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Research article

Complementary therapy and alternative medicine: effects on induction of labour and pregnancy outcome in low risk post-dates women

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ABSTRACT

Background: Complementary therapy and Alternative medicine (CAM) is used worldwide for many ailments and is a popular option amongst pregnant women for general wellbeing and managing symptoms. Many studies investigating the use of CAM in the antenatal and intrapartum period have been conducted however there is a lack of evidence regarding its effects on induction of labour and delivery. We established a post-dates clinic comprising of an antenatal check and CAM for low risk pregnant women to determine the impact of CAM on these outcomes.
Methods: This was a cohort study with convenience sampling. A total of 1044 women were included. 397 received a combination of three CAM techniques (acupressure, reflexology and aromatherapy) and 647 women received standard clinical practice. The primary outcome was rate of induction of labour and secondary outcomes such as rates for epidural, length of labour, oxytocin use for induction or augmentation of labour, mode of delivery, blood loss during delivery, postpartum haemorrhage, significant perineal trauma, shoulder dystocia and admission of the baby to a special care unit were analysed.
Findings: CAM did not have an effect on rates of induction of labour in nulliparous or multiparous women attending the post-dates clinic. However, we noted that nulliparous women who received CAM had shorter labours (mean 8.4 vs 10 h, $p = 0.0002$), less oxytocin augmentation (23% vs 35%, $p = 0.0002$), lower epidural rates (41% vs 50.5%, $p = 0.02$) and reduced blood loss regardless of mode of delivery (mean reduction 82ml, $p = 0.03$; 95%CI = -159 to -5). There were no significant differences in secondary outcomes when CAM was used in multiparous women apart from a 5.3 times increased risk of significant perineal trauma (6% vs 2%, $p = 0.004$) and those who had their labours induced after CAM had a higher risk of requiring an emergency caesarean section (5% vs 1%, $p = 0.012$). There was no difference on shoulder dystocia and neonatal admissions rates with CAM.
Conclusion: There is no reduction in induction of labour rates with the use of CAM. The other effects of CAM on labour and delivery outcomes are varied and potentially only beneficial in a selected group of women. Further research must be carried out before making any clear recommendations on its use.

1. Introduction

During pregnancy many women prefer to avoid taking medications and may seek alternative options to manage pregnancy and non-pregnancy health conditions. A significant proportion of pregnant women use complementary therapy and alternative medicine (CAM) worldwide [1, 2, 3, 4, 5], as do a substantial part of the general population [6]. CAM includes a range of non-pharmaceutical treatment modalities such as reflexology, massage, acupressure, yoga, aromatherapy, hypnosis and herbal therapies. Studies from around the world have estimated the use of CAM in pregnancy to be generally widespread [4, 7] CAM has been used in various stages of pregnancy for relief of common symptoms such as nausea and vomiting [8]. It is also known to be used for perinatal mental health problems and for pain relief during labour [9, 10]. However, the use of CAM in later stages of pregnancy such as induction of labour has not been explored as extensively.

The number of women having their labour induced is on the rise in the UK, with an approximate rate of increase at 1–2% per annum and national rates for 2014/2015 at 26.8% [11]. Robust evidence evaluating the association between induction of labour and the risk of caesarean section is lacking [12]. There is some evidence that induction of labour increases the risk of caesarean section, particularly for nulliparous

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women as reported by Vrouenraets and colleagues [13]. National guidance currently suggests that when pregnancy exceeds the 40 weeks estimated due date (EDD), an induction of labour should be offered to women from 41 weeks [14]. The process of induction of labour incorporates techniques such amniotomy with or without vaginal prostaglandins and intravenous oxytocin. It should be noted that women's experiences of undergoing induction are not always positive [15]. The perception of increased pain experienced during induction of labour, longer hospital inpatient stay and the subsequent effect on immediate family has prompted women to pursue other less medicalised methods to encourage onset of labour. One study found the usage of CAM in pregnancy to be as high as 87% [7]. Some women may not fully disclose their use of CAM to healthcare professionals which may be dangerous, particularly where CAM is contraindicated with pre-existing medical conditions or medications.

In line with directives set to promote normal birth and reduce interventions rates, maternity units have sought different means to promote normality. A study of 66 post-date women by Ingram and colleagues found that women using shiatsu were significantly more likely to labour spontaneously, with increased number going into labour if they used the three acupressure points (GB21, SP6, LI4) [16]. Other units have demonstrated some successes from post-dates CAM clinics [17, 18]. A Cochrane systematic review of the use of acupuncture for the inducing labour in post-dates pregnancies showed mixed results and concluded the need for well-designed randomised control trials to objectively assess outcomes [19]. A systemic review by Mollart et al found that the use of acupressure may reduce length of labour particularly in the first stage [20].

Within the authors' NHS Trust a service was established in November 2012 for low risk, post-dates women to attend a joint clinic of CAM with an antenatal check and an optional membrane sweep. The CAM provided combined approach of acupressure, reflexology and aromatherapy massage. Manual stimulation of specific acupressure and reflex zone points may stimulate uterine contractions whilst aromatherapy massage may have a role in reducing pain in labour [21]. Aromatherapy has also been shown to significantly reduce stress and enhance immune function in pregnant women which may be useful in labour [22]. Similarly, another study suggested aromatherapy can be effective in reducing maternal anxiety, fear and pain in labour [23].

Stimulation of the foot reflexology point for the pituitary gland aims to facilitate oxytocin output [24]. From our initial data we observed a reduction in the number of post-dates inductions as a result of the clinic [18]. Patient feedback surveys obtained from women who attended the clinic were also extremely positive. These preliminary results were encouraging however in order for us to fully evaluate the service and effects of CAM it was decided that an extended review of our data collected and outcomes were needed.

2. Methods

2.1. Study design, setting and participants

This was a service evaluation project and a formal permission was sought from local Research & Development department. A written approval letter (R&D reference number 001/SEP16) was received from R&D.

In this cohort study, we recruited women from 1st November 2012 to 30th June 2014 through a post-dates clinic set in one of the NHS district general hospitals in Cambridgeshire. The service was offered to low risk women from 40 weeks gestation who were referred to the clinic by their community midwife or obstetric team. All women without any antenatal risk factors who had been managed under midwifery-led care were considered as low risk. Exclusion criteria were previous caesarean section, spontaneous rupture of membranes (SROM), multiple pregnancy, any pre-existing medical conditions (e.g. diabetes, pre-eclampsia) and patients having an elective caesarean section. Both nulliparous and multiparous women were included in the study. Women were followed-up from onset of labour, whether spontaneous, induced or augmented till the end of third stage.

All women who attending the post-dates clinic had a standardised assessment by trained midwives involving a routine antenatal check with measurement of blood pressure, a urine dipstick analysis, abdominal palpation and auscultation of the fetal heart. An optional membrane sweep was offered and the final decision was recorded using a review tool. The procedure of CAM was fully explained to women by the midwife before verbal consent was obtained. The type of CAM performed consisted of acupressure, reflex zone therapy and aromatherapy massage in accordance with the regimen advocated by previous research protocols [25]. The first NHS Trust to utilise this regime was West Middlesex hospital who reported some success following implementation [17]. All CAM procedures were performed by midwives who were trained to provide the treatments.

Women first had acupressure performed on them. Three acupressure points were used; namely GB21, LI4 and SP6 as in indicated by Tiran, Ingram et al and Mollart et al.1 [16, 20, 24] GB21 is on the gallbladder meridian and located at the highest point of the shoulder, which was defined as the midpoint of a line between the seventh cervical vertebrae and the lateral extremity of the acromion. LI4 is on the large intestine meridian and located at the back of the hand between the thumb and forefinger, in the middle of the second metacarpal bone radially. SP6 is on the spleen meridian, located 3cm above the medial malleolus of the ankle. Reflexology was carried out next on the 'pituitary zone' on the big toe of both feet Firm, pulse-like pressure was applied 30 times to each big toe reflex zone and to each acupressure point, which was for approximately 30 s each, or for as long as the woman could tolerate.

Aromatherapy is currently the most commonly used complementary therapy despite the minimal evidence which exists regarding its use. Chen et al and Burns et al demonstrated that it may have positive effects in labour [22, 23]. Thus, a 10-min session of aromatherapy was included in our study. This was carried out using a specific combination of oils which was made by us. Tiran suggests a complementary post-dates regime which incorporates a 3% blend of the essential oils; lavender, clary sage and jasmine mixed within a base carrier oil such as grapeseed (i.e. 1 drop of each essential oil in 5ml of grapeseed) [26]. Locally, midwives trained in aromatherapy, blended a 3% blend containing 60 mL of grapeseed oil with 12 drops each of Jasmine, Lavender, and Clary Sage. The blended oil was used to massage the feet, shoulders or hands depending on the woman's preference. Any woman with allergies to any of the oils was massaged with grapeseed oil only.

Women who had opted for a vaginal examination and a membrane sweep had this performed before they received CAM. After CAM the fetal heart was auscultated for 1 min using a handheld sonicaid. The woman was allowed home from clinic if there were no further concerns. Follow up of these women was attended by their community midwife, and they were offered induction of labour (IOL) as per local protocol i.e. after 40^{+10} weeks of pregnancy.

2.2. Data measurement

A database was set up to capture relevant data from all women who had received CAM at the clinic. A review tool was devised for the clinic to enable data collection. Similar data was also obtained from a separate group of low risk women who had given birth at $\geq$40 weeks the year prior to the set-up of the clinic service (1st November 2011 to 30th October 2012) who had not received CAM. Additional data was retrieved from a maternity database software system and women's hospital notes. In both groups women were offered IOL as per the local protocol with prostaglandin analogues after 40^{+10} weeks of pregnancy if they did not go into spontaneous labour.

2.3. Outcomes

The primary outcome measured was the rate of induction of labour (IOL). Secondary outcomes included epidural rate, length of labour, use of oxytocin for induction or augmentation of labour, mode of delivery (vaginal delivery, instrumental delivery or emergency caesarean section), blood loss during delivery (EBL), primary postpartum haemorrhage (primary PPH) rate i.e. EBL>1500 ml, significant perineal trauma rate, shoulder dystocia rate and admission to special care (SCBU). Significant perineal trauma was defined as any perineal trauma that required repair in theatre including extensive 2nd, 3rd and 4th degree perineal tears.

2.4. Study size

In order to make this as valid a cohort study as possible a large number of data was reviewed. We included 397 women in the CAM group and 647 in the standard clinical care group (Control group).

2.5. Statistical methods

Categorical variables were analysed using Chi Square or Fisher's test to review the statistical difference. P value of ≤ 0.05 was considered statistically significant difference. 95% Confidence intervals were also obtained of a proportion.

Continuous variables were analysed using descriptive statistics with range, mean with standard deviation. Mean were compared using t test. Data was found to have a normal distribution; therefore, relevant comparative statistical tests were used to analyse the difference. P value of ≤ 0.05 was considered statistically significant difference.

3. Results

A total of 1044 women were included in this study, of which 397 received complementary therapy (CAM group) and 647 women received standard clinical practice (Control group). All suitable women were offered CAM at gestation $\geq$40 weeks.

Demographics of the population are described in Table 1. The study population included 57% nulliparous women in CAM group and 55% in control group. The CAM group had similar baseline demographics and clinical characteristics as the control group except that the proportion of women with BMI>30 was significantly higher in control group (20% vs 14%, p = 0.01). There was no statistically significant difference in the IOL rate in CAM and control group (37% vs 39%).

Results were compared first from all labours in the CAM and control groups. A further sub-analysis was carried out with comparison of results in primiparous and multiparous women, and into those who had spontaneously laboured or required induction of labour after CAM.

Table 1
Demographics of the population.

	Complementary Therapy group N = 397	Control Group N = 647
Age (years) mean (range; SD)	29.8 (16–45; 5)	29 (15–45; 6)
Nulliparous: n (%)	226 (57%)	356 (55%)
BMI: mean (range; SD)	24.7 (18–46; 4.4)	26 (15–63; 6)
*BMI>30: n (%)	54 (14%)	127 (20%)
Spontaneous onset of labour: n (%)	251 (63%)	398 (61%)
Induction of labour: n (%)	146 (37%)	249 (39%)
Gestation age at delivery: mean (range)	41^{+2} (40^{+0}- 42^{+6})	41^{+2} (40^{+0}- 43^{+1})
Birth weight (grams), mean (range; SD)	3704 (2710–4945; 411)	3682 (2415–5490; 446)
Neonatal admission: n (%)	6 (1.5)	15 (2.3)

*p = 0.01.

3.1. CAM versus control group: all labours (Table 2)

A similar proportion of women had IOL in the CAM group compared to the control group (37% vs 39%). In women who had IOL, the interval from induction to onset of labour was 2 h and 36 min longer for women in the CAM group compared to the control group (mean 17.2 vs 14.6 h, p = 0.009). This was also reflected in the duration from IOL to birth, which was 3 h and 12 min longer for women in the CAM group (mean 23.8 vs 21.2 h, p = 0.0001). Conversely, the length of labour, defined as the duration between onset of labour to end of third stage, was not significantly different in these groups. There was no difference in use of oxytocin for labour induction (41% vs 35%, p = 0.24) however use of oxytocin for augmentation of labour was 7.5 % less likely in the CAM group (17% vs 24.5%, p = 0.007; RR 0.68). The risk of significant perineal tears was more than twice as likely to occur in the CAM group (6.5 vs 3%, RR = 2.3, p = 0.008). There were no significant differences in epidural rates, mode of delivery, PPH rates, shoulder dystocia and neonatal admission rates in the CAM versus control group.

3.2. CAM versus control group: nulliparous women (Tables 3, 5 and 6)

To determine if the results obtained were influenced by parity, we divided and compared the data based on parity alone i.e. nulliparous and multiparous women (Tables 3 and 4). There was no significant difference between IOL rates in the CAM and control groups (44% vs 42%). However, we noted statistically significant differences in some secondary outcomes between the two groups. Nulliparous women in the CAM group were 20% less likely to require an epidural than those in the control

Table 2
All Labours-CAM versus Control group.

All Labours	CAM Group	Control Group	Statistical Significance
	All Labours N = 397	All Labours N = 647	
In Induction group IOL to Onset of labour Interval (hours), mean (range; SD)	17.2 (1–109; 20)	14.6 (1–189; 18)	2.6 h more in CAM group; P = 0.009
In Induction group IOL to Delivery Interval (hours), mean (range; SD)	23.8 (1–128; 21.5)	21.2 (1–200; 19.2)	3.2 h more in CAM group; p = 0.0001
**Length of labour (hours), mean (range; SD)	6.5 (0.5–36; 4.4)	7.2 (0.5–42; 5)	p = 0.75
Epidural* rate: n (%)	110 (28)	213 (33)	p = 0.08
Use of oxytocin for induction: n (%)	60 (41)	87 (35)	p = 0.24
Use of oxytocin for labour augmentation: n (%)	56 (17)	137 (24.5)	P = 0.007; RR = 0.68 (CI 0.5–0.9)
Vaginal delivery with no intervention (including vaginal breech delivery): n (%)	276 (69.5)	451 (70)	p = 0.9
***Instrumental: n (%)	63 (16)	127 (20)	p = 0.1
Emergency Caesarean Section (EMCS): n (%)	58 (15)	69 (11)	p = 0.1
Mean Blood loss in all deliveries ml (SD)	458 (384)	477 (451)	p = 0.5
Mean Blood loss excluding caesarean sections: n (SD)	410 (340)	435 (425)	p = 0.36
Major PPH(>1500ml) in vaginal deliveries: n/total vaginal deliveries (%)	10/339 (3)	24/578 (4)	p = 0.47
Significant Perineal Trauma: n (%)	22/339 (6.5)	16/578 (3)	p = 0.008; RR 2.3 (95% CI 1.2–4)
Shoulder dystocia: n (%)	6/339 (2)	9/578 (1.6)	p = 0.79
Neonatal Admission: n (%)	6 (1.5)	15 (2.3)	p = 0.40

* Epidural for labour analgesic.
** Length of labour-from onset of labour to delivery.
*** includes both ventouse and forceps delivery.

Table 3
CAM versus Control in Nulliparous women.

All Nulliparous Women	CAM N = 397	Control N = 647	Statistical Significance
	Nulliparous N = 226 (57%)	Nulliparous N = 356 (55%)	
Age Mean (range; SD)	28.6 (16–42; 5)	28.1 (15–44; 5.7)	p = 0.28
BMI Mean (range; SD)	24.3 (18–46; 4.2)	25.1 (15–48; 5)	p = 0.04
Induction of labour rates: n (%)	100 (44)	148 (42)	p = 0.52
*Epidural rate: n (%)	92 (41)	180 (50.5)	RR = 0.80 CI = 0.67–0.9 p = 0.02
**Length of labour (hours), mean (range; SD)	8.4 (1–36; 5)	10 (1–42; 5)	1.6 h less p = 0.0002 95% CI-2.4 to -0.76
Use of syntocinon for induction: n/total induction (%)	50/100 (50)	70/148 (47.3)	p = 0.70
Use of syntocinon for labour augmentation: n (%)	52 (23)	124 (35)	RR = 0.64 95%CI = 0.48 to 0.85 p = 0.002 NNT = 8
Vaginal (including breech) delivery with no intervention: n (%)	118 (52)	177 (50)	p = 0.5
***Instrumental: n (%)	58 (26)	115 (32)	p = 0.09
Emergency Caesarean Section (EMCS): n (%)	50 (22)	64 (18)	p = 0.22
Mean blood loss in all deliveries (ml): n (SD)	498 (360)	580 (515)	p = 0.03 (95%CI = -159 to -5)
Mean blood loss excluding caesarean sections: n (SD)	453.5 (356)	525 (498)	p = 0.09
Major PPH(>1500ml) in vaginal deliveries: n (%)	6/176 (3)	17/292 (6)	p = 0.24
Significant Perineal Trauma: n (%)	16/176 (9)	14/292 (5)	p = 0.08
Shoulder dystocia: n (%)	1/176 (0.6)	5/292 (2)	p = 0.3
Neonatal Admissions: n(%)	6 (2.7)	12 (3.4)	p = 0.6

Table 4
CAM versus Control in Multiparous women.

All Multiparous Women	CAM N = 397	Control N = 647	Statistical significance
	Multiparous N = 171	Multiparous N = 291	
Age Mean (range; SD)	31.4 (22–45; 4.6)	30.8 (18.5–45; 5.2)	p = 0.21
BMI Mean (range; SD)	25.2 (18–38; 4.5)	26.2 (17–63; 6)	p = 0.004, 95% CI -1.7 to -0.3
Induction of labour rates: n (%)	46 (27)	101(35)	p = 0.09
*Epidural rate: n (%)	18 (10.5)	33 (11)	p = 0.79
**Length of labour (hours), mean (range; SD)	4.2 (0.5–15; 3)	4.4 (0.5–28; 3.4)	p = 0.52
Use of syntocinon for induction: n (%)	11 (6.4)	17 (6)	p = 0.80
Use of syntocinon for labour augmentation: n (%)	7 (4)	13 (4.5)	p = 0.85
Vaginal (including breech) delivery with no intervention: n (%)	158 (92)	274 (94)	p = 0.47
***Instrumental: n (%)	5 (3)	12 (4)	p = 0.51
Emergency Caesarean Section (EMCS): n (%)	8 (5)	5 (1.7)	p = 0.08
Mean blood loss in all deliveries (ml): n (SD)	405 (409)	351.4 (314)	p = 0.11
Mean blood loss excluding caesarean sections: n (SD)	363 (316)	343 (309)	p = 0.51
Major PPH(>1500mls) in vaginal deliveries: n (%)	4/163 (2.5)	7/286 (2.4)	p = 1.0
Significant Perineal Trauma: n/total vaginal deliveries (%)	6/163 (4)	2/286 (0.7)	RR = 5.3 p = 0.04, 95%CI = 1.1–25
Shoulder dystocia: n (%)	5/163 (3)	4/286 (1.4)	p = 0.24 RR = 2
NICU Admissions: n(%)	0	3	-

group (RR 0.8, p = 0.02). The CAM group was also 36% less likely to require oxytocin use for labour augmentation (RR 0.64, p = 0.0002) and were more likely to have a shorter length of labour (8.4 vs 10 h, p = 0.0002). Mean blood loss was also significantly less in the CAM group (360 ml vs 515ml, p = 0.03).

The above benefits were noted to be statistically significant in the subgroup of nulliparous women who went into spontaneous labour after having CAM. Epidural rates were 32% lower in nulliparous women who spontaneously laboured (RR 0.68, p = 0.01), however no difference was found in those who had their labours induced. The mean length of labour was also 1hour 36 min less in spontaneous labourers in the CAM group (p = 0.004, 95% CI-2.9 to -0.52) and no difference found in those who had their labours induced. The CAM group was 27% less likely to require oxytocin for labour augmentation in both spontaneous (27%, p = 0.002) as well as in induced (57%, p = 0.007) labours. Nulliparous women in the CAM group were 30% more likely to achieve a normal vaginal delivery without intervention (RR 1.3, p = 0.006) (Table 6) if they laboured spontaneously but conversely 27% less likely if labour was induced (RR 0.73, p = 0.04). Incidentally nulliparous women who had IOL after CAM also had an 80% increased risk of having an emergency caesarean section (EMCS) (p = 0.005; RR1.8) (Table 6).

3.3. CAM versus control group: multiparous women (Tables 4, 5, and 6)

There were no statistically significant advantages of using CAM in multiparous women in fact the CAM group had a 5.3 times increased risk of significant perineal trauma (4% vs 0.7%, p = 0.004). This increase was not reflected in the instrumental delivery rates. Both CAM and control groups had similar normal vaginal delivery rates (92 vs 94%). As with the nulliparous group, we investigated these results further and compared the outcomes in multiparous women based on whether they spontaneously laboured or were induced after CAM. We found no evidence of benefit of CAM in multiparous women who went into spontaneous labour. These women also had an increased risk of significant perineal trauma compared to their counterparts yet this risk was not evident in multiparous women who were induced. In multiparous women who were induced after CAM, the striking significant risk observed was an 11 times higher risk of EMCS (p = 0.012; RR 11) (Table 6).

The overall benefits and risks of CAM in nulliparous and multiparous women are summarised concisely in Table 7.

4. Discussion

Despite the limited evidence around the use of CAM, many trusts in United Kingdom are offering this service with the rationale that CAM reduces the risk of IOL and other medical interventions in an otherwise low risk pregnancy. The use of reflexology and foot massage also tends to attract excellent feedback from women. We conducted our study to establish the effects of CAM on induction of labour in post-dates women and specifically in the subgroups of parity and onset of labour. There is a lack of research into the use of CAM in later stages of pregnancy and previous studies have shown inconsistent outcomes. Our findings from initial data showed an apparent reduction in post-dates induction rates however our final results showed no significant overall effect of CAM on reducing induction of labour or on increasing spontaneous vaginal delivery rates.

The effects of CAM may be beneficial only in a selective group of women, as described in our results above. Nulliparous women were more likely to have a shorter labour, less likely to require oxytocin

Table 5
Nulliparous vs Multiparous; Spontaneous labours.

Spontaneous labours N = 649	Nulliparous N = 334			Multiparous N = 315		
	CAM N = 126 (38%)	Control N = 208 (62%)	Statistical significance	CAM N = 125 (40%)	Control N = 190 (60%)	Statistical significance
Age Mean (range; SD)	28 (16–42; 5.1)	28 (15–41; 5.6)	p = 1	31.3 (22–42; 4.3)	30.7 (19–45.3; 5.2)	p = 0.28
BMI, mean (range; SD)	24 (19–37; 4)	25 (15–47.5; 5)	p = 0.06	25 (19–38; 4)	26 (17–63; 6)	p = 0.1
Epidural* rate: n (%)	36 (29)	87 (42)	p = 0.01 95%CI 0.49 to 0.9 RR = 0.68	7 (6)	17 (9)	p = 0.39
GA at delivery, mean (range)	40^{+6} (40^{+0}-41^{+3})	41^{+1} (40^{+1}-42^{+0})		41^{+0} (40^{+1}-42^{+2})	41^{+1} (40^{+1}-42^{+0})	
** Length of labour (hours), mean (range; SD)	8.6 (1–36; 5)	10.3 (2–42; 5.5)	1.7 h less p = 0.004 95% CI -2.9 to -0.52	4.5 (0.5–15; 3)	5 (1–16; 3)	p = 0.15
Use of syntocinon for labour augmentation: n(%)	38 (30)	86 (41)	P = 0.04 95%CI 0.53 to 0.90 RR = 0.73	4 (3)	8 (4)	p = 0.77
Vaginal (including breech) delivery with no intervention: n (%)	82 (65)	104 (50)	p = 0.006 95%CI 1.08 to 1.56 RR = 1.3	119 (95)	179 (94)	p = 0.80
***Instrumental: n (%)	32 (25)	72 (35)	p = 0.09	3 (2)	7 (4)	p = 0.75
Emergency Caesarean Section: n(%)	12 (10)	32 (15)	p = 0.14	3 (2)	4 (2)	p = 1.0
Mean blood loss in all deliveries (ml), mean (range; SD)	470 (50–2200; 369)	540 (100–3375; 468)	p = 0.15	384 (100–2000; 356)	321 (100–2400; 234)	p = 0.06
Blood loss excluding caesarean sections (ml), mean (range; SD)	445 (50–2200; 357)	476 (100–3200; 403)	p = 0.50	362 (50–1900; 319)	310 (100–2400; 222)	p = 0.09
Major PPH(>1500mls) in vaginal deliveries: n/vaginal deliveries (%)	4/114 (3.5)	6/176 (3)	p = 1.0	3/122 (2.5)	1/186 (0.5)	p = 0.30
Episiotomy: n/vaginal deliveries (%)	47/114 (41)	85/176 (48)	p = 0.28	5/122 (4)	15/186 (8)	p = 0.24
Birth Weight (grams), mean (range; SD)	3619 (2730–4460; 378)	3609 (3600–4890; 412)	p = 0.82	3768 (2900–4945; 402)	3730 (2885–4950; 429)	p = 0.43
Significant Perineal Trauma: n/vaginal deliveries (%)	11/114 (10)	9/176 (5)	p = 0.16	5/122 (4)	0	-
Shoulder dystocia: n/vaginal deliveries (%)	0	5/176 (3)	-	3/122 (2.5)	2/186 (1)	p = 0.39
Neonatal Admission: n (%)	4 (3)	6 (3)	p = 1.0	0	3 (2)	-

Table 6
Nulliparous vs Multiparous; Induced labours.

Induced labours N = 395/1044	Nulliparous N = 248			Multiparous N = 147		
	CAM N = 100	Control N = 148	Statistical significance	CAM N = 46	Control N = 101	Statistical significance
Age Mean (range; SD)	29.3 (18–40; 5.1)	28.3 (18–44; 5.9)	p = 0.17	31.6 (23–45; 5.5)	31 (18.5–42; 5.4)	p = 0.54
BMI, mean (range; SD)	25 (18–46; 5)	26 (16.8–43.7; 5)	p = 0.12	26 (18–38; 5)	27 (17.3–57; 7)	p = 0.93
Epidural* rate: n(%)	54 (54)	93 (63)	p = 0.18	11 (24)	16 (16)	p = 0.26
Gest age at del, mean (range)	41^{+6} (39^{+5}-42^{+6})	41^{+4} (40^{+0}-42^{+4})		41^{+4} (40^{+3}-42^{+3})	41^{+1} (40^{+0}-43^{+1})	
IOL-Onset of labour interval (days), mean (range; SD)	19 (0–109; 22)	17 (0–189; 21)	p = 0.47	13 (0–64, 15)	12 (0–85; 13)	p = 0.68
Length of labour**(hours): Range, Mean, (SD)	8 (1–19; 4)	9 (1–27; 5)	p = 0.09	3.5 (0.5–12; 3)	3.5 (0.5–28; 4)	p = 1.0
Use of syntocinon for induction: n (%)	50 (50)	70 (47)	p = 0.70	10 (22)	17 (17)	p = 0.47
Use of syntocinon for labour augmentation: n (%)	11 (11)	38 (26)	p = 0.007 95%CI 0.23 to 0.79 RR 0.43	3 (6.5)	5 (5)	p = 0.71
Vaginal (including breech) delivery with no intervention: n (%)	36 (36)	73 (49)	p = 0.04 95%CI 0.53 to 0.9 RR = 0.73	39 (85)	95 (95)	p = 0.11
***Instrumental: n (%)	26 (26)	43 (29)	p = 0.67	2 (4)	5 (5)	p = 1.0
Emergency Caesarean Section (EMCS): n (%)	38 (38)	32 (22)	p = 0.005 95%CI 1.2 to 2.6 RR 1.8	5 (11)	1 (1)	p = 0.012 95%CI 1.3 to 91 RR = 11
Mean blood loss in all deliveries (ml), mean (range; SD)	532 (100–2148; 348)	636 (100–4200; 572)	p = 0.11	463 (50–3200; 528)	408 (50–2300; 421)	p = 0.50
Mean blood loss excluding caesarean sections ml), mean (range; SD)	469 (100–2148; 354)	599 (100–4200; 609)	p = 0.12	366 (50–1500; 310)	404 (50–2300; 421)	p = 0.60
Major PPH(>1500mls) in vaginal deliveries: n (%)	2/62 (3)	10/116 (9)	p = 0.22	0/41	4/100 (4)	p = 0.32
Episiotomy: n/vaginal deliveries (%)	34/62 (55)	57/116 (49)	p = 0.53	4/41(10)	4/100 (4)	p = 0.23
Birth Weight (grams), mean (range; SD)	3685 (2750–4820; 401)	3678 (2505–4910; 479)	p = 0.90	3804 (2710–4830; 499)	3747 (2605–5490; 477)	p = 0.51
Significant Perineal Trauma: n/vaginal deliveries (%)	5/62 (8)	5/116 (4)	p = 0.32	1/41 (2)	2/100 (2)	p = 1.0
Shoulder dystocia: n/vaginal deliveries (%)	1/62 (2)	0/116	-	2/41 (5)	2/100 (2)	p = 0.58
Neonatal admission: n (%)	2 (2)	6 (4)	p = 0.48	0	0	-

Table 7
Benefits and Risks of Complementary Therapy compared to standard control group.

Use of complementary therapy	Nulliparous (All labourers, spontaneous & induced)	Multiparous (All labourers, spontaneous & induced)
Benefits	20% less likely to require epidural Shorter labour (1.6 h) 36% less likely to require oxytocin augmentation for labour Reduced average blood loss at delivery (regardless of mode of delivery)	
Risks		5 times more likely to have significant perineal trauma
No Difference	IOL, mode of delivery, major PPH, shoulder dystocia, perineal trauma and neonatal admission rates	No clear advantage at reducing chances of induction/oxytocin induction, epidural rates, length of labour, need for emergency caesarean section nor blood loss at delivery, shoulder dystocia and neonatal admission rates

Use of complementary therapy	Nulliparous	
	Spontaneous labours	Induced labours
Benefits	32% less likely to require epidural Shorter labour (1.7hours) 27% less likely to require oxytocin augmentation for labour 30% more likely to achieve a vaginal delivery without intervention	57% less likely to need oxytocin augmentation for labour
Risks	-	24% less likely to achieve a vaginal delivery without intervention 80% more likely to have an emergency caesarean section
No Difference	Gestational age at delivery, instrumental delivery or EMCS, blood loss, major PPH, neonatal birth weight, perineal trauma, shoulder dystocia and neonatal admission rates	Epidural rate, length of labour, use of oxytocin for IOL, Gestational age at delivery, instrumental delivery, blood loss, major PPH, neonatal birth weight, perineal trauma, shoulder dystocia and neonatal admission rates

Use of complementary therapy	Multiparous	
	Spontaneous labours	Induced labours
Benefits	No apparent benefits	No apparent benefits
Risks		11 times more likely to have an emergency caesarean section
No Difference	No clear advantage on reducing epidural rates, length of labour, need for oxytocin augmentation. Gestational age at delivery, mode of delivery, blood loss, major PPH, neonatal birth weight, perineal trauma, shoulder dystocia and neonatal admission rates	No clear advantage on reducing need for oxytocin augmentation, epidural rates, length of labour and instrumental delivery Gestational age at delivery, blood loss, major PPH, neonatal birth weight, perineal trauma, shoulder dystocia and neonatal admission rates

augmentation in labour and significantly less likely to have an epidural for analgesia in labour. There was reduced average blood loss at delivery regardless of the mode of delivery and these effects appeared to be more evident in nulliparous women who laboured spontaneously after receiving CAM. Nulliparous women who had their labours induced after receiving CAM had almost three times increased risk of having an EMCS. Similarly, a randomised controlled trial in Australia by Levett et al showed that nulliparous women who used CAM were more likely to have a reduced epidural use, reduced rate of labour augmentation, shorter labours, lower caesarean section rates and less perineal trauma [27]. The study did not note any significant differences in overall blood loss at delivery nor in rates of spontaneous onset of labour. In comparison there were six types of CAM used in this study which included acupressure, visualisation and relaxation, breathing, massage, yoga techniques, and facilitated partner support. It also involved a 2-day antenatal education programme which was more extensive than the service our hospital provided.

A systemic review by Mollart et al reported that the two most studied acupressure points were SP6 and LI4. It also concluded that acupressure may reduce the length of labour, particularly in the first stage [20]. Makvandi and colleagues conducted a meta-analysis which also suggested that acupressure may decrease the length of labour and reduce caesarean section rates [28].

The findings of this cohort study showed no significant differences in primary and secondary outcomes in multiparous women who received CAM. The most significant findings were in fact, that CAM was associated with a five times increased risk of sustaining significant perineal trauma. In terms of absolute numbers, there were six women in the multiparous CAM group versus two women in the multiparous control group with significant perineal trauma. There was no difference in maternal or perinatal outcomes if multiparous women laboured spontaneously after receiving CAM however if their labour was induced, there was an 11 times increased risk of EMCS. At the time of publication, we did not identify other CAM studies reporting a similar association with an increased risk EMCS.

One of the strengths of this cohort study is that it is the largest study focusing on the effects of CAM in labour and delivery outcomes conducted so far in low risk population after 40 weeks. Currently, limited data surrounding this topic of interest exists and to our knowledge, no other study has previously analysed the effects of CAM in subgroups such as parity and onset of labour. These results can therefore be used as a baseline data for future randomised controlled studies.

Any potential benefits or risks of CAM must be interpreted with caution due to the limitations of this study from self-selection bias and lack of a power calculation. Nulliparous women who accepted CAM may be more motivated to achieve a 'natural' labour and may have also opted to avoid having an epidural. These women would have been more mobile in labour, which would may have helped with progression in the latent, first and second stages. Additionally, if these patients were less likely to have oxytocin augmentation in labour this may have influenced the epidural rates, and subsequently resulted in slightly shorter labours. The finding of increased perineal trauma in multiparous women may have been incidental and involved only six women. Thus, it would require further investigation and larger trials to determine if this effect was of statistical significance or due to chance. This is also relevant to some of the results in the subgroup analysis e.g. multiparous women in the CAM group who had their labours induced ($n = 64$) had an 11 times increased risk of having an EMCS. Due to the limited size of the data these results should be interpreted with caution. Another limitation of this study is that only a single CAM session was offered to women and this may not accurately reflect the effects of CAM. A study involving more than one session of CAM would need to be conducted to evaluate this further.

This study did not take into consideration other factors which may influence a patient's perception of labour and delivery such as socio-economic status. The majority (>90%) of patients were of Caucasian ethnicity and perhaps future studies should review the effects of ethnicity

on outcomes. The demographics of both groups were similar apart from slightly higher number of obese (BMI>30) patients in the control group.

Our study suggested that there may be a place for the use of CAM particularly in nulliparous women within the limitations mentioned above. Also, our results showed no real benefits for multiparous women who laboured spontaneously after CAM. Therefore, we strongly recommend that women should be counselled appropriately regarding limitation of the data in this area, and that effects of CAM may vary according to parity and whether onset of labour is spontaneous or induced. Women should be informed that CAM may carry some risks in terms of use of oxytocin for induction or augmentation of labour, significant perineal trauma, and EMCS.

It would be pertinent to carry our further research into the effects of CAM on labour and delivery before making any clear recommendations on its use in pregnancy and certainly prior to consideration of establishing a regular CAM service at obstetric units nationally. Women should be counselled about the potential benefits and risks of CAM, and appropriate patient selection must take place. Larger scale randomised-controlled trials are needed to fully assess the risks and benefits of CAM in labour, induction and delivery outcomes.

5. Conclusions

The use of CAM has varied effects on induction of labour and delivery outcomes. There was no difference in induction of labour rates in women receiving CAM. However, CAM appeared to have a beneficial effect on certain secondary outcomes in nulliparous women. There was no demonstrable benefit of CAM in multiparous women. We noted a high rate of perineal tears in multiparous women receiving CAM though the absolute number (n = 4) of affected women was small and thus lacked statistical power to draw a conclusion from. Further research is needed to establish the benefits and risks of CAM in pregnancy based on parity.

Declarations

Author contribution statement

Li Mei Koh: Analyzed and interpreted the data; Wrote the paper.

Rebecca Percival: Performed the experiments; Contributed reagents, materials, analysis tools or data.

Tara Pauley: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data.

Sangeeta Pathak: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

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Competing interest statement

The authors declare the following conflict of interests: Tara Pauley and Rebecca Percival provided CAM clinic locally. The other authors declare no conflicts of interest.

Additional information

No additional information is available for this paper.

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