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The efficacy, safety, and acceptability of medical abortion provided by nurse midwives or physicians- a randomized controlled equivalence trial


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Background

- Task shifting is defined as shifting less advanced medical tasks to staff who have a lower level education but still the right level of education
- In medical abortion, surgical and provision of caesarian sections this has been shown to be safe in a low resource setting
- In Sweden nurse midwives
 - have 4,5 years of university education (nurse 3 yrs- midwife 1,5 yrs)
 - provide contraceptive advice and prescriptions to healthy women
 - insert IUDs
 - Supervise all uncomplicated pregnancies
 - manage all uncomplicated vaginal deliveries
 - oversee all uncomplicated medical abortion

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Preparation for the study




- 2 nurse midwives experienced in abortion care were trained in vaginal ultrasound
 - Theoretical education
 - Practical education, 50 supervised ultrasounds, 50 ultrasound passed after confirmation by physician.
- Women were eligible if they had a pregnancy of less than 9 weeks and 0 days estimated according to LMP.
- There was no pre-examination or screening.
 - 597 women were randomized to the nurse midwife group
 - 583 women were randomized to the physician group.

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Treatment

- 200 mg mifepristone
- 800mcg misoprostol vaginally after 24-48 hours at home or in the clinic
- 400mc misoprostol po if no bleeding after 3 hours
- Follow-up with low sensitivity u-hcg (cut off 500 IU/ml) by nurse midwife after 3-4 weeks
- Questionnaire at follow-up



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Reasons for exclusion after allocation

Reason	Allocated to Nurse midwife	Allocated to physician	Total number of women
Language difficulties	1	2	3
Withdraw consent	0	2	4
Ectopic pregnancy	3	3	6
Postponed abortion	4	3	7
Miscarriage	8	4	12
Kept pregnancy	10	5	15
Too advanced gestational age	16	12	28
Chose surg abortion	18	12	30
Total	62	43	105

None of the differences reached significance


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Reason for second opinion


Reason for consultation	Allocated to nurse midwife N (%)	Allocated to physician N (%)	Total N (%)
No consult	396 (74)	510 (95.7)	906 (84.8)
Multiple pregnancy	7 (1.3)	1 (0.2)	8 (0.7)
High s-hCG	0 (0)	1 (0.2)	1 (0.9)
Information	3 (0.6)	1 (0.2)	4 (0.4)
Medical reasons	13 (2.4)	4 (0.8)	17 (1.6)
Ultrasound	59 (11)	8 (1.5)	67 (6.3)
Unknown	3 (0.6)	4 (0.8)	7 (0.7)
Prescription/second opinion for bacterial vaginosis	54 (10)	4 (0.8)	58 (5.4)
Total	535	533	1068

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Follow up after 3-4 weeks

- 54 women in nurse midwife group were lost to follow up
- 76 patients in the physician group were lost to follow up
- Significant difference between groups



500 IU/ml cut off

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Overview of outcome measures

Outcome measure	Allocated to nurse midwife (%)	Allocated to physician (%)	Total (%)
Efficacy	476/481 (99)	445/467 (97.4)	923/940 (98.2)
Safety	453/473 (95.8)	414/443 (93.5)	867/916 (94.7)
Acceptability	200/535 (37.4)	12/533 (2.3)	212/1068 (19.9)

- Efficacy defined as no need for surgical intervention.
- Safety defined as no complication (no intervention for presumed complication)
- Acceptability defined as women preferring their allocated provider.


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Primary outcome measure- efficacy




- Risk difference for surgical intervention was 1,6% with CI 0.2-3.0%
 - Nurse midwife group 5 patients
 - Physician group 12 pat
 - Total 17 patients = 1,8%
- Equivalence was used as nurse midwife provision may have additional advantages for women
 - Having to meet only one provider
 - Shorter waiting times
 - Increasing access

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Contraceptive advice

- Nurse midwives prescribed long acting reversible contraceptives to 290/532 women
- Physicians prescribed LARC to 241/528 women
- The difference is statistically significant $p=0.004$.

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Conclusion

- Nurse midwife provision of medical abortion in a high resource setting where vaginal ultrasound is part of the protocol is
 - Effective
 - Safe
 - Highly acceptable
- Nurse midwives prescribe LARCs to a larger extent than physicians which may have impact on repeat abortion rates
- Nurse midwife provision of medical abortion may increase access to medical abortion services

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