

Treatment Approaches for Preeclampsia in Low-Resource Settings: The Springfuser pump for delivery of magnesium sulfate

Thomas Easterling
University of Washington

Hillary Bracken
Gynuity Health Projects
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SUPPLIES COALITION

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Background

- MgSO_4 is inexpensive and effectively prevents and treats seizures associated with preeclampsia
- IM administration
 - painful and associated with patient and provider dissatisfaction, limiting utilization.
- Electric infusion pumps
 - expensive and not available in many low-resource settings
- Gravity-driven IV drip systems
 - higher risk of under or over-dosing given imprecise flow rates and lack of monitoring
- **Springfusor pump offers alternative to IM or gravity-driven IV drip systems in settings where electronic pumps not available**

Springfusor Pump



- Manufactured by GoMedical (Australia)
- Costs:
 - (\$35) Springfusor pump - durable/reusable
 - (\$3) Disposable flow control tubing set including syringe
 - Pump is portable and may be worn attached to the arm or on a lanyard around the neck

Gynuity's clinical and operations research on Springfusor pump

Pregnancy Hypertension: An International Journal of Women's Cardiovascular Health 2 (2012) 32–38



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Original Article

Treatment approaches for preeclampsia in low-resource settings: A randomized trial of the Springfusor pump for delivery of magnesium sulfate

Shuchita Mundle^a, Annie Regi^b, Thomas Easterling^c, Bivas Biswas^b, Hillary Bracken^{d,*}, Vaishali Khedekar^e, D. Ratna Shekhavat^f, Jill Durocher^d, Beverly Winikoff^d

^a Government Medical College, Nagpur, India

^b Christian Medical College, Vellore, India

^c University of Washington, Seattle, Washington, USA

^d Gynuity Health Projects, New York, NY, USA

^e Daga Memorial Women's Hospital, Nagpur, India

^f Matra Sewa Sangh, Nagpur, India

“A randomized trial comparing treatment of severe preeclampsia with a magnesium sulfate regimen administered with the Springfusor infusion pump to a continuous (IV) regimen”

Authors: T Easterling, M Hebert, H Bracken, MC Ramadan, S Shaarawy, E Darwish, D Charles and B. Winikoff

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www.bjog.org

Maternal medicine

Magnesium sulphate for prevention of eclampsia: are intramuscular and intravenous regimens equivalent? A population pharmacokinetic study

DH Salinger,^{a,b} S Mundle,^c A Regi,^d H Bracken,^e B Winikoff,^e P Vicini,^{a,f} T Easterling^g

^a Department of Bioengineering, University of Washington, Seattle, WA, USA ^b Amgen Inc., Seattle, WA, USA ^c Department of Obstetrics and Gynaecology, Government Medical College, Nagpur, India ^d Department of Obstetrics and Gynaecology, Christian Medical College, Vellore, India ^e Gynuity Health Projects, New York, NY, USA ^f Pfizer Inc., San Diego, CA, USA ^g Department of Obstetrics and Gynecology, University of Washington, Seattle, WA, USA

Correspondence: Dr T Easterling, Department of Obstetrics and Gynecology, University of Washington, 1959 Pacific NE, Box 356460, Seattle, WA 98195, USA. Email easter@u.washington.edu

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Summary of Gynuity Springfusor studies

	Mundle et al. (2012)	Mundle et al (2012)	Easterling et al (unpublished)
Setting	2 tertiary hospitals in urban India	2 secondary hospitals in urban India	2 tertiary hospitals in urban Egypt
Study design	RCT	Open label	RCT
Sample size	300	85	200
Comparator	4g IV over 20 min +10g IM +5g IM every 4h	--	4g IV over 20 min+1g per hour
MgSO4 regimen with Springfusor*	4g IV over 20 min+ 4g every 4 hours up to 24 hours	4g IV over 20 min+ 4g every 4 hours up to 24 hours	6g loading dose IV over 30 min +2g over 10 min every 2 hours up to 12 hours
# of flow control tubings req'd	2	2	1
Provider administering MgSO4.	Physicians, residents	Physicians, residents	Physicians (Cairo), nurses (Alexandria)

Springfusor offers safe alternative to IM administration

	SPRINGFUSOR (n=147)	IV/IM (n=153)
Completed 24h of treatment	91.2% (134)	92.2% (141)
Stopped early due to woman's request, side effects, oliguria or renal failure, or signs of toxicity (n,%)	4.0% (6)	6.5% (10)
Stopped early due to staff error or provider preference (n, %)	4.8% (7)	1.3% (2)

Mundle et al. 2012. Differences not statistically significant ($p>0.05$)

Maternal outcomes

	SPRINGFUSOR (n=147)	IV/IM (n=153)
Caesarean delivery (% ,n)	49.3% (72)	43.0% (65)
Seizures post-treatment (% ,n)	0.6% (1)	0.6% (1)
Woman's status at discharge (% ,n)		
Recovered	95.9% (141)	91.5% (140)
Improving	3.4% (5)	7.2% (11)
Unchanged	0.7% (1)	1.3% (2)

Mundle et al. 2012. Differences not statistically significant ($p > 0.05$)

Springfusor reduces side effects associated with IM administration

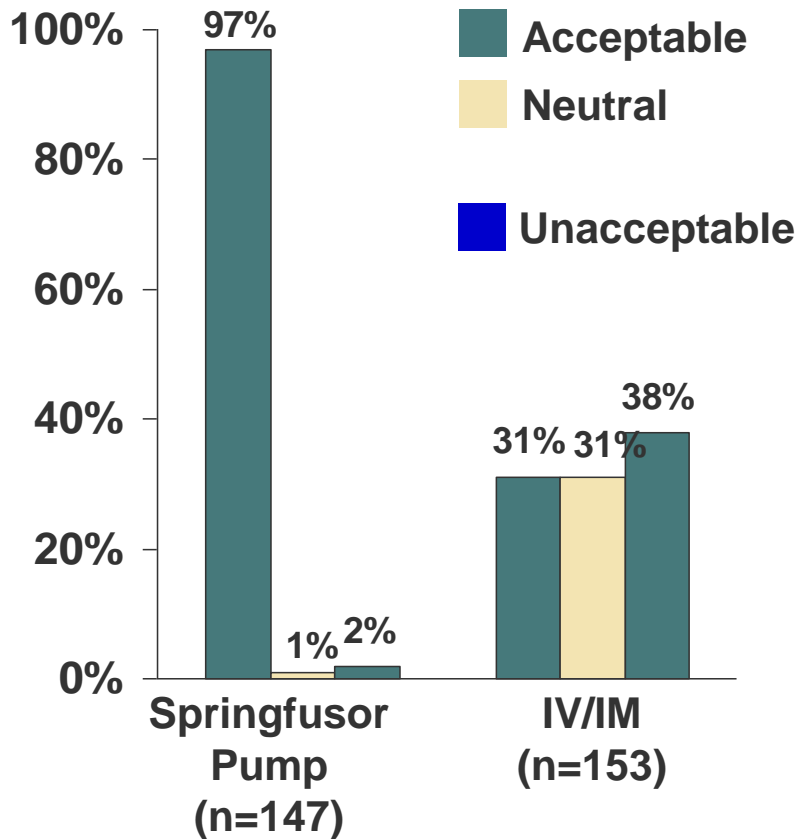
	SPRINGFUSOR (n=147)	IV/IM (n=153)
Flushing [^]	63.3% (94)	75.2% (115)*
Nausea [^]	18.4% (27)	32.7% (50)*
Vomiting [^]	10.2% (15)	11.8% (18)
Headache	4.8% (7)	12.4% (19)*
Drowsiness	15.6% (23)	49.0% (75)*
Diplopia	3.4% (5)	7.8% (12)*

[^] Sides effects frequently associated with rapid infusion of loading dose

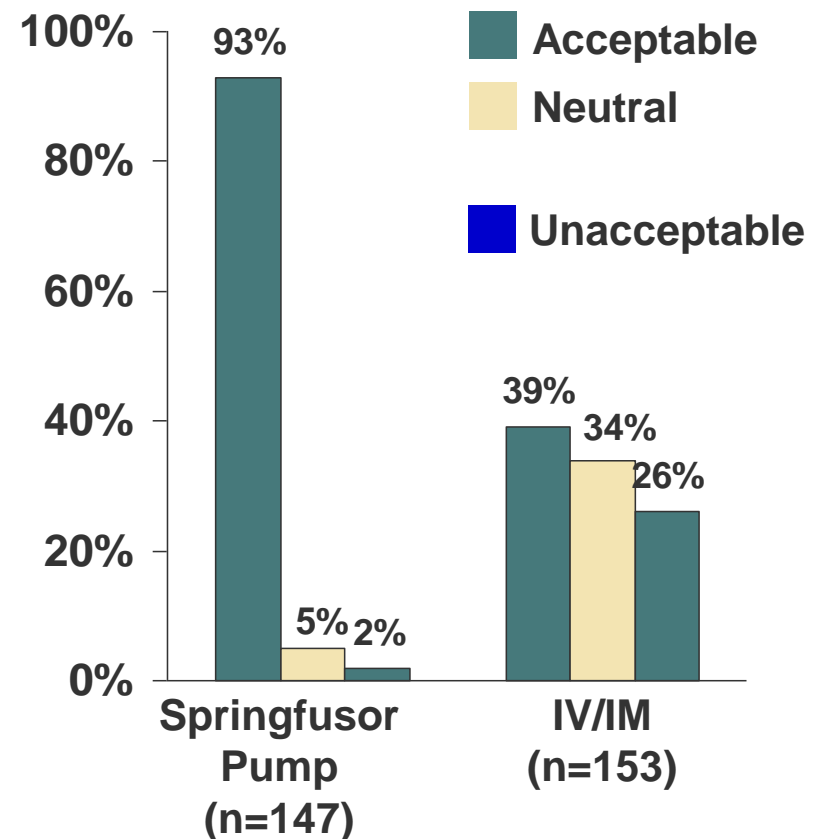
Mundle et al (2012). Differences statistically significant (p<0.05)

Springfuser: Patient acceptability

Pain



Side Effects



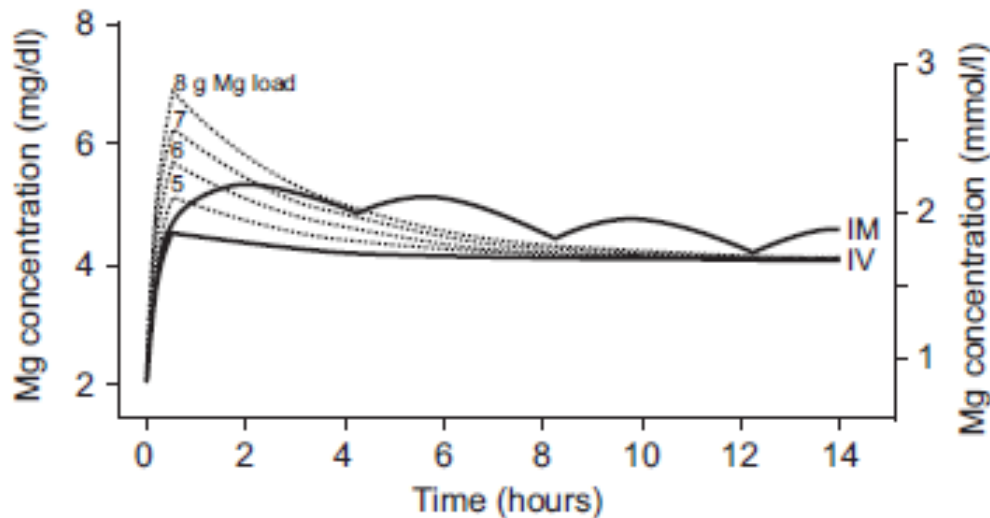
Mundle et al. 2012. Differences statistically significant ($p < 0.05$)

Can Springfusor be used outside a tertiary-care center?

- Open-label trial conducted at secondary care centers in India (n=85)
- Almost all women (82 of 85 or 96.5%) completed the full course of MgSO_4 treatment.
- No case received an excessive dose of MgSO_4
- No eclamptic seizures after study entry
- One woman was successfully referred to tertiary care center with the pump in situ.

Mundle et al (2012).

Refining the Springfusor regimen: Results from a PK analysis



An increased loading dose could provide a higher-concentration time profile in the first 6-8 hours, more comparable to IM

Figure 4. Typical concentration–time profiles for the intravenous and intramuscular dose groups, superimposed with simulations of intravenous dosing with loading dose increased from 4 g to 5, 6, 7 and 8 g.

Conclusions

- Springfusor can be used by health care personnel (nurses and MD) in low resource settings
- Requires little technical support: Providers received three hour training on use of Springfusor pump
- Standardized protocols eliminate the need for user to program a pump or calculate an error rate for magnesium sulfate
- Serial bolus protocol and continuous IV pharmacologically equivalent
 - Serial bolus may offer a “third option” to continuous IV or IM magnesium sulfate
 - decreases cost of Springfusor tubing by 50%

Thank you!



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Opportunities to Improve Care of Hypertensive Pregnant Women



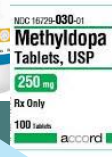
Diagnosis



MgSO₄



Blood Pressure Control



Delivery Induction of Labor



Postpartum Care





Diagnosis

MgSO₄



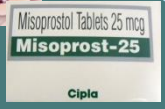
Blood Pressure Control



Postpartum Care



Delivery Induction of Labor



A low-cost paper-based urine test for early diagnosis of pre-eclampsia to reduce pre-eclampsia morbidity and mortality in resource-limited areas

The Research Institute at Nationwide Children's Hospital Columbus, OH, USA





Diagnosis



MgSO₄



Blood Pressure Control




MERCK

Merck for mothers
Committed to Saving Lives



Gynuity
HEALTH PROJECTS



A randomized open-label study to compare the clinical outcomes and magnesium serum concentrations obtained in the treatment of severe pre-eclampsia with a repeat bolus intravenous magnesium sulfate regimen administered with the Springfusor infusion pump to the MAGPIE intramuscular magnesium sulfate regimen



Delivery Induction of Labor

Postpartum Care



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Diagnosis



MgSO₄



Blood Pressure Control



Delivery Induction of Labor

Postpartum Care



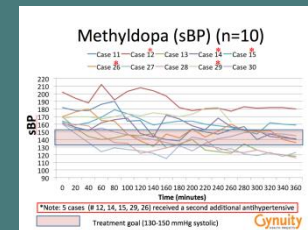
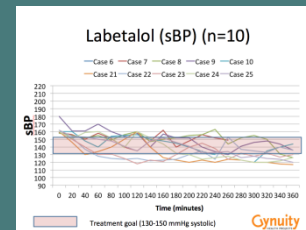
PRE-eclampsia
Eclampsia
Monitoring,
Prevention &
Treatment



Gynuity
HEALTH PRODUCTS

A pilot study of three oral antihypertensive regimens for management of hypertension in pregnancy

- **Primary aim:** To determine the efficacy of oral medications for management of acute, severe hypertension in pregnant women.
- **Secondary aims:**
 - To assess adverse outcomes and necessity for additional hypertensive treatment.
 - To assess maternal and fetal outcomes.





Diagnosis

MgSO₄



Blood Pressure Control



Induction of labour in pre-eclamptic women: a randomised trial comparing the Foley balloon catheter with oral misoprostol

Rationale

- Between 40,000 and 80,000 pregnant women die annually from pre-eclampsia and eclampsia.
- Prompt delivery of the baby, preferably by vaginal route, is vital in order to achieve good maternal and neonatal outcomes.
- WHO recommends two low cost interventions for induction of labour [IOL] - oral misoprostol tablets and transcervical Foley catheterization [1]
- Both misoprostol and Foley catheter are used in low resource settings, but their relative risks and benefits are not known.

[1] World Health Organization, Dept. of Reproductive Health and Research. WHO recommendations for induction of labour. 2011.

Study Design

- Open-label randomized trial
- Study sites
 - Government Medical College, Nagpur, India
 - Daga Women's Hospital, Nagpur, India
- Sample size: 602 women



Delivery Induction of Labor

Postpartum Care



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Future Directions

- Protocols require use of MgSO₄ 50% solution, which may not be available in all settings
 - Springfusor could be pre-packaged in a treatment pack with a supply of 50% solution
- Test use in primary health care facilities where burden of disease may be greatest
- Test use in all women requiring MgSO₄ including eclamptic patients