

Sublingual Misoprostol Versus Manual Vacuum Aspiration for Treatment of Incomplete Abortion in Enugu, Nigeria: *A randomized control study*

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Introduction-1

- Incomplete abortion - Fetal tissues in uterus
 - A global maternal health challenge
- Abortion complications → maternal mortality
 - Globally: 8% of maternal mortality (WHO, 2014)
 - Nigeria: 11% (FMoH Nigeria, 2007)
 - Enugu, South-East Nigeria: 5.7% (Ezugwu et al, 2011)
 - Ebonyi State, S-E Nigeria: 4.1% (Nwagha et al, 2010)

Introduction-2

- Post abortion care concept → wider patronage of Manual vacuum aspiration (MVA) but,
- Surgical evacuation - lots of constraints including:
 - theatre space, sterile instruments, & skilled providers, peculiar complications, cost
- Need to explore non-surgical options
 - effective, accessible, & acceptable
- Ready option = Misoprostol

Introduction-3

- Misoprostol – prostaglandin E₁ analogue
 - Sterilized ~~equipment~~, ~~theatres~~, skilled ~~personnel~~
 - Less expensive, No refrigeration
 - Several different routes
 - Single dose 600mcg oral: recommended for incomplete abortion (Blum et al., 2007)
 - Route that allows lower dose → economical & convenient
 - Single dose 400mcg sublingual = promising (Sochet et al, 2012)

Aim

- Compare efficacy of single dose sublingual misoprostol to MVA in the treatment of incomplete abortion in Enugu, South-east Nigeria

Specific objectives

- Incidence of complete uterine evacuation in women with incomplete abortion after 400mcg single dose of sublingual misoprostol, &
 - Compare with that of women that had manual vacuum aspiration
- Compare side effects & patient satisfaction between the two groups

Study methods

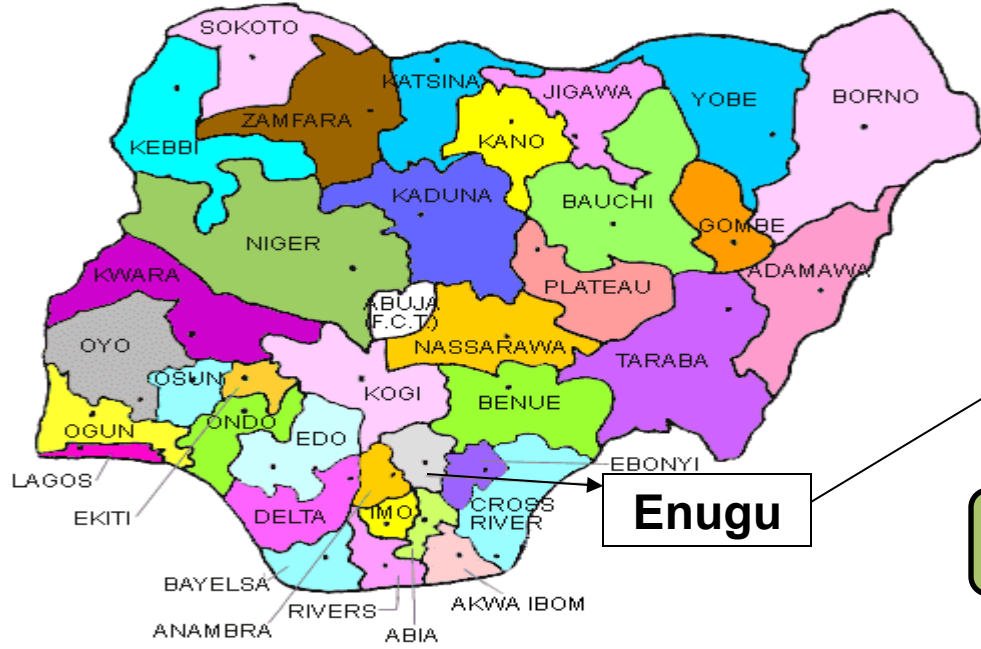
Methods - 1

- Randomized control study
- Study centers:
 - University of Nigeria Teaching Hospital, Enugu &
 - Julius Memorial Specialist Hospital, Enugu, Nigeria
- Study period: Aug. 2014 – Feb. 2015
- Eligibility: Consenting women at GA \leq 12 wks with incomplete abortion (clinical & ultrasound)

Methods - 2

- Exclusion criteria:
 - clinically unstable patients
 - excessive vaginal bleeding or severe anaemia
 - evidence of genital infection:
 - offensive vaginal discharge,
 - uterine tenderness & pyrexia
 - hx of allergy to prostaglandins
 - No suspicion of ectopic pregnancy_

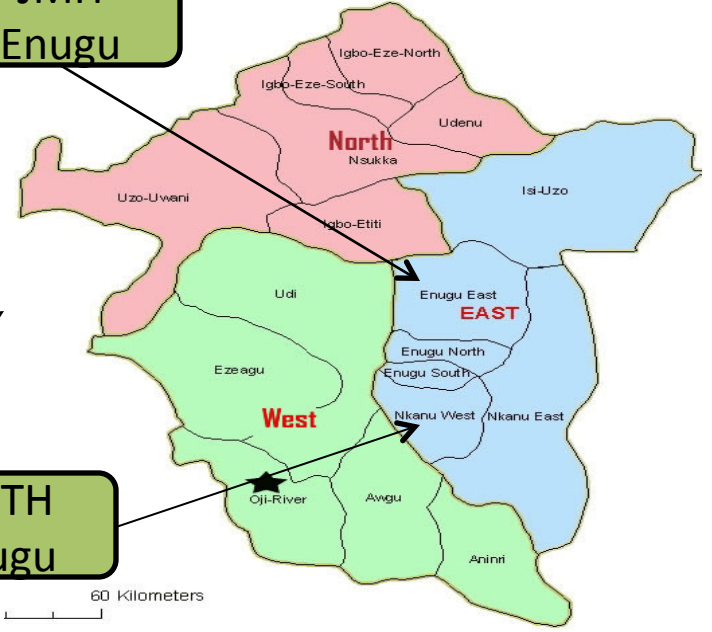




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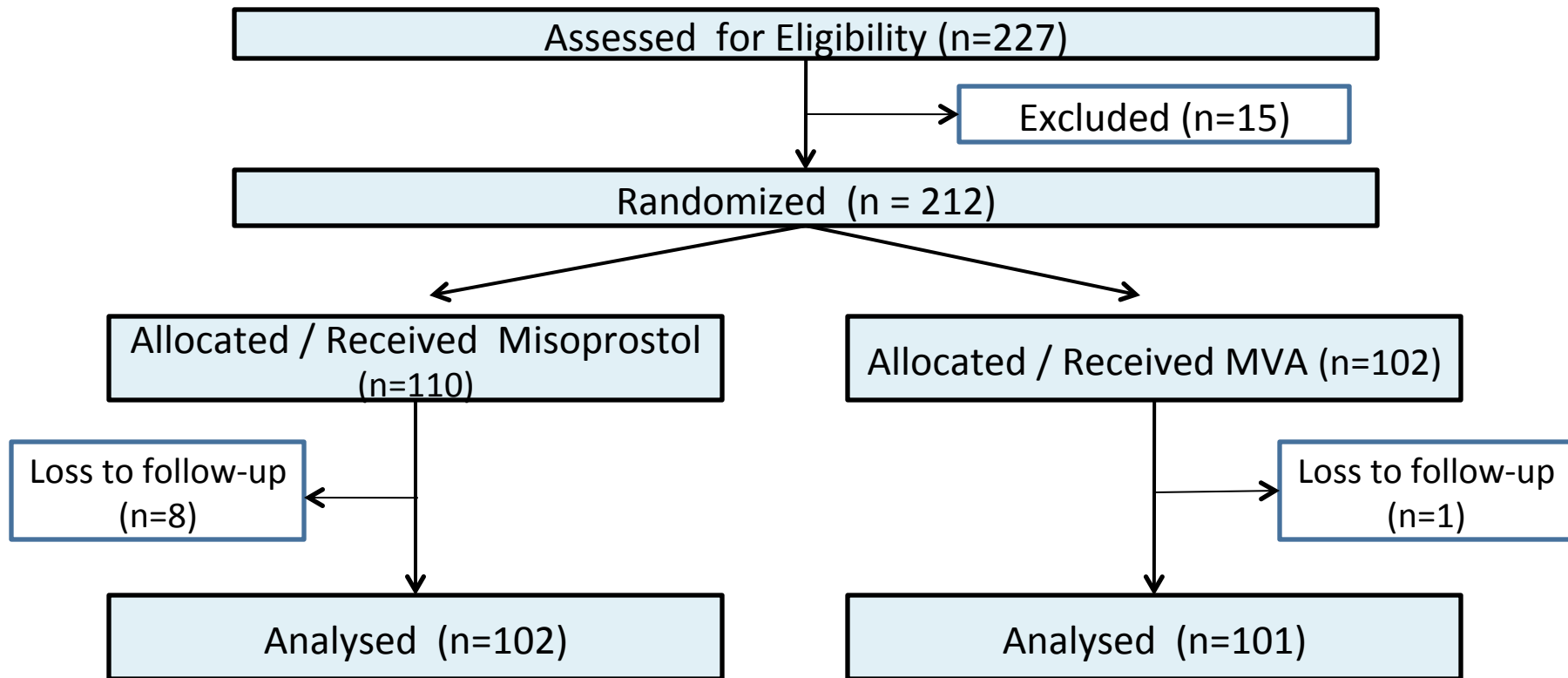
JMH
Enugu

UNTH
Enugu



Enugu state, Nigeria

Method - Study flow diagram



Methods - 3

- Data analyses: per protocol
 - descriptive & inferential at 95% confidence level
 - Software: SPSS version 20 for windows (IBM Corporation)
- Ethical clearance: Ethical Board of UNTH Enugu

Results

Participants' Basic Characteristics

Characteristic		Misoprostol Group (n=102)	MVA Group (n=101)	P value
Age (years)	Mean ±SD	28.7 ± 5.83	29.0 ± 6.49	0.795
Parity	Mean ±SD	1.8 ± 1.53	2.0 ± 1.78	0.378
GA (weeks)	Mean ±SD	9.1 ± 2.0	9.1 ± 2.1	0.975

Basic characteristics-1

Characteristic	Sub-group	Misoprostol Group (n=102)	MVA Group (n=101)	P value
		Freq (%)	Freq (%)	
Age (years)	< 20	1 (1.0)	4 (4.0)	0.219
	20 – 29	54 (52.9)	47 (46.5)	
	30 – 39	43 (42.2)	41 (40.6)	
	≥ 40	4 (3.9)	9 (8.9)	
Marital status	Married	75 (73.6)	79 (78.2)	0.435
	Single	27(26.5)	22(21.8)	

Basic characteristics-2

Characteristic	Sub-group	Misoprostol Group (n=102)	MVA Group (n=101)	P value
		Freq (%)	Freq (%)	
Educational status	Primary	1 (1.0)	4 (4.0)	0.260
	Secondary	43 (42.2)	47 (46.5)	
	Tertiary	58 (56.9)	50 (49.5)	
Parity groups	0	31 (30.4)	26 (25.7)	0.634
	1	14 (13.7)	18 (17.8)	
	2 – 4	52 (51.0)	49 (48.5%)	
	≥5	5 (4.9)	8 (7.9)	

Incidence of complete evacuation

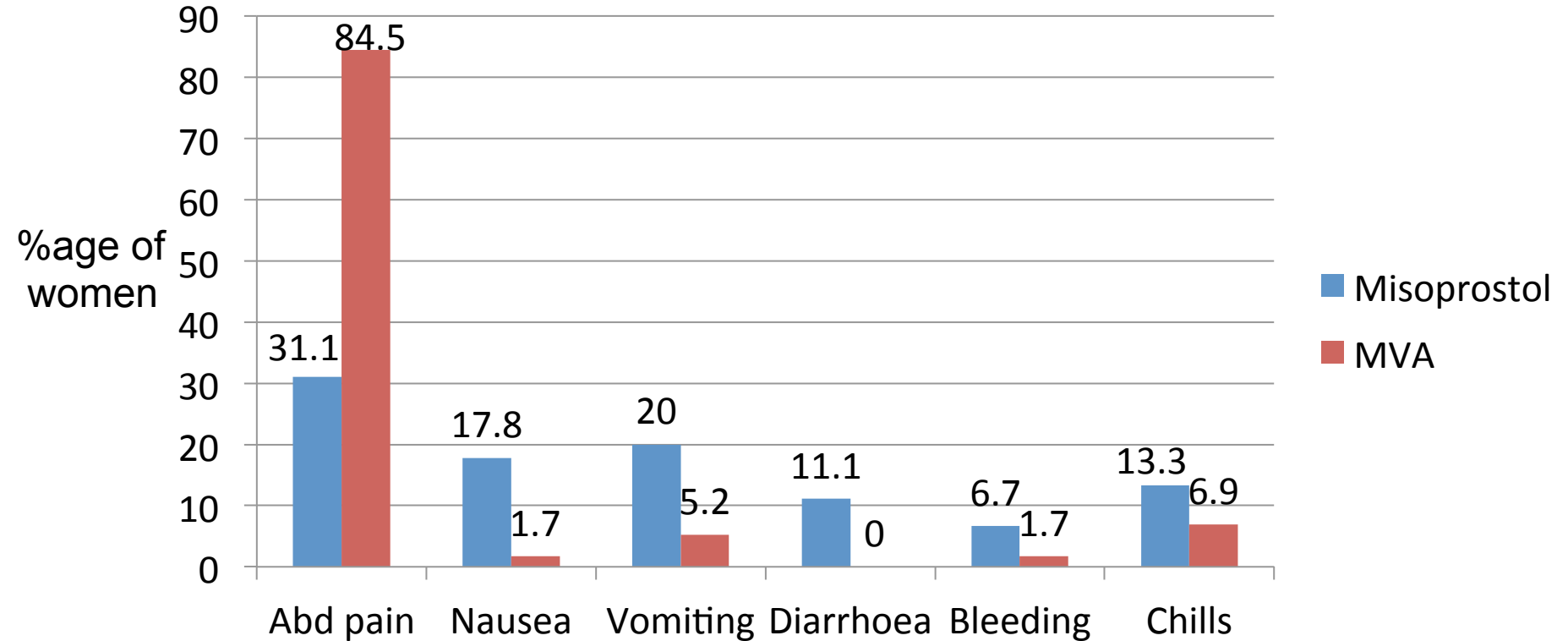
Study group	Complete evacuation		P value	RR (CI 95%)
	Yes	No		
	Freq (%)	Freq (%)		
Misoprostol group (n=102)	88 (86.3)	14 (13.7)	< 0.001	0.86 (0.80, 0.93)
MVA group (n=101)	101 (100.0)	0 (0.0)	-	-



Side effects

Study group	Side effects		P value	RR (CI 95%)
	Yes Freq (%)	No Freq (%)		
Misoprostol group (n=102)	90 (88.2)	12 (11.8)	< 0.001	1.5 (1.28, 1.84)
MVA group (n=101)	58 (57.4)	43(42.6)	-	-

Side effects by study groups



Side effects details

Side effect	Misoprostol	MVA	P value	RR (CI 95%)
	(n=90)	(n=58)		
	Freq (%)	Freq (%)		
Abdominal pain	28 (31.1)	49 (84.5)	< 0.001	0.4 (0.30, 0.57)
Nausea ←	16 (17.8)	1 (1.7)	< 0.001	1.7 (1.38, 2.01)
Vomiting ←	18 (20.0)	3 (5.2)	0.01	1.5 (1.20, 1.91)
Diarrhoea ←	10 (11.1)	0 (0.0)	< 0.001	1.7 (1.50, 1.99)
Bleeding	6 (6.7)	1 (1.7)	0.17	1.4 (1.03, 2.00)
Chills	12 (13.3)	4 (6.9)	0.22	1.3 (0.92, 1.74)

Treatment satisfaction

- Misoprostol group > MVA group
 - 86.7 mm ± 14.11 mm versus 81.4 mm ± 11.10
 - Using Visual analogue scale
 - $P < 0.001$

Procedure recommendation

Study group	Recommend treatment		P value	RR (CI 95%)
	Yes Freq (%)	No Freq (%)		
Misoprostol group (n=102)	80 (78.4)	22 (21.6)	0.012	1.3 (1.05, 1.51)
MVA group (n=101)	63 (62.4)	38(37.6)	-	-

Discussion

- Abortion is common
 - Some → incomplete
- Nigeria has restrictive abortion laws
 - Abortion services → largely underground & unsafe
 - Increasingly self induced !
- Incomplete abortion - public health concern

Discussion – 1

- Misoprostol group → 86.3% success!
 - Similar to 84.4% in Ibadan Nigeria (Fawole et al., 2012), 86.9% in Burkina Faso (Blandine et al, 2013)
 - Lower than 98.3% in Egypt (Dabash et al 2010) & 91.8% in sub-Saharan Africa (Shochet et al., 2012)
- Longer follow-up (2 wks) → higher evacuation rate (Fawole et al, 2012; Shochet et al, 2012; Blandine et al, 2013)
 - Not feasible in our study / environment

Conclusion

- Efficacy of sublingual misoprostol (400 mcg) for incomplete abortion in Enugu - very high
 - But, < that of MVA
- Higher patients' satisfaction for misoprostol
 - Despite causing more side effects !

Recommendations

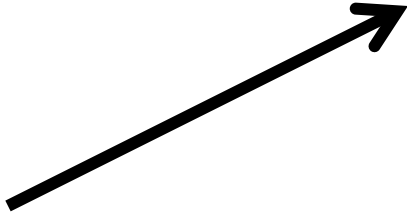
- Sublingual misoprostol (400 mcg) for incomplete abortion - selected cases of post-abortion care in study area
- Re-training of health workers at primary health centers
 - Expand patients' treatment choices

Say No to Unintended pregnancy

- Encourage:
Contraceptives'
use

OR

- “Zip-up”



Thank you

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