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Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial

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Objective To determine whether primary midwife care (caseload midwifery) decreases the caesarean section rate compared with standard maternity care.

Design Randomised controlled trial.

Setting Tertiary-care women's hospital in Melbourne, Australia.

Population A total of 2314 low-risk pregnant women.

Methods Women randomised to caseload received antenatal, intrapartum and postpartum care from a primary midwife with some care by 'back-up' midwives. Women randomised to standard care received either midwifery or obstetric-trainee care with varying levels of continuity, or community-based general practitioner care.

Main outcome measures Primary outcome: caesarean birth. Secondary outcomes included instrumental vaginal births, analgesia, perineal trauma, induction of labour, infant admission to special/neonatal intensive care, gestational age, Apgar scores and birthweight.

Results In total 2314 women were randomised–1156 to caseload and 1158 to standard care. Women allocated to caseload were less likely to have a caesarean section (19.4% versus 24.9%; risk ratio [RR] 0.78; 95% CI 0.67–0.91; $P = 0.001$); more likely to have a spontaneous vaginal birth (63.0% versus 55.7%; RR 1.13; 95% CI 1.06–1.21; $P < 0.001$); less likely to have epidural analgesia (30.5% versus 34.6%; RR 0.88; 95% CI 0.79–0.996; $P = 0.04$) and less likely to have an episiotomy (23.1% versus 29.4%; RR 0.79; 95% CI 0.67–0.92; $P = 0.003$). Infants of women allocated to caseload were less likely to be admitted to special or neonatal intensive care (4.0% versus 6.4%; RR 0.63; 95% CI 0.44–0.90; $P = 0.01$). No infant outcomes favoured standard care.

Conclusion In settings with a relatively high baseline caesarean section rate, caseload midwifery for women at low obstetric risk in early pregnancy shows promise for reducing caesarean births.

Keywords Caesarean, caseload midwifery, continuity of care, randomised controlled trial.

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Introduction

There is international concern about the growing proportion of women giving birth by caesarean section, particularly in high-income countries, given the increased risks in subsequent pregnancies (unexplained stillbirth,[1–3] placenta accreta and percreta,[1,2,4] placental abruption,[4] decreased fertility, ectopic pregnancy and spontaneous abortion[4]); increased infant morbidity (neonatal respiratory problems,[1,5]) and possible associations with childhood asthma,[6]

food allergies[6] and childhood-onset type 1 diabetes.[7] Caesarean section is also associated with slower maternal recovery from the birth,[8] and places an additional burden on the resources of health services.[8]

Reports from the USA and Australia have shown that the increase in caesarean births is related partly to nonclinical factors such as demographics, physician practice patterns and maternal choice.[9,10] In Australia, intervention rates are highest among women with private health insurance,[10,11] and there is concern about the high rate of planned caesarean section without medical indication.[10] In Victoria, Australia in 2008, 31% of births were by caesarean section; a rate that has doubled since 1985.[12]

Evidence from randomised controlled trials (RCTs) shows that midwife-led care is associated with a reduction in analgesia during labour, episiotomy and instrumental vaginal delivery, and an increase in spontaneous vaginal births, initiation of breastfeeding and women feeling of being in control during labour.[13] Many of these RCTs have also reported increased satisfaction for women,[14–16] with no statistically significant differences in overall fetal loss or death, although the numbers of deaths are relatively small and hence estimates of effect have wide confidence intervals.[13] An Australian RCT of team midwifery demonstrated a decrease in caesarean sections from 18% to 13%,[17] but when combined with other RCTs in a Cochrane review of midwife-led care, no differences were found in caesarean rates compared with standard care.[13]

In Australia in recent years, midwife-led models have focused more on continuity of carer (one-to-one models); however, the Cochrane review was dominated by 'team midwifery' models, where the effect of teams of care providers (commonly six to twelve midwives) was measured. In contrast, caseload midwifery is a model where women are cared for by a primary midwife (with one or two backup midwives) throughout pregnancy, birth and the early postnatal period. The Cochrane review included only two trials of caseload midwifery[18,19] (neither of which decreased caesarean births), and there is a lack of evidence regarding the safety and efficacy of the model.

This study aimed to determine whether caseload (one-to-one) midwifery care for women at low risk of obstetric complications decreases the proportion of women giving birth by caesarean section compared with women receiving standard care.

Methods

Study design and population

The study used a two-arm, randomised controlled design, to compare caseload midwifery care with standard maternity care. The primary outcome was caesarean section. Secondary outcomes including induction of labour, obstetric analgesia, instrumental vaginal births, perineal trauma, infant outcomes and postpartum length of hospital stay are also reported. Women identified as being at low obstetric risk were recruited from the Royal Women's Hospital (RWH), a public tertiary women's hospital in Melbourne, Australia, which has approximately 6500 births per year.

All eligible women booking to have a baby at the RWH between September 2007 and June 2010 were approached to participate (Figure 1). Inclusion criteria were: able to speak, read and write in English; fewer than 24 completed weeks gestation; a singleton pregnancy; and considered low obstetric risk at recruitment including an uncomplicated obstetric history–no history of: stillbirth or neonatal death, three or more consecutive miscarriages, previous fetal death *in utero*, previous preterm birth (<32 weeks), previous midtrimester loss/cervical incompetence/cone biopsy/known uterine anomaly, previous early onset of pre-eclampsia (<32 weeks gestation), or rhesus iso-immunisation; no complications during the current pregnancy (such as multiple pregnancy or fetal abnormality); and no precluding medical conditions (such as cardiac disease, essential hypertension, renal disease, pre-existing diabetes, previous gestational diabetes, epilepsy, severe asthma, substance use, significant psychiatric disorders and obesity [body mass index >35] or significantly underweight [BMI < 17]).[20] Women with a previous caesarean section were excluded. Data were collected on ineligibility and why women declined participation. Caseload midwifery was not available to women outside the trial.

Sample size

Initial power calculations were based on the caesarean rate for women who were at low risk at booking at the RWH in 2005. It was hypothesised that the caseload model would decrease the caesarean rate from 19% to 14%.[17] To detect such a difference (with 80% power and 95% confidence), 904 women were needed in each trial arm. Allowing for 10% loss to follow up, 2008 women were required—1004 in each group. However, given the rising caesarean rate, the data monitoring committee reviewed the sample size to check that the study remained adequately powered after two years of recruitment, and recommended an increase to 2290 (1145 women in each arm) to detect a 5% difference in the risk of caesarean section (from 25% to 20%, with 80% power and 95% confidence, assuming 1% loss to follow-up; as was being achieved).

Procedures

Research midwives approached potentially eligible women attending for their pregnancy booking visit in the antenatal clinic and explained the study. A few women contacted the research team directly and in those cases, eligibility was assessed, then a copy of the consent form and background

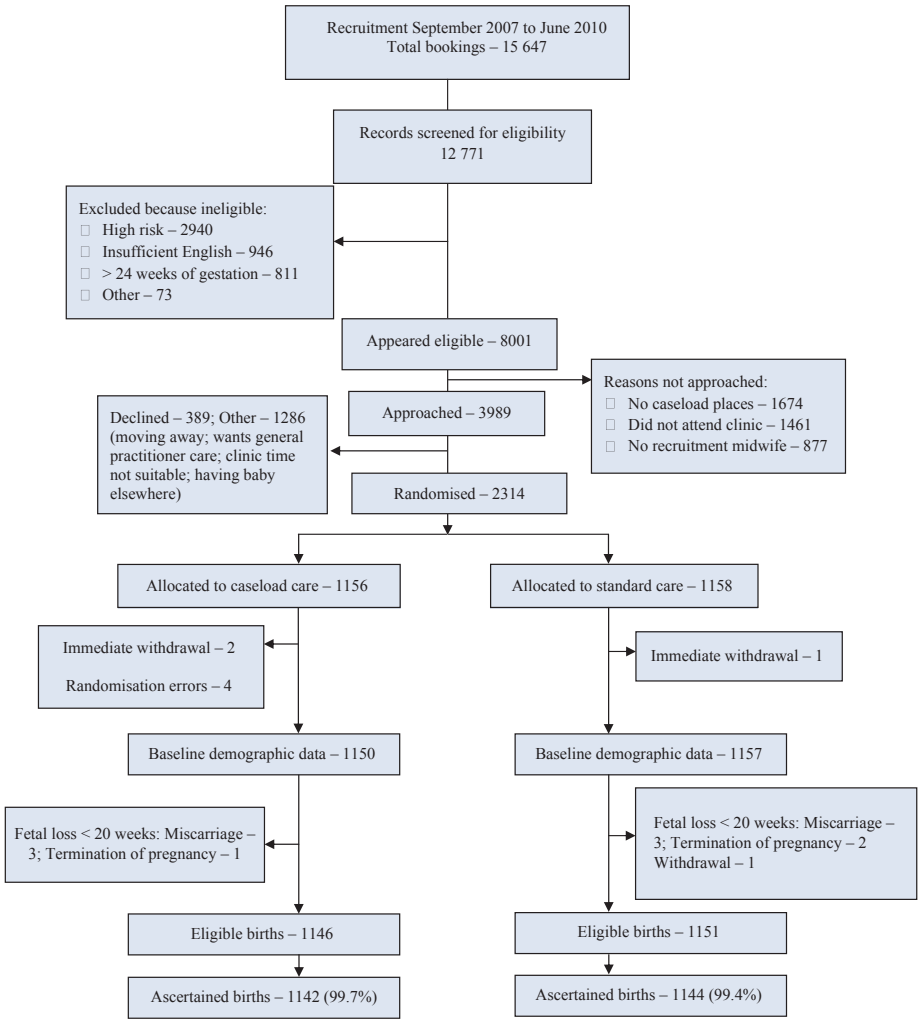

Figure 1. Trial profile.

questionnaire was mailed to women with a reply paid envelope. Women were randomised only after written consent was obtained and the background questionnaire (collecting demographic data) was completed. Randomisation was undertaken using an interactive voice response system activated by telephone (http://www.ctc.usyd.edu.au) using stratified permuted blocks of varying size.[20] Randomisation was stratified by parity (first or subsequent birth). Obstetric and medical outcome data (including type of birth) were obtained directly from the electronic obstetric database, blinded to treatment allocation. Data not available this way (e.g. continuity of carer) were manually abstracted (unblinded) from the medical record.

Caseload care

Women allocated to the intervention received the majority of their care from a 'primary' caseload midwife at the hospital. If complications developed, the primary midwife collaborated with obstetricians and other health professionals and continued to provide caseload care. During pregnancy, women saw an obstetrician at booking, at 36 weeks gestation and postdates if required, and usually had one or two visits with a 'back-up' midwife. Intrapartum care was provided in the hospital birthing suite. The primary midwife was on call for the woman's labour and birth except in designated circumstances such as annual leave, sick leave, having already worked more than 12 hours in a 24-hour period, having more than one woman in labour, or if it was on one of the two days per week that the midwife was scheduled neither to work nor be on call. Care was then provided by a back-up midwife, or on occasion, by non-caseload midwives. The primary midwife (or a back-up) attended the hospital on most days to provide some postnatal care and provided domiciliary care following discharge from hospital. Fulltime midwives had a caseload of 45 women per annum. All care was provided

according to hospital guidelines and protocols (Appendix S1 shows hospital guidelines used that are relevant to the study; see Supplementary material). During the trial there were 7.5 (at commencement) to 12 full-time equivalent midwives employed in caseload care, equating to 10–14 midwives.

Standard care

For women allocated to standard care, options included midwifery-led care with varying levels of continuity, obstetric trainee care and community-based care 'shared' between a general medical practitioner (GP) and the RWH, where the GP provided the majority of antenatal care. In the midwife and GP-led models women saw an obstetrician at booking, 36 weeks gestation and postdates if required, with other referral or consultation as necessary. In all standard-care options, women were cared for by whichever midwives and doctors were rostered for duty when they came into the hospital for labour, birth and postnatal care. Care was provided according to the same hospital guidelines and protocols as for the women in caseload care.

Intervention fidelity

At trial commencement, the caseload midwives attended information sessions emphasising the need to adhere to the RWH clinical guidelines and to provide caseload care as defined in the study protocol. Adherence to intervention protocols was measured via interviews with caseload midwives at the beginning and end of the trial; regular meetings between caseload midwives and research team members; and data collected from the medical records. Intervention exposure measures included assessing the extent to which care was provided by the primary midwife (medical record data) and women's recollection of having had a known care provider during labour, birth and the postnatal period (women's survey data two months postpartum, to be reported elsewhere).

Data analysis

Analyses were by intention to treat. Proportions of women having a caesarean section were compared using chi-square tests; risk ratios (RR) and their 95% confidence intervals (95% CI) were calculated. Comparison of means was undertaken for continuous variables using Student's *t* tests where data were normally distributed or medians were compared otherwise using Mann–Whitney *U* tests. STATA 10 was used for data analysis (Stata Corp., College Station, TX, USA).[21]

Results

Participants

Figure 1 shows the flow of participants through the trial. During the recruitment period September 2007 to June 2010, there were 15 647 bookings. Of those, 12 771 women's medical records were screened, from which 8001 women appeared eligible. Subsequently 3989 women were approached to participate. Reasons that women were not approached were: caseload bookings temporarily full because of the limited number of midwives employed in the model ($n = 1674$); non-attendance at a scheduled antenatal appointment ($n = 1461$); and no recruitment midwife available ($n = 877$).

Of the 2314 women recruited to the study, 1156 were allocated to caseload midwifery and 1158 to standard care. Six women in caseload care and one in standard care were excluded because they withdrew immediately or were randomised in error. Later, four women were lost from the caseload group because of fetal loss before 20 weeks of gestation, and six were lost from the standard care group because of fetal loss before 20 weeks of gestation ($n = 5$) and withdrawal ($n = 1$), resulting in 1146 and 1151 eligible births in the respective groups. There was over 99% ascertainment in both groups for the primary outcome.

Of women allocated to caseload care, 38 received other care: nine at the RWH (most of the remainder moved away from Melbourne). Of those allocated to standard care, 78% (900/1151) had antenatal care with midwives, 2% (20/1152) had obstetric trainee care; 15% (172/1151) had GP shared care; and 5% (59/1151) transferred their care from the RWH (at varying times during pregnancy) to other hospitals or alternative models such as birth centre care or home birth. In both trial arms, women had additional specialist obstetric care as required, and in both, a few women gave birth elsewhere after having all their care at the RWH (e.g. preterm births).

Demographic data are presented in Table 1. Background characteristics were similar in the two groups except for slight differences in government benefits as a main family income (3.7% caseload care; 5.9% standard care) and completion of a degree or diploma (77.5% caseload care; 74.0% standard care). There was no difference in gestation at booking.

Intervention exposure

Women allocated to caseload midwifery had a mean of 4.1 (SD 1.5) pregnancy visits with their primary midwife, and 98.7% (1125/1140) saw their primary midwife at least once. They had a mean of 1.8 (SD 1.2) pregnancy visits with a back-up midwife and 84.7% (966/1140) had at least one visit with a back-up midwife. During labour, either the primary or the back-up midwife provided intrapartum care for 89% of the women (1016/1142 births). The primary midwife provided intrapartum care 57% of the time (650/1142 births) and the back-up midwife 48% of the time (552/1142 births). On some occasions both the primary and back-up midwives provided care.

Table 1. Participant characteristics

	Caseload (*n* = 1150) *n* (%)	Standard care (*n* = 1157) *n* (%)
Age at booking visit, mean (SD)	31.2 (4.7)	31.3 (4.7)
Gestation at booking (weeks), mean (SD)	16.3 (2.8)	16.3 (2.9)
Expecting first baby	804 (70.0)	806 (69.7)
Married/living with partner (1133/1131)*	1079 (95.2)	1066 (94.3)
Highest education level (1132/1125)*		
Completed degree/diploma	877 (77.5)	833 (74.0)
Completed secondary school	187 (16.5)	210 (18.7)
Did not complete secondary school	68 (6.0)	83 (7.3)
Total family income/year (**AUD**) (1142/1134)*		
<$33,800 per year	123 (10.8)	137 (12.1)
$33,801–51,999 per year	201 (17.6)	170 (15.0)
$52,000–72,799 per year	218 (19.1)	238 (21.0)
$72.800–103,999 per year	311 (27.2)	298 (26.3)
$104,000 or more per year	289 (25.3)	291 (25.7)
Government benefit main family income (1146/1145)*	42 (3.7)	67 (5.9)
Employed (part-time or fulltime) (1133/1130)*	839 (74.1)	820 (72.6)
Smoked before pregnancy (1147/1145)*	199 (17.3)	208 (18.2)
Smoking at recruitment (1132/1135)*	44 (3.9)	36 (3.2)
Born in Australia (1119/1118)*	653 (58.4)	645 (57.7)
First language English (1144/1149)*	892 (78.0)	897 (78.1)
Intention to breastfeed (1139/1142)*	1104 (96.9)	1100 (96.3)

*Numbers in parentheses indicate number for whom this information was available (Caseload/Standard care).

Caesarean section

Women in the caseload arm were less likely to have a caesarean birth compared with women in standard care (19.4% versus 24.9%; RR 0.78; 95% CI 0.67–0.91; $P = 0.001$) (Table 2). Adjusting for the small baseline differences in pension and education did not change this, so unadjusted results are presented throughout.

Other outcomes

Table 3 shows that women in caseload care were more likely to have a spontaneous vaginal birth and this difference was most obvious in primiparous women (51.8% versus 41.5%; RR 1.25; 95% CI 1.12–1.39; $P < 0.001$). Instrumental births did not differ between the groups (17.7% versus 19.4%; RR 0.91; 95% CI 0.77–1.08; $P = 0.29$). Episiotomies were less common in the caseload group (23.1% versus 29.4%; RR 0.79; 95% CI 0.67–0.92; $P = 0.003$) and the rates of third-degree and fourth-degree tears did not differ. Epidural analgesia during labour was lower for women receiving caseload care (30.5% versus 34.6%; RR 0.88; 95% CI 0.79–0.996; $P = 0.04$). There was no difference between the groups in the proportion of women whose labour was induced, mean gestational age at birth, the proportion of women who gave birth before 37 weeks of gestation, estimated blood loss or postpartum haemorrhage rates.

There were no maternal deaths. Nine women in caseload care compared with three women in standard care were admitted to a high dependency or intensive-care unit ($P = 0.09$). For women in caseload care, reasons included: chorioamnionitis and postpartum haemorrhage ($n = 1$), eclampsia ($n = 1$), pre-eclampsia ($n = 1$), postpartum haemorrhage ($n = 4$), maternal cardiac abnormality ($n = 1$) and possible pneumonia ($n = 1$). In standard care reasons were postpartum haemorrhage ($n = 2$), and seizure secondary to hyponatraemia ($n = 1$).

Mean length of maternal postpartum stay was 55.4 hours (SD 0.97) in the caseload group and 60.5 hours (SD 0.78) in the standard care group ($P < 0.001$). Including only women who had a vaginal birth, the mean was 49.8 hours (SD 1.0) in the caseload group and 53.5 hours (SD 0.8) in standard care ($P = 0.005$). There was no difference for women who had a caesarean birth–caseload care 79.1 hours (SD 2.0) and standard care 81.3 hours (SD 1.2) ($P = 0.3$).

Infants of women allocated to caseload care were less likely to be admitted to the special-care nursery or neonatal intensive-care unit (4.0% versus 6.4%; RR 0.63; 95% CI 0.44–0.90; $P = 0.01$), with no difference in neonatal intensive-care unit admissions (1.3% versus 1.9%, RR 0.71; 95% CI 0.37–1.40; $P = 0.31$). No infant outcomes favoured standard care (Table 4). Five babies in the caseload group and

Table 2. Primary outcome: caesarean section

	Caseload (*n* = 1142) *n* (%)	Standard (*n* = 1144) *n* (%)	RR (95% CI)	*P* value
Caesarean section	221 (19.4)	285 (24.9)	0.78 (0.67–0.91)	0.001
Unplanned	186 (16.3)	245 (21.4)	0.76 (0.64–0.90)	0.002
Planned	35 (3.1)	40 (3.5)	0.88 (0.56–1.37)	0.56
Caesarean—primiparas only (802/793)*	200 (24.9)	257 (32.4)	0.77 (0.66–0.90)	<0.001
Unplanned	173 (21.6)	227 (28.6)	0.75 (0.63–0.89)	0.001
Planned	27 (3.4)	30 (3.8)	0.89 (0.53–1.48)	0.65
Caesarean—multiparas only (340/351)*	21 (6.2)	28 (8.0)	0.78 (0.45–1.34)	0.36
Unplanned	13 (3.8)	18 (5.1)	0.75 (0.37–1.50)	0.41
Planned	8 (2.3)	10 (2.9)	0.83 (0.33–2.07)	0.68

NB: Subgroup analyses by parity and planned/unplanned caesarean were not pre-specified in the protocol
*Numbers in parentheses indicate number for whom this information was available (Caseload/Standard care)

Table 3. Secondary maternal outcomes

	Caseload (*n* = 1142) *n* (%)	Standard (*n* = 1144) *n* (%)	RR (95% CI)	*P* value
Birth type (caesarean births included in denominator)				
SVB	719 (63.0)	637 (55.7)	1.13 (1.06–1.21)	<0.001
Instrumental	202 (17.7)	222 (19.4)	0.91 (0.77–1.08)	0.29
Forceps	67 (5.9)	88 (7.7)	0.76 (0.56–1.0)	0.08
Vacuum	135 (11.8)	134 (11.7)	1.0 (0.81–1.3)	0.94
Birth type (primiparas only) (803/793)*				
SVB	415 (51.8)	329 (41.5)	1.25 (1.12–1.39)	<0.001
Instrumental	187 (23.3)	207 (26.1)	0.89 (0.75–1.06)	0.20
Forceps	63 (7.9)	83 (10.5)	0.75 (0.55–1.03)	0.07
Vacuum	124 (15.5)	124 (15.6)	0.99 (0.79–1.24)	0.92
Onset of labour**				
Spontaneous (1082/1036)*	767 (70.9)	718 (69.3)	0.95 (0.83–1.08)	0.43
Gestation at birth (weeks)				
Mean, SD (1111/1086)*	39.5 (1.8)	39.4 (2.1)	*t* = 1.65	0.1
<37 weeks (1111/1086)*	42 (3.8)	45 (4.1)	0.91 (0.60–1.4)	0.66
Epidural analgesia in labour**				
All women (1068/1035)*	326 (30.5)	358 (34.6)	0.88 (0.79–0.996)	0.04
Primiparae only (741/712)*	290 (39.1)	325 (45.6)	0.86 (0.76–0.97)	0.01
Estimated blood loss (1109/1084)*				
Mean, SD	400 (360)	402 (315)	*t* = 0.14	0.89
≥1000 ml	53 (4.8)	65 (6.0)	0.80 (0.56–1.13)	0.21
Perineal trauma (vaginal births)				
Episiotomy (901/811)*	208 (23.1)	238 (29.4)	0.79 (0.67–0.92)	0.003
Episiotomy (SVB only) (702/597)*	63 (9.0)	76 (12.7)	0.70 (0.51–0.96)	0.03
Third- or fourth-degree tear (821/722)*	41 (5.0)	38 (5.3)	0.95 (0.62–1.5)	0.81

SVB, spontaneous vaginal birth.
NB: Subgroup analyses by parity and planned/unplanned caesarean were not pre-specified in the protocol
*Numbers in parentheses indicate number for whom this information was available (Caseload/Standard care).
**Excludes women with no labour.

nine in the standard care group were stillborn (defined as at least 20 weeks of gestation or, if gestation was unknown, weighing at least 400 g),[12] or had an early neonatal death (data were only available to discharge from hospital) (Tables 4 and 5). Of the stillbirths and neonatal deaths, one caseload care infant, and six standard care infants had a fetal anomaly. All neonatal deaths occurred within one hour of birth (Table 5). The perinatal death rate in this

Table 4. Infant outcomes

	Caseload (*n* = 1146) *n* (%)	Standard (*n* = 1151) *n* (%)	RR (95% CI)	*P* value
Apgar <7 at 5 minutes (1112/1080)*,**	15 (1.4)	20 (1.9)	0.73 (0.37–1.41)	0.35
Stillbirth/neonatal death in hospital (per 1000 births) (*n* = 1142/1143)*	5 (4.4)	9 (7.9)	0.56 (0.19–1.65)	0.28
SCN or NICU** admission (1122/1111)*	45 (4.0)	71 (6.4)	0.63 (0.44–0.90)	0.01
NICU admission (1139/1137)*,**	15 (1.3)	21 (1.9)	0.71 (0.37–1.40)	0.31
Small for gestational age (birthweight <10th percentile) (1107/1078)*	91 (8.2)	111 (10.3)	0.80 (0.61–1.04)	0.09
Low birthweight <2500 g (1,107/1,083)*	29 (2.6)	48 (4.4)	0.59 (0.38–0.93)	0.02
Mean birthweight (g) (1107/1083)* (mean, SD)	3477 (542)	3449 (584)	*t* = −1.14	0.25

NICU, neonatal intensive-care unit; SCN, special-care nursery.
*Numbers in parentheses indicate number for whom this information was available (Caseload/Standard care).
**Live births only.

Table 5. Perinatal mortality

	Diagnosis	Gestation (weeks)	Cause
Caseload (*n* = 5)	Neonatal death*	24	Induced for fetal anomaly
	Stillbirth	23	Preterm, prelabour rupture of membranes
	Stillbirth	25	Fetal death *in utero* (antepartum haemorrhage at 23 weeks; decreased fetal movements)
	Neonatal death*	24	Antepartum haemorrhage at 21 weeks
	Stillbirth	41	Fetal death *in utero* (decreased fetal movements 24 hours; polyhydramnios; possible group B streptococcus).
Standard care (*n* = 9)	Stillbirth	25	Fetal death *in utero* (decreased fetal movements 24 hours).
	Stillbirth	30	Fetal death *in utero* (placental abruption)
	Stillbirth	21	Fetal death *in utero* (multiple abnormalities; placental infarction)
	Stillbirth	23	Induced for fetal anomaly
	Neonatal death*	22	Induced for fetal anomaly
	Stillbirth	23	Induced for fetal anomaly
	Neonatal death*	23	Induced for fetal anomaly
	Stillbirth	22	Induced for fetal anomaly
	Stillbirth	40	Unknown (no autopsy); maternal pre-eclampsia

*All neonatal deaths <1 hour from time of birth.

study compares favourably with 12.4 perinatal deaths and 9.4 stillbirths per 1000 births in Victoria as a whole in 2008,[12] although they are not directly comparable because the statewide rate includes stillbirths and neonatal deaths within 28 days of birth, whereas the rates in this study include stillbirths and those neonatal deaths that occurred before hospital discharge; and the statewide rate includes babies born to women at all levels of risk, whereas this study included only women at low risk of complications.

Discussion

This randomised controlled trial showed that caseload midwifery for women at low obstetric risk in early pregnancy reduced the caesarean section rate compared with standard maternity care. The difference was primarily related to a reduction in unplanned caesareans. The larger proportion of women with a spontaneous vaginal birth in the caseload group was essentially explained by fewer caesareans because instrumental births did not differ. Reductions were also seen in epidural pain relief for labour, episiotomy, maternal postpartum length of hospital stay, infant special-care nursery or neonatal intensive-care unit admissions and proportion of low-birthweight babies.

Our primary finding is in contrast to the Cochrane review on midwife-led care that compared other models of maternity care[13] and did not find any effect on the caesarean rate, although the addition of our findings is likely to change the conclusion of the review from no effect of continuity of midwife-led care on caesarean rates to a sta-

tistically significant reduction. Our secondary outcomes are consistent with the review; that the caseload model was associated with more spontaneous vaginal births, less intrapartum analgesia and fewer episiotomies.[13]

It is unknown what component of the caseload model in our study affected the primary outcome. The Cochrane review included subgroup analyses comparing studies of caseload models[18,19] with team midwifery models;[15,17,22–28] studies of women at low risk,[19,23–25,27,28] with both low and high risk,[15,17,18,22,26] and studies where antenatal care was provided in the community[17,18,25] versus in hospital,[15,19,22–24,26–28] and found no evidence of any effects on the caesarean section rates.

In our study, around 90% of the women had a known carer in labour. The two caseload care trials included in the Cochrane review reported different levels of women having known intrapartum caregivers–95% in one[18] and in the other, 33% of women were transferred out of caseload care before labour.[29] Neither trial found a decrease in caesarean births, although reducing caesarean sections was not the primary hypothesis of either trial; both aimed to reduce interventions overall. Continuity expressed only as seeing a known midwife intrapartum may be an unlikely single explanation for the reduced caesarean section rate in the caseload arm of our trial.

Our study included a large proportion of primiparous women (70% in each arm) compared with the Cochrane caseload trials with 33%[18] and 54%[29]. It would therefore be helpful to plan subgroup analyses by parity in future studies.

Another explanation for the difference between our findings and those of the Cochrane review could be the higher caesarean rate in low-risk women at the study site compared with the settings where women gave birth in the studies included in the Cochrane review. It may be easier to reduce caesarean rates in sites where there is a higher baseline rate. Participating in a trial where caesarean is the primary outcome may also have affected the care provided by the midwives in the caseload care arm, even if the primary outcome was not openly discussed.

The views and attitudes of care providers may also affect outcomes. It is not possible to randomise providers to different models for various logistic and practical reasons, so in our trial, as in all the trials in the Cochrane review, and as is usual in practice, midwives self-selected into the model. It is possible that those who chose to work in the caseload model in our study were more philosophically committed to achieving spontaneous birth than either standard care midwives or midwives in the other included Cochrane trials. Similarly, professional background may affect outcomes. In the Cochrane review, midwife-led care is compared with 'other' models of care; however, the 'other' models had varying degrees of medical involvement and in many cases midwives were the principal carers. In our study the caseload model was compared with care provided predominantly by midwives (78% of women in standard care), so we cannot conclude that it was the professional background of the carer that explained the observed difference in caesarean section rates. This is supported by studies conducted in Sweden where midwife-led birth centre care was compared with midwife-led standard care for low-risk women.[30,31] In contrast to the caesarean rate, the secondary outcomes in our study were similar to those in the Cochrane review.[13] Episiotomies were less frequent in the caseload group, which suggests a non-interventionist approach by the caseload midwives, and the lower rate of epidural analgesia could also be explained by midwives' attitudes and by women having become more confident when cared for by a known midwife. The shorter length of postnatal stay in hospital could also be related to increased parental confidence developed through the relationship continuity in the caseload group. As in the review, the reduction of interventions in our caseload group did not appear to jeopardise infant health.

Even if evaluations of a 'package' of care, like caseload midwifery, do not allow conclusions about which specific aspects of care contribute to the outcomes, our findings suggest that a model with only one lead midwife with one or two back-up midwives who self select into a caseload model, and who provide women with comprehensive care from pregnancy to the postnatal period, can make a difference by reducing the caesarean section rate.

Our findings need to be taken in context. This was a single site study with strong management and organisational support and there may have been unique and unmeasured factors that make it different from other settings. The views and experiences of intervention and standard care midwives are also important factors to consider and data on midwives' satisfaction and burnout have been collected and will be reported elsewhere. Besides the relatively high baseline caesarean section rate in the study hospital, women in the sample were slightly different from the overall population of women who gave birth in the public sector in the state of Victoria in 2007 and 2008. Women in this study were more likely than the overall population to be married or living with a partner (95% versus 81%), more likely to be expecting their first baby (70% versus 42%), and less likely to be born in Australia (58% versus 69%) (Report provided by Victorian Consultative Council on Obstetric and Paediatric Morbidity and Mortality, June 2011).

Conclusion

In settings with a relatively high baseline caesarean rate, caseload midwifery (care provided by a primary midwife

with one or two back-up midwives throughout pregnancy, birth and the early postnatal period) for women of low obstetric risk in early pregnancy shows promise for reducing the caesarean section rate.

Disclosure of interests

The authors have no competing interests to disclose.

Contribution to authorship

HM, DF, MAD, TF and LG originally conceived the study; HM, DF, MAD, UW, LG, JO and LA designed the study; HM, DF, MAD, TF, LG, UW and LA wrote the initial grant application; HM, DF, MAD, TF and MAB conceived and developed the intervention; DF and TF were responsible for implementation of the intervention; HM, DF, MAD, MAB and MF were responsible for ongoing review of trial processes; HM, DF, MAD, JO and MAB developed safety committee and data monitoring committee protocols and ongoing processes; HM, DF, MAD, MAB, LG and MF developed data collection tools; MAB, MF, HM, DF and MAD had data collection and management responsibilities; HM, DF and MAD undertook data analysis; and HM, DF and UW drafted the primary outcome paper. All authors contributed to and approved the final manuscript.

Details of ethics approval

Ethics approval was obtained from the RWH Human Research Ethics Committee (Reference 07/01, April 2007) and La Trobe University Human Ethics Committee (Reference 07-04, March 2007).

The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN012607000073404).

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Hospital guidelines used that are relevant to the study.

Please note: Wiley-Blackwell is not responsible for the content or functionality of any supporting information supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author. ■

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