sweeping prior to 40 weeks (Hill et al 2008, Parlakgumus et al 2014, Yildirim et al 2009 and Zamzami and Al Senani 2014) versus those 40 weeks onwards (De Miranda et al 2006, Andersen et al 2013, and Ugwu et al 2014), found both to be favourable in promoting spontaneous labour. In the membrane sweep group of trials conducted prior to 40 weeks, women were approximately 15% more likely to go into spontaneous labour compared to the control group (CI 6.5% - 24.5%). In the sweeping group of trials conducted at 40 weeks and over, women were on average 26% more likely to labour (CI 14.7% - 38.9%). Both results were statistically significant. The main difference between the two groups was again in the statistical test for heterogeneity. This was significant in the group performing membrane sweeping prior to 40 weeks ($p=0.055$, $I^2 = 60.47\%$) and not significant in the other group ($p=0.70$, $I^2 =0\%$).

Discussion

When reviewed individually, the results from six of the seven studies reported found that membrane sweeping was effective in promoting spontaneous labour, whilst the other study found there to be no difference. All the five studies that examined formal induction of labour for postmaturity, found it reduced the numbers of formal inductions.

All of the trials stated that women were randomly allocated to treatment groups, however one of these studies did not describe the method of randomisation (Parlakgumus et al 2014), and two were not explicit in how allocation was concealed (Parlakgumus et al 2014, Yildirim et al 2009), which could have led to an element of bias. Blinding of participants was attempted in two of the trials (Hill et al 2008, Parlakgumus et al 2014), but it is acknowledged that the nature of the intervention makes blinding highly improbable, as the discomfort of the procedure itself would mean that women would be aware whether they had received membrane sweeping or not. This limitation is addressed by the majority of studies, but as it is the same for every woman experiencing a membrane sweep in every study, it is considered unlikely to have any significant effect on the outcome or risk of bias. Blinding of the study personnel is discussed in four of the studies (De Miranda et al 2006, Hill et al 2008, Parlakgumus et al 2014 and Yildirim et al 2009), but again this was impossible in those studies where the person delivering the intervention is part of the study personnel. It is questionable as to how much impact this lack of blinding could have had on the number of women ultimately entering into spontaneous labour, but nonetheless it is acknowledged that this may have introduced an element of bias. The reporting of all the outcome data was of good quality throughout the studies. All the women that entered into the trials were accounted for at the end of the process,

and there was no apparent selective reporting of the results. However, there were substantial inconsistencies in the reporting of statistical data throughout the studies. One study incorrectly reported Relative Risk as Odds Ratios (Ugwu et al 2014), and two studies incorrectly calculated percentages and p values from their raw data (Parlakgumus et al 2014 and Ugwu et al 2014). Hill et al (2008) and Zamzami and Al Senani (2014) were both limited in their reporting of statistical data, quoting only p values. This overall mixed reporting of statistics meant that calculations had to be checked and statistical data calculated from raw data by the author of this review prior to conducting an analysis of the results.

A total of 2252 women from seven trials were included in the meta-analysis performed in this systematic review, making this the largest review of relevant research on this subject since the Cochrane review twelve years ago. The results concluded that membrane sweeping appears to be an effective method for reducing postmature pregnancies by promoting spontaneous labour. The analysis was also able to demonstrate that overall, there was no statistically significant increase in either maternal or fetal morbidity which occurred from membrane sweeping and therefore the procedure appeared safe.

The subgroup analyses suggest that both single and multiple membrane sweeping is effective in promoting spontaneous labour, and that membrane sweeping may be beneficial when performed from 38 weeks onwards.

This systematic review adds to the body of existing evidence around membrane sweeping. These findings support the previous Cochrane review by Bouvain et al (2005) of 2389 low-risk pregnant women. The current review also supports the Cochrane review in finding no evidence of a difference in the risk of maternal or

neonatal infection. However, this review has found membrane sweeping from 38 weeks appears to be effective in promoting spontaneous labour and reducing the need for formal induction of labour for postmaturity. This conclusion is not shared by the earlier review which found that although there was an overall reduction in risk of formal induction of labour of 14%, that routine use of sweeping of membranes from 38 weeks of pregnancy onwards does not seem to produce clinically important benefits. This may be at least in part be due to the fact that they found important heterogeneity in their results and suggest caution on their interpretation. This review also differs in conclusion from a more recent, smaller systematic review and meta-analysis involving three trials and 419 women by Rogers (2010), which concluded that there was no benefit in performing a single membrane sweep at term (37-42 weeks) to reduce the -incidence of post-term pregnancies.

Strengths and limitations of the review

A decision was made to include randomised controlled trials (RCT's) only in this review, as they are considered to be the 'gold standard' for health care research (Aveyard 2007), and the most rigorous way of determining whether a cause-effect relation exists between treatment and outcome (Sibbald and Roland). The rationale was that heterogeneity between studies and risk of bias would be limited, leading to a more reliable result from the review. However, whilst this was a strength of this review, it is acknowledged that this limitation may have excluded other studies that may have had relevance to the review question.

Strengths and limitations of the included studies

The level of homogeneity between the included studies is considered to be a major strength of this systematic review, allowing for greater confidence in the results of

the meta-analysis. There were however two results from the subgroup analysis that demonstrated a significant level of heterogeneity, and therefore the reliability and validity of those individual results must be interpreted with caution. It is also acknowledged that despite the WHO definition of term pregnancy being from 37 weeks, no studies were identified that measured the desired outcomes in pregnancies of this gestation.

Recommendations

All of the trials in this review included a mixture of primiparous and multiparous women in order to demonstrate a generalisable effect of the intervention. Of the seven studies included, only one (DeMiranda et al 2006) published results based on parity. Although this trial found membrane sweeping to be effective regardless of parity, it is recommended that further research is undertaken with a larger population to establish if there are any differences in the primary outcome between primiparous and multiparous women. It is also a recommendation that further qualitative research may be useful to better understand women's experiences of membrane sweeping and the associated side effects of pain or discomfort; and how this may impact on their decision making with regards to the procedure.

In conclusion, this meta-analysis demonstrated that membrane sweeping is both a safe and effective method of promoting spontaneous labour and therefore reducing formal induction of labour for postmaturity. It was also able to demonstrate that membrane sweeping is effective when performed from 38 weeks gestation, and that a single membrane sweep may be as effective as multiple membrane sweeps.

Declarations of interest statement

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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