

First alongside midwifery led unit in a high complexity public hospital in Spain: Maternal and neonatal outcomes

Lucía Alcaraz-Vidal^{a,b,c,1}, Inés Velasco^{b,d,*,1}, Montse Pascual^e, Roser Gol i Gomez^{c,f},
Ramón Escuriet^{g,h}, Carmina Comas^b

^a Department of Gender and Social Determinants in Health, Sevilla University, Sevilla, Spain

^b Department of Obstetrics and Gynecology, University Hospital Germans Trias i Pujol, Badalona, Spain

^c Research Group on Sexual and Reproductive Healthcare (GRASSIR) (2021-SGR-01489), 08007 Barcelona, Spain

^d Institute for Health Science Research Germans Trias i Pujol (IGTP), Badalona, Spain

^e Management of Organization and Management Systems, Metropolitana North Region, Catalan Health Institute, Barcelona, Spain

^f Primary Care Management in Sexual and Reproductive Healthcare, Metropolitana North Region, Catalan Health Institute, Barcelona, Spain

^g Head of the Affective, Sexual and Reproductive Health Plan of the Ministry of Health, Government of Catalonia, Spain

^h Global Health, Gender and Society Research Group, Facultat de Ciències de la Salut Blanquerna, Universitat Ramon Llull, Barcelona, Spain

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ABSTRACT

Problem: Midwifery led units are rare in Spain.

Background: Midwife-Led Care (MLC) is a widely extended model of care and, within this, the alongside midwifery-led units (AMLU) are those hospital-based and located in close connection with obstetric units. In Spain, CL is the first center belonging to the National Health System of these characteristics.

Aim: To evaluate the first year of activity of this pioneering unit.

Methods: An observational cross-sectional study was carried out to assess maternal and neonatal outcomes of births facilitated at CL by comparing with those births that fulfilled the criteria to be admitted at the AMLU but were assisted at the standard obstetric care unit of the hospital.

Findings: 174 (20,3%) women and birthing people decided to give birth at CL, whereas 684 (79,7%) gave birth at the Obstetric Unit of the Hospital. Women assisted at the AMLU had lower intervention rates (episiotomy, epidural analgesia) and a higher rate of breastfeeding practice. There were no statistical differences in maternal outcomes (postpartum hemorrhage, third-or-four-degree laceration) or neonatal outcomes (Apgar < 7 at 5 min; birth weight < 2500 gr; macrosomia; shoulder dystocia, neonatal care transfer).

Discussion: There were differences in transfers from MLU to OU between nulliparous and multiparous; the main reason for transfer is the request for analgesia. Epidural analgesia should be considered when analyzing maternal outcomes.

Conclusion: An alongside midwifery-led unit is a safe option with a low incidence of complications. This model of care can be positively implemented at the Public Healthcare System.

Statement of Significance

Problem or Issue

Families are increasingly seeking greater choice in birthplace, including options such as birth centers and home births, which

allow greater autonomy and/or fewer interventions. Although midwife-Led Care (MLC) is a widely extended model of care, these units are scarcely settled in Spain and, particularly, within the Public Health System.

* Correspondence to: Department of Obstetrics and Gynecology, University Hospital Germans Trias i Pujol, Carretera del Canyet s/n, 08916 Badalona Barcelona, Spain.

E-mail address: ivelasco.germanstrias@gencat.cat (I. Velasco).

¹ These authors have equally contributed to this work and share first authorship.

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What is Already Known

Childbirth is one of the most important events in human life. Giving birth in a midwifery-led unit is safe and with a low incidence of complications. The effectiveness of such a model has been demonstrated in many countries, but the implementation in our country is scarce.

What this Paper Adds

The first year of activity at Casa Laietania, an AMLU belonging to the National Health Service, showed that there were no significant differences in maternal and neonatal outcomes in comparison to Obstetric Unit of the HGT for women who met admission criteria. Those results demonstrated that MLU is a safe and valid model of care for women of low-risk and extended low-risk at labour, assessed at 37 weeks of gestation.

Background

Childbirth is one of the most important events in human life. The way in which women and newborns receive care during childbirth makes a difference to their health outcomes. The structure and organization of health-care systems and the economic, social, and cultural contexts in which they operate differ widely between countries, in turn influencing the models of maternity care available to women [1].

In many countries, especially high-income regions worldwide, most women give birth in hospitals and both uncomplicated and complicated pregnancies have traditionally been attended to similarly [2]. In 2018, the World Health Organization (WHO) published new recommendations for intrapartum care to make childbirth a more positive experience and to encourage the minimization of interventions in healthy women during childbirth [3].

Additionally, women and birthing people are increasingly seeking greater choice in birthplace, including options such as birth centers and home births, which allow greater autonomy and/or fewer interventions [4]. In this context, various innovative models of midwifery-led care have been developed [5].

A midwifery-led unit (MLU) is a maternity unit where the midwife is the professional undertaking shared decision making with the woman and providing autonomous care, in contrast to the conventional maternity units located in clinics and hospitals [6]. Within this model of MLUs, it can be distinguished between a) Alongside midwifery-led units (AMLUs), placed at the same building or architectural complex that the conventional obstetric units; and b) Freestanding midwifery units (FMUs), which are usually 15–40 min away from an obstetric centre and transfer will normally involve a journey by ambulance or car [7].

Midwifery units often use the name “birth centers”, implying health care facilities where midwives usually provide prenatal and birthing care to healthy childbearing people with minimal intervention in a home like environment [8]. However, in certain countries (i.e, USA) birth centers are not all midwife-led [9]. Consequently, MLUs refer to units in which midwives are independent and self-reliant, taking primary professional responsibility for care [10].

Planning birth in a MLU was associated with a reduced chance of the woman having an intervention during labour or birth, including augmentation, epidural/spinal analgesia and an instrumental or caesarean birth [11]. However, there is a wide variation in provision of midwife-led care and midwifery units in Europe [12], and the gap between current provision and potential access has not been determined [6].

In Spain, so far, there have been 4 MLUs: one FMU privately funded (Migjorn center near Barcelona), one AMLU within a public-private hospital (Hospital Sant Joan de D  u in Martorell, currently temporary

closed), one AMLU within a private hospital (Marbella Birth Center) and our unit, an AMLU embedded in a tertiary public hospital (CL, Casa Laietania, Hospital Germans Trias I Pujol, Badalona), which was launched in 2021. Three of the Spanish MLUs are in Catalonia, a northern region of Spain.

In our country, 80% of births take place in public hospitals from the National Health System, whereas 20% of births occur in private centers [13]. In both clinical settings, doctors hold the decision-making process and midwives are dedicated to provide care.

CL represents the first public AMLU as an integrated part of the national health system and aims to pioneer the experience of MLUs as valid and safe public birth settings in our country. The effectiveness of such a model has been demonstrated in many countries, but the implementation in our country requires to be assessed to i) offer an available option for families who do prefer this kind of care and, ii) extend these units within the Public Health System in Spain.

Methods

The purpose of this study is to analyse the first year of midwifery-led care by comparing maternal and neonatal outcomes between women who chose CL (AMLU) and those who were admitted the Obstetric Unit (OU) of the hospital. Comparisons of these outcomes from a homogeneous sample was important, only women who were classified as low risk at labour were included in the study. The study was carried out in accordance with the ResQu Index [14] guidelines for research about place of birth and reported following the STROBE guidelines for reporting observational studies [15].

This is an observational, cross-sectional study which analyzes the outcomes of mother-baby pairs from low birth-risk pregnancies admitted at the University Hospital Germans Trias (HGT) from July 2021 to the end of June 2022, according to the pathway initially chosen as birthplace. The HGT is a tertiary hospital which offers public health assistance to approximately 2000 women in labour per year from the upper half coast of the province of Barcelona (districts Barcelon  s and Maresme).

Group 1 included all those women who were admitted perinatal care at the alongside midwifery-led unit CL (AMLU). Group 2 included women without antepartum or intrapartum contraindications to birth there during the same period and were facilitated to give birth at the standard Obstetric Unit (OU) of the HGT.

Regarding inclusion criteria for admission at CL, the sample consists of women at low risk of complications, at term (from 37 to 41 weeks of gestation), with a single baby and cephalic presentation, and spontaneous onset of labour. Inclusion criteria have been established similar to the GAIN evidence-based guideline [7] (Supplementary Table 1). With independence from gestational risk [16], we distinguish 2 categories for admission: i) low birth-risk itself (criteria to be admitted at any MLU) and ii) extended low birth-risk (criteria that allow admission only at AMLU, not FMU). (Supplementary Table 1).

Models for midwifery care

The HGT is a referral tertiary hospital, with all the medical specialties and medico-surgical services represented. The staff of the OU is constituted by a team of midwives who provides care and support. There are a second line of professionals (obstetricians, anesthesiologists, and pediatricians) who intervene in cases of non-spontaneous vaginal births/caesarean sections, to provide epidural analgesia or neonatal assistance.

CL offers a personalized model of assistance, with one-to-one care with a midwife also in the antenatal period and a second midwife who attends the birth. Women remain at a home-like environment throughout labour process and are transferred to the traditional OU if a complication arises or if the woman request epidural analgesia. The model is completely led by midwives.

Maternal and neonatal outcomes

Maternal and perinatal outcomes are defined according to international guidelines (Supplementary Table 2). Regarding maternal variables, we consider type of birth (spontaneous vaginal births, assisted vaginal birth and caesarean section); episiotomy; type of analgesia (none, lidocaine, epidural analgesia and general anesthesia); postpartum hemorrhage (greater than 500 mL estimated blood loss associated with vaginal delivery or greater than 1000 mL estimated blood loss associated with caesarean delivery) [17]; hemorrhage requiring blood transfusion; third-degree tear (injury to perineum subtypes a, b, and c, depending on the degree of involvement of the anal sphincter complex) and fourth-degree tear (injury to perineum involving the anal sphincter complex and anorectal mucosa) [18] and breastfeeding at hospital discharge. At CL, the only analgesic agent available was lidocaine locally administered in case of episiotomy. Epidural analgesia was exclusively available at OU. Regarding perinatal outcomes, we consider gestational age at birth, birth weight, Apgar score less than 7 at the fifth minute of life, birth weight less than 2500 g or higher than 4000 g at term, shoulder dystocia or admission at Neonatal Care Unit.

Statistical analysis

Quantitative variables were expressed as the mean (SD) and categorical variables as percentages. T- Student test was used to compare quantitative variables and Chi-squared test for the qualitative ones. In cases that contingency tables displayed small figures, Fisher's exact test was performed. Additionally, Odds Ratio (OR) was also calculated for 2-by-2 tables of variables, as a measure of association between exposure and an outcome. We set an alpha error of 0.05. Statistical analyses were performed using the software SPSS, version 27.0 (SPSS, Chicago, IL).

Ethical approval

This study is based on a quality assurance of clinical assistance: the human data used were previously anonymized for this analysis to protect any confidential information from women and their families; so, there were no ethical issues concerning informed and free consent and confidentiality.

We exclusively carried out the statistical analysis of clinical records in a cross-sectional way, without recruitment of participants nor interventions so, the Ethical Committee complies with all applicable Spanish laws and regulations, including a waiver of informed consent in cases of data extraction from anonymized clinical database.

Results

Study groups

Our study included a sample of 858 women, 174 who chose to give birth at CL (AMLU), whereas 684 women were admitted at Obstetric Unit of the University Hospital Germans Trias (OU). Sociodemographic and clinical characteristics of both groups of women are described in Table 1.

Women assisted at the AMLU were significantly older, with lower BMI, and mostly European in comparison with those women who gave birth at the HGT. There were no differences in parity, previous miscarriages, or preterm deliveries between the groups of study.

Regarding risk assessment, women who planned to give birth at the AMLU presented a low gestational risk (only a 4% had been classified as highrisk during pregnancy, compared to a 7.2% of those women who were admitted at the hospital; $p < 0.001$). Nevertheless, the re-assessment made at 37 weeks of gestation, did not show significant differences in the level of risk at labour between the two groups.

Table 1

Sociodemographic and clinical characteristics of women admitted to AMLU and Obstetric Unit of the Hospital (HGT).

	Obstetric Unit HGT N = 684	AMLU N = 174	p
Maternal age (mean±SD)	30,48 ± 5,52	34,08 ± 3,93	< 0.001 ^a
Pre-pregnancy BMI (median, kg/m ²)	24.74	22.64	< 0.001 ^a
BMI < 30 kg/m ²	596 (87%)	169 (97,1%)	< 0.001 ^b
BMI ≥ 30 kg/m ²	86 (13%)	5 (2,9%)	
Origin	476 (69,6%)	167 (96%)	< 0.001 ^b
European	74 (10,8%)	1 (0,6%)	
Arabian/Magreb	64 (9,4%)	1 (0,6%)	
India/Pakistan	18 (2,6%)	–	
East Asia	7 (1%)	–	
Sub-Saharan Africa	45(6,6%)	5 (2,9%)	
Others			
Parity	360 (52,6%)	93 (53,4%)	0.456 ^b
Nulliparous	324 (47,4%)	81 (46,6%)	
Multiparous			
Previous Preterm births	669 (97,8%)	173 (99,4%)	0.217 ^b
No	15 (2,2%)	1 (0,6%)	
Yes			
History of miscarriages	464 (67,8%)	129 (74,1%)	0.338 ^b
No	220 (32,2%)	45 (25,9%)	
Yes			
Living children	352 (51,5%)	95 (54,6%)	0.370 ^b
No	332 (48,5%)	79 (45,5%)	
Yes			
Risk level at pregnancy	391 (57,1%)	116 (66,6%)	< 0.001 ^b
Low risk	242 (35,4%)	51 (29,3%)	
Intermediate risk	49 (7,2%)	7 (4,0%)	
High risk			
Risk level at giving birth	598 (87,4%)	161 (92,5%)	0.148 ^b
Low risk	86 (12,6%)	13 (7,5%)	
Extended Low risk			

^aT Student Test; ^b Chi-squared test.

Maternal and neonatal outcomes

There were significant differences in gestational age, episiotomy rate, need of analgesia and breastfeeding practice between the two groups of women. However, no differences in neonatal outcomes were found (Table 2).

Considering the analgesia during labour, 48 (27.6%) women who initially planned to give birth at CL eventually received epidural analgesia, whereas 595 (84.6%) women in the hospital group had an epidural. When a comparison between the group of women who gave birth with epidural analgesia and those women who did not, we found significant differences in episiotomy rate (22.7% for those with epidural vs 1.86% for those without it; $p < 0.001$) and breastfeeding practices (74.6% of breastfeeding in the epidural group and 89.3% in the group without epidural analgesia; $p < 0.001$). There were no differences in neonatal outcomes according to the use of epidural analgesia.

If we excluded the caesarean sections, the rate of episiotomy was found to be associated to epidural analgesia [OR: 12.8 (95% CI: 4.8–33.8)] and/or associated to assisted vaginal birth [OR:17.3 (95% CI: 10.5–28.1). On the other hand, when women who received epidural analgesia were excluded, there were 4 women who had an episiotomy at OU and none of those who gave birth at the AMLU ($p = 0.031$).

The comparison between low-risk (those women who met criteria for being admitted at any MLU, both FMU and AMLU) and extended low-risk (women who could only be admitted at an AMLU but not at FMUs) showed significant differences in maternal age, BMI, parity and birth weight, with no significant differences in maternal nor neonatal outcomes (Table 3).

However, when the comparison was made according to parity, there were significant differences in maternal age, pre-gestational BMI and birth weight. All these variables showed greater values in multiparous

Table 2

Comparison of maternal and neonatal outcomes of births at AMLU with those assisted at the Obstetric Unit of HGT.

	Obstetric Unit HGT N = 684	Casa Laetanaia N = 174	p
Type of Birth	521 (76,2%)	145 (83,3%)	0.105 ^b
Vaginal delivery	85 (12,4%)	13 (7,5%)	
Assisted vaginal delivery	78 (11,4%)	16 (9,2%)	
Cesarean section			
Gestational age at birth (days) (mean ± SD)	278,54 ± 10,24	281,24 ± 6,95	<
Birth weight (gr) (mean ± SD)	3353,70 ± 407,98	3398,91 ± 404,52	0.001 ^a
Episiotomy	546 (79,8%)	162 (93,1%)	<
No	138 (20,2%)	12 (6,9%)	0.001 ^b
Yes			
Postpartum Hemorrhage	677 (99%)	170 (97,1%)	0.075 ^c
No	7 (1%)	4 (2,9%)	0.431 ^c
Yes	682 (99,9%)	173 (98,9%)	
Hemorrhage requiring treatment	2 (0,1%)	1 (1,1%)	
No			
Yes			
Third and fourth-degree laceration	667 (97,5%)	173 (99,4%)	0.092 ^c
No	17 (2,5%)	1 (0,6%)	
Yes			
Analgesia	55 (8,0%)	67 (38,5%)	0.002 ^b
None	33 (4,8%)	57 (32,8%)	
Local agents (lidocaine)	595 (84,6%)	48 (27,6%)	
Peridural	2 (0,3%)	2 (1,1)	
Others			
Breastfeeding	520 (76%)	152 (87,4%)	0.001 ^b
Yes	164 (24%)	22 (12,6%)	
No			
Apgar Score at 5 min < 7	3 (0,4%)	0 (0,0%)	0.382 ^c
Birth weight < 2500 gr	4 (0,6%)	1 (0,6%)	0.988 ^c
Birth weight > 4000 gr	44 (6,4%)	13 (7,5%)	0.623 ^b
Shoulder dystocia	9 (1,3%)	3 (1,7%)	0.452 ^c
Admission at Neonatal Care Unit	31 (4,5%)	10 (5,7%)	0.502 ^b

^a T Student Test; ^b Chi-squared test; ^c Fisher's exact test.

women (Table 4). The rate of assisted vaginal births, caesarean sections, episiotomy and third- and fourth degree tears were significantly higher in nulliparous women, meanwhile local anesthesia was most used in multiparous women. Regarding neonatal outcomes, birth weight greater than 4000 g was more frequent in multiparous and admission in Neonatal Care Unit occurred more in nulliparous.

Transfers from AMLU to HGTiP

From those 174 women who intended to give birth at the AMLU, 116 remained in the AMLU and gave birth. Fig. 1 shows the transfers from MLU to the OU.

There were 75 transfers from AMLU to OU (43%): 11 (14.7%) antepartum; 47 (62.6%) intrapartum and 17 (22.7%) postpartum. The most frequent reason for transfer (41.2% of total) was the desire of epidural analgesia, 5 cases antepartum and 26 cases during active labor (Fig. 1).

However, the distribution of transfers was significantly different between nulliparous (16.6% antepartum; 70.4% intrapartum and 13% postpartum) and multiparous (9.5% antepartum; 42.9% intrapartum and 47.6% postpartum) respectively, $p = 0.006$. According to this, of the 93 nulliparous admitted at the AMLU, 46 (49%) gave birth there, and 54 (58%) were transferred to the OU. For the multiparous, 70 of 81 (86%) gave birth at the AMLU and a total of 21 (25.9%) were transferred to the OU (Fig. 1).

From the transferred cases, 10 newborns needed support at the Neonatology unit (respiratory distress or neonatal hypoglycemia) and other 3 were transferred as prevention of complications (maternal fever

Table 3

Comparison between low risk (may be assisted at any MLUs) and extended low-risk (admitted only at AMLUs).

	Low risk at birth N = 759	Extended low risk N = 99	p
Casa Laetania	161 (92,5%)	13 (7,5%)	0.060 ^a
Maternity Hospital	598 (87,4%)	86 (12,6%)	
Maternal age (years)	31,01 ± 5,29	32,74 ± 6,21	0.001 ^b
Pregestational BMI	23,44 ± 3,06	31,00 ± 4,54	<
Gestational age at birth (days)	279 ± 9,97	279 ± 7,61	0.495 ^b
Birth weight (grams)	3344 ± 397,92	3504 ± 451,94	<
Parity	414 (54,5%)	37 (37,4%)	0.007 ^a
Nulliparous	345 (45,5%)	62 (62,6%)	
Multiparous			
Type of Birth	594 (78,3%)	72 (72,7%)	0.334 ^a
Vaginal delivery	86 (11,3%)	12 (12,1%)	
Assisted vaginal delivery.	79 (10,4%)	14 (15,2%)	
Cesarean section			
Episiotomy	136 (17,9%)	14 (15,2)	0.352 ^a
Breastfeeding	597 (78,7%)	75 (75,8%)	0.510 ^a
Postpartum hemorrhage	11 (1,4%)	1 (1%)	0.991 ^c
Hemorrhage requiring treatment	3 (0,4%)	0 (0%)	0.589 ^c
Third and fourth-degree laceration	16 (2,1%)	2 (2%)	0.918 ^c
Apgar score at 5 min < 7	3 (0,4%)	0 (0%)	0.996 ^c
Birth weight < 2500 gr	3 (0,4%)	2 (2%)	0.104 ^c
Birth weight > 4000 gr	47 (6,2%)	10 (10,1%)	0.137 ^a
Shoulder dystocia	10 (1,3%)	2 (2%)	0.427 ^c
Admission at Neonatal Care Unit	37 (4,9%)	4 (4%)	0.449 ^c

^aT Student Test; ^b Chi-squared test; ^c Fisher's exact test.

Table 4

Comparison between nulliparous and multiparous.

	Nulliparous N = 453	Multiparous N = 395	p
Casa Laetania	93 (53.4%)	81 (46.6%)	0.993 ^b
Maternity Hospital	360 (53.4%)	314 (46.6%)	
Maternal age (years)	30,49 ± 5,56	31,94 ± 5,20	0.001 ^a
Pregestational BMI	23,83 ± 3,86	24,79 ± 4,23	<
Gestational age at birth (days)	279,42 ± 11,80	278,89 ± 6,56	0.217 ^a
Birth weight (grams)	3296,35 ± 376,89	3437,40 ± 428,90	<
Type of Birth	297 (65.7%)	359 (90.9%)	<
Vaginal delivery	79 (17.4%)	19 (4.8%)	0.001 ^b
Assisted vaginal delivery	77 (17.0%)	17 (4.3%)	
Cesarean section			
Episiotomy	118 (26%)	32 (8.1%)	<
Breastfeeding	351 (77.5%)	312 (79%)	0.001 ^b
None or local analgesia	83 (18.3%)	127 (32.2%)	0.597 ^b
Postpartum hemorrhage	9 (2%)	3 (0.8%)	0.001 ^b
Hemorrhage requiring treatment	6 (1.3%)	1 (0.3%)	0.154 ^c
Third and fourth-degree laceration	16 (3.5%)	2 (0.5%)	0.130 ^c
Apgar score at 5 min < 7	3 (0.7%)	0 (0%)	0.003 ^c
Birth weight < 2500 gr	2 (0.4%)	3 (0.8%)	0.253 ^c
Birth weight > 4000 gr	18 (4%)	38 (9.6%)	0.668 ^c
Shoulder dystocia	5 (1.1%)	6 (1.5%)	<
Admission at Neonatal Care Unit	29 (6.4%)	11 (2.8%)	0.001 ^b
			0.763 ^c
			0.013 ^b

^aT Student Test; ^b Chi-squared test; ^c Fisher's exact test.

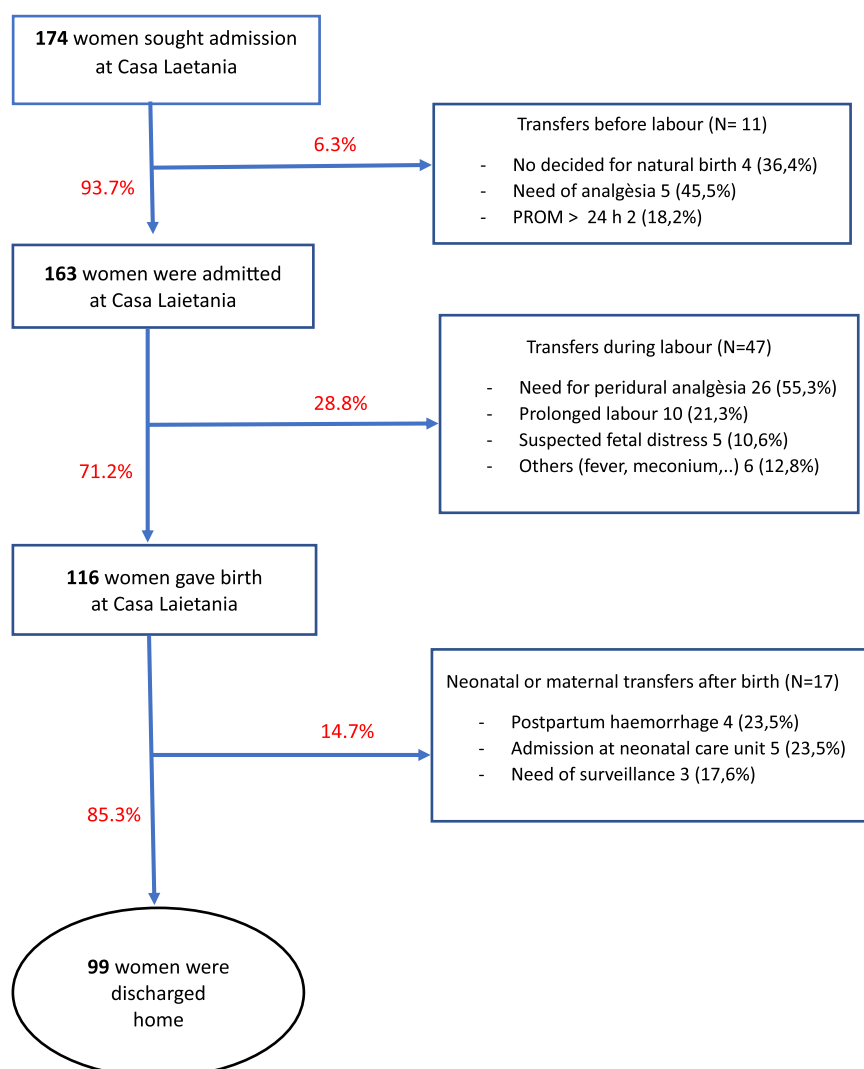


Fig. 1. Transfers from Casa Laetania to Obstetric Unit HGT.

during labor), although none of them required admission at the Neonatal Intensive Care Unit (NICU).

Healthcare satisfaction

During the first year, no healthcare satisfaction surveys were used at CL. However, one out of nine women who birthed at the MLU sent a letter of appreciation, versus 1 woman in 602 in the OU group.

Discussion

The first year of activity at CL, an AMLU belonging to the National Health Service, showed that there were no significant differences in maternal and neonatal outcomes in comparison to Obstetric Unit of the HGT for women who met ADMISSION CRITERIA FOR mlus. Those results demonstrated that MLU is a safe and valid model of care for women of low-risk and extended low-risk at labour, assessed at 37 weeks of gestation.

Gestational age at birth was significantly higher in our AMLU group, probably related to a more expectant attitude (wait and see). For MLUs users, there may be critical periods of pregnancy (e.g., the third trimester) when individualized education and counseling could considerably enhance clients' knowledge, consequently increasing their autonomy [8]. The MLU group also exhibited higher rates of

breastfeeding at discharge than the OU group, although our results are in consonance with previous reported rates from the same geographical area [19,20].

Although the difference between the frequencies of postpartum hemorrhage (PPH) between the two groups was not statistically significant, it should be noted that a higher percentage was observed in the AMLU. There is evidence that physiological third stage of labour results in fewer PPHs, rather than more. It is uncertain whether there was a difference between active and expectant management in third stage of labour for severe PPH or maternal Hb less than 9 g/dL (at 24 to 72 h) [21], but the expectant way of birthing the placenta, instead of active management, was mostly used at the AMLU. On the other hand, the incidence of PPH in low-risk women is around one to three percent when bleeding is estimated subjectively [22], but it can reach 10% when an objective estimate is made [23]. Since we did not use an objective method of estimation, it is likely that there was an underreporting of this complication in the group of women from the OU.

Neonatal outcomes did not present significant differences between the two groups, what is in consonance with all the studies [24]. When the comparison was made between low-risk and extended low-risk groups, the extension meant higher maternal age, higher pre-gestational BMI, more multiparous as well as higher birth weight; but there were no differences in maternal nor neonatal outcomes.

The main differences were found when considering parity: the

distribution nulliparous/multiparous was similar at AMLU and OU. However, the type of birth was significantly different, with higher rates of assisted vaginal births and caesarean sections in nulliparous women. Consequently, higher rates of episiotomy, third-and fourth-degree tears as well as higher frequency of admissions at the Neonatal Care Unit occurred in this group. In nulliparous women planning non-OU birth the risk of intervention increased with increasing age, but women of all ages planning a birth in the AMLU experienced a reduced risk of intervention [25].

Concerning the transfers from MLU to OU, there also were clear differences between nulliparous and multiparous women, with more frequent transfers at antepartum and intrapartum periods in nulliparous women compared to postpartum transfers in case of multiparous women. In our study, the main reason for transfer was the need of analgesia. In MLU the only analgesic options during labor were physiological methods [massages, local heat application, immersion in warm water, and transcutaneous electrical nerve stimulation (TENS) [26]] but we do not administer any pharmaceutical pain relief.

In some MLUs, some analgesic agents such as nitric oxide [27] or even fentanyl (intranasal/subcutaneous) and pethidine (intramuscular) [28] can be used. Probably, the more available analgesic options, the less transfer rates will happen due to analgesic request.

The role of epidural analgesia should be analyzed in detail. When the episiotomy rates in AMLU and in OU were compared, it was significantly higher in the OU group. When epidural analgesia cases were removed, this difference was reduced but remained significant. Despite of this, the episiotomy rate at the OU was below the reported one from public hospitals in our region (20.2% vs 28.6%) [29], which shows a tendency to approach the WHO recommendations (not to exceed 15% of episiotomies in spontaneous deliveries of low-risk women). Additionally, the odds ratio for episiotomy is strongly associated to epidural analgesia and assisted vaginal births. Epidural anesthesia affects the mechanism of birth leading to an increase in the number and intensity of additional medical procedures - episiotomy, perineal laceration, and operative delivery [30]. In this regard, the comparison between MLU and the OU need to consider the role of epidural analgesia as potential confounder.

Our results show some limitations. The first year of activity in MLU included a reduced number of women who have demanded the pathway of MLU, since the availability of this birthplace option was not fully disseminated. So, we cannot guarantee that all women that were admitted at the OU did really know the existence of CL. We cannot assess women and professionals individual experience, since no satisfaction enquires or scales were used: it would be desirable to design or adapt validated questionnaires to evaluate factors such as one-to-one service, spaces, access to information, privacy and other factors that can substantially improve the birthchild experience. So far, users experience could only be assessed through letters of gratitude.

However, our first analysis offers substantial information: the implementation of an AMLU within a public tertiary hospital is not only feasible but also effective. The leadership of the MLU by midwives, from its conception to its implementation, with protocols and transfer circuits established and agreed upon with the OU team, is already established in our center. Considering that MLU provides a personalized care (one-to-one model), the midwife-woman relationship contributes to a woman's feeling of empowerment [31]. The possibility of a pathway of care adapted to uncomplicated pregnancies enriches the health-care system coverage [32]. Besides, professionalization and leadership should enable midwifery to regain a partnership in designing and changing healthcare, at the same level as other health professionals [33].

As pending tasks, we must design a method (questionnaire, validate scale) to assess the quality of care, the satisfaction among users and professionals. The cost-effectiveness of this model in our public system is also mandatory. And new challenges are coming: the consolidation and spread of this model requires an investment in i) professionals who held the appropriate skills to lead MLUs ii) dissemination of advantages and security of MLUs in our reference area and, iii) deployment of MLUs in

our region, particularly as a public healthcare service.

Conclusion

CL represents a model of midwifery-led care recognized as having the potential to benefit women both as services users and midwives as providers of care. This is the first time that an AMLU has been included in the Public Healthcare System in Catalonia, Spain.

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Ethical statement

This study is based on a quality assurance of clinical assistance: the human data used were previously anonymized for this analysis to protect any confidential information from women and their families; so, there was none ethical issues concerning informed and free consent and confidentiality. We exclusively carried out the statistical analysis of clinical records in a cross-sectional way, without recruitment of participants nor interventions so, there was no need of informed consent to participate or for publication and Ethical Statement is not applicable.

Declaration of Competing Interest

The authors have no conflicts of interest to declare. All co-authors have seen and agree with the contents of the manuscript and there is no financial interest to report.

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Author contributions

LA and IV designed the study, performed statistical analysis and wrote the first draft of the manuscript, MP and RG extracted data from clinical records, RE and CC were major contributors in writing the manuscript. All authors read and approved the final manuscript.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.wombi.2024.01.003](https://doi.org/10.1016/j.wombi.2024.01.003).

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