EBM

Therapeutic reports with controls tend to have no enthusiasm…

Reports with enthusiasm tend to have no controls,

David Sackett, 1986

EBM based Clinical Practice

Is it possible to get all the

EVIDENCE ?

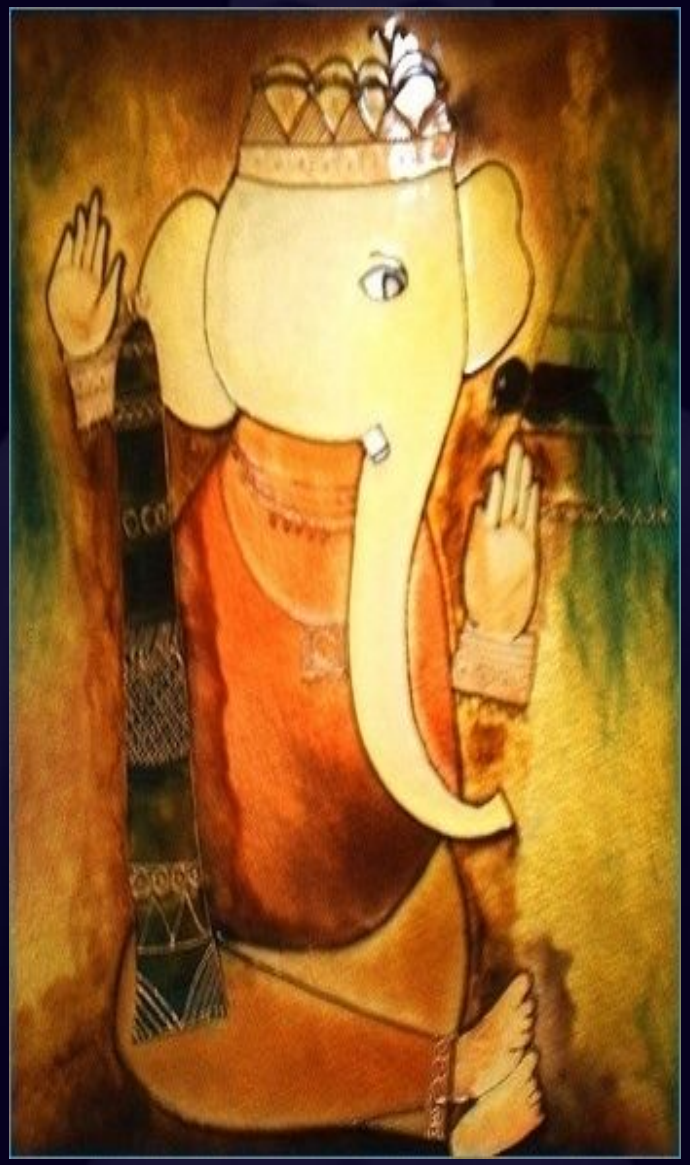
The dilemma of a newly independent India — English cannot continue but has Hindi developed enough to knit regions together?

Is it possible…?

CLINICAL PRACTICE

only based on

EBM



EBM- Current Clinical Practice

HYPERTENSION

Joshi Suyajna D.

Professor of OBG,
VIMS- Bellary

EVIDENCE TO PRACTICE

PRACTICE TO EVIDENCE

PROTOCOLS

GUIDELINES

(RESEARCH & ANALYSIS)

To be made mandatory for all institutions

EVIDENCE TO PRACTICE
PRACTICE TO EVIDENCE

Ideally speaking

EBM

a circular integration of

best research evidence,

clinical expertise, and patient values.

EBM

clinical observation and experience are placed last in the evidence,

RCT

randomized controlled trial

held as the standard for clinical intervention

EBM

clinical decision is supposed to be based on evidence.

what counts as evidence is far from being established.

Some definition of ‘‘proof’’ is needed to distinguish between

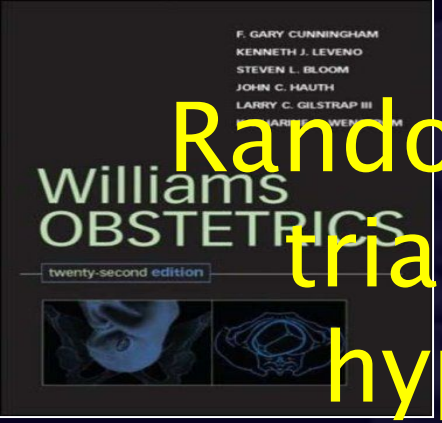
scientific medicine and charlatanism.

EBM – Actual treatment

ELDERLY PRIMIGRAVIDA

31 weeks of Gestation
146/98 mm Hg
148/98 mm Hg
148/98 mm Hg

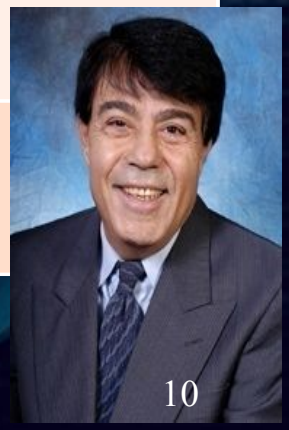
TO TREAT OR NOT TO TREAT !!!



Randomised- placebo controlled trials for mild to moderate hypertension of pregnancy

Sebai et al 1987 (a)	Labetalol 100	Placebo 100
Sebai et al 1992 (b)	Nifedipine 100	Placebo 100
Pickles et al 1992	Labetalol 70	Placebo 74
Wide-Swensson 1995	Isradipine 54	Placebo 57

NO BENEFIT WITH ANTIHYPERTENSIVE THERAPY



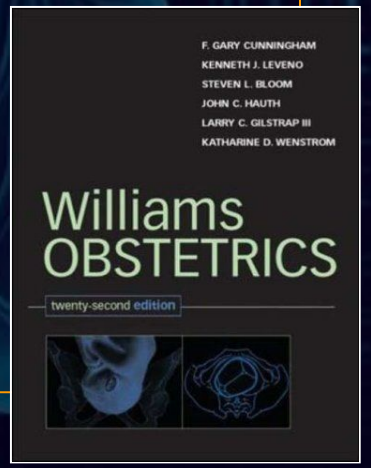
Conclusion

NO BENEFIT WITH ANTIHYPERTENSIVE THERAPY

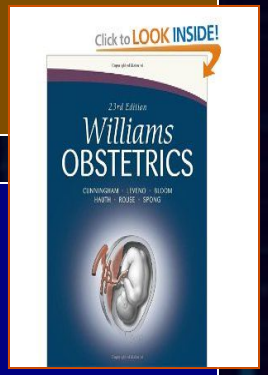
Von Dadelszen and Magee 2002,

Antihypertensive induced decresed BP – adversely affects foetal growth

William's Textbook of Obstetrics, 23rd ed.



Abalos et al 2007



REVIEW OF 46 TRIALS with antihypertensive for

mild to moderate hypertension

1. Risk of developing Severe Htn. Is **Decreased**.

2. Foetal Growth Restriction was **not** increased.

William's Textbook of Obst. 23rd ed.

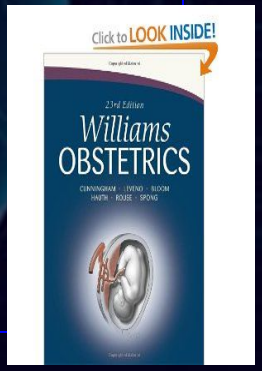
B-blockers in pregnancy

August & Lindheimer, 2009

NO RISK OF IUGR- B-blockers given throughout pregnancy in chr. Hypertension.

Umans et al: same findings

William's Textbook of Obstetrics. 23rd ed



treatment of women with uncomplicated

mild to moderate hypertension is not beneficial

because it does not improve perinatal outcome. acog…rcog…!

But

it will not worsen…if proper drug is used…!

What Are the Benefits of Treating Mild Hypertension in Pregnancy?

- Data are insufficient to either prove or disprove effects on perinatal outcome
  - All trials had inadequate sample size
  - Most were un-blinded
  - Few women enrolled in first trimester
  - 15 different drugs or combinations were studied

EBM

Maternal mortality ?

EXPERIENCE…my…

supporters of the evidence-based medicine movement,

the best empirical basis is contributed by

randomised controlled trials

(RCTs)

Evidence
Lack of evidence

even if we have well-conducted RCTs,

all we can achieve is

a "weight of evidence"

because of

conflicting results from RCTs

EBM…A PARADOX…

RCTs cannot be easily conducted

for

practical or ethical reasons

Letrazole…mesoprostol

EBM- A PARADOX…

In many cases RCTs cannot be conducted,

often they are not relevant

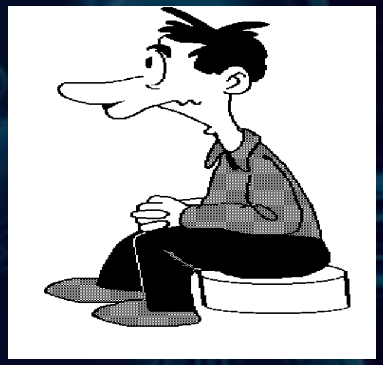
Eg. Instrumental evacuation for Incomplete abortion

Very good in EBM…

BAD CLINICIAN…!

Mr. EBM

- Mr. EBM will convey the FACT (?) as on today,
- He has no VISION
- He can not THINK



GUIDELINES CHANGE FASTER THAN WE CAN ANALYSE THEM

SO…WHAT TO PRACTICE ?

Recommended best practice

based on

clinical experience of the guideline development group

EBM ...just a reference

EBM in reality….

A Language with Lot of Difficulties

TIME- PLACE- ACTION ?

MORE THAN 1000 CASES

- MATERNAL MORTALITY-
- PERINATAL MORTALITY-
- CAESAREAN SECTION RATE-

SDM-' VIMS' regimen is 'simple '

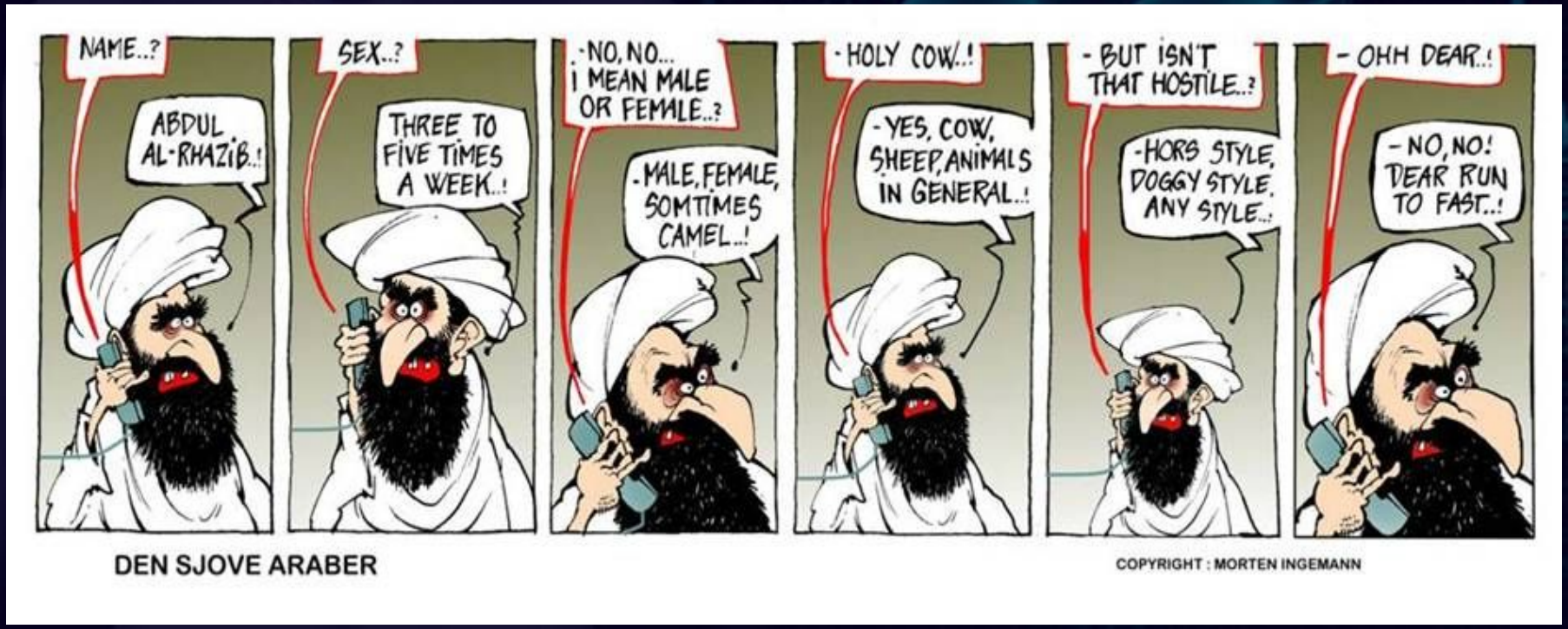
SDM- can be safely used outside the established Obstetric centers

at Primary Health care level itself where maximum cases of eclampsia occur

JOSHI SUYAJNA D.

EBM in reality….

A Language with Lot of Difficulties



Pritchard's Regimen....

54 years old !

- **Pritchard JA.**

  " The use of the magnesium ion in the management of eclamptogenic toxemias."

Surg Gynecol Obstet. 1955; 100: 131-140

1985 To 1995 REBIRTH

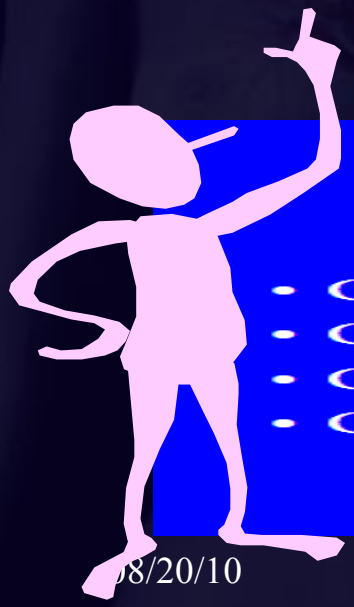
for Mgso4

- Pritchard JA, Cunningham FG, Pritchard SA.
- The Parkland Memorial Hospital protocol for treatment of eclampsia: Evalauation of 235 cases.
- *Am J Obstet Gynecol.* 1984; 148: 951-960

NEED OF THE DAY

STUDY – RESEARCH – ANALYSIS WING

TO DECIDE WHAT IS GOOD FOR YOUR PLACE OF WORKING



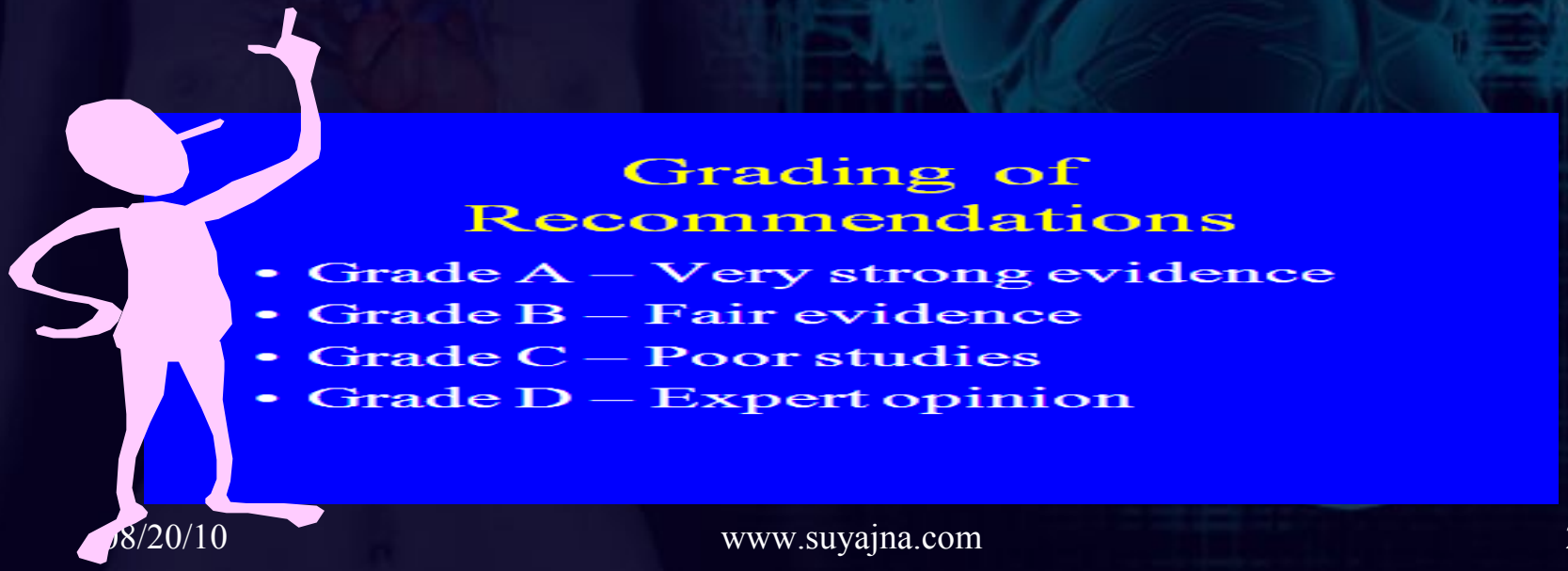
Grading of Recommendations

- Grade A — Very strong evidence
- Grade B — Fair evidence
- Grade C — Poor studies
- Grade D — Expert opinion

NEED OF THE DAY

1. PROTOCOLS
2. GUIDELINES

For your INSTITUITION



VISRA

VIJAYANAGARA INSTITUTE of Medical Sciences STUDY REASEARCH & ANALYSIS- VISRA

DR. JOSHI SUYAJNA D.

VISRA-PROJECTS

1. Hypertensive Disorders of Pregnancy
2. Anaemia of Pregnancy
3. Intrapartum- INSTRUMENTAL DELIVERIES, CORD ROUND THE NECK
4. VISRA & SAFE MOTHERHOOD COMMITTEE
5. Multicentric Study on SDM

ANAEMIA OF PREGNANCY

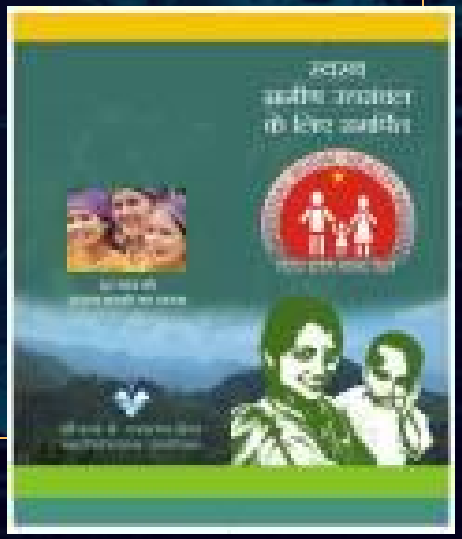
1. Antepartum Intravenous SUCROSE
(As a part of a study by ARTIST)

2. Postpartum I V SUCROSE-
500 cases- funded by
VIMS DEVELOPMENT TRUST, BELLARY

VISRA & SAFE MOTHERHOOD COMMITTEE– BELLARY

REDUCING MMR BY INTRODUCING VIMS-SDM REGIMEN IN THE FRUs.

'24X7' HELPLINE service for all MOs



VISRA- LONG TERM STUDIES

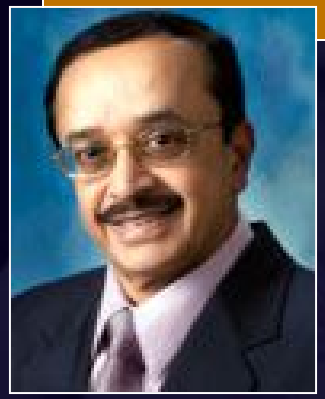
More than 10 years:

1. VIMS REGIMEN for eclampsia and severe pre-eclampsia
2. Acute ascites in pregnancy

More than 5 years

1. CT scan in Eclampsia
2. CT scan in htn related BLINDNESS

FOGSI PROJECTS



'REACHING THE UNREACHED'

Sanjay Gupte's vision for
FOGSI INITIATIVE 2010

FOGSI- NER MULTI-CENTRIC STUDY

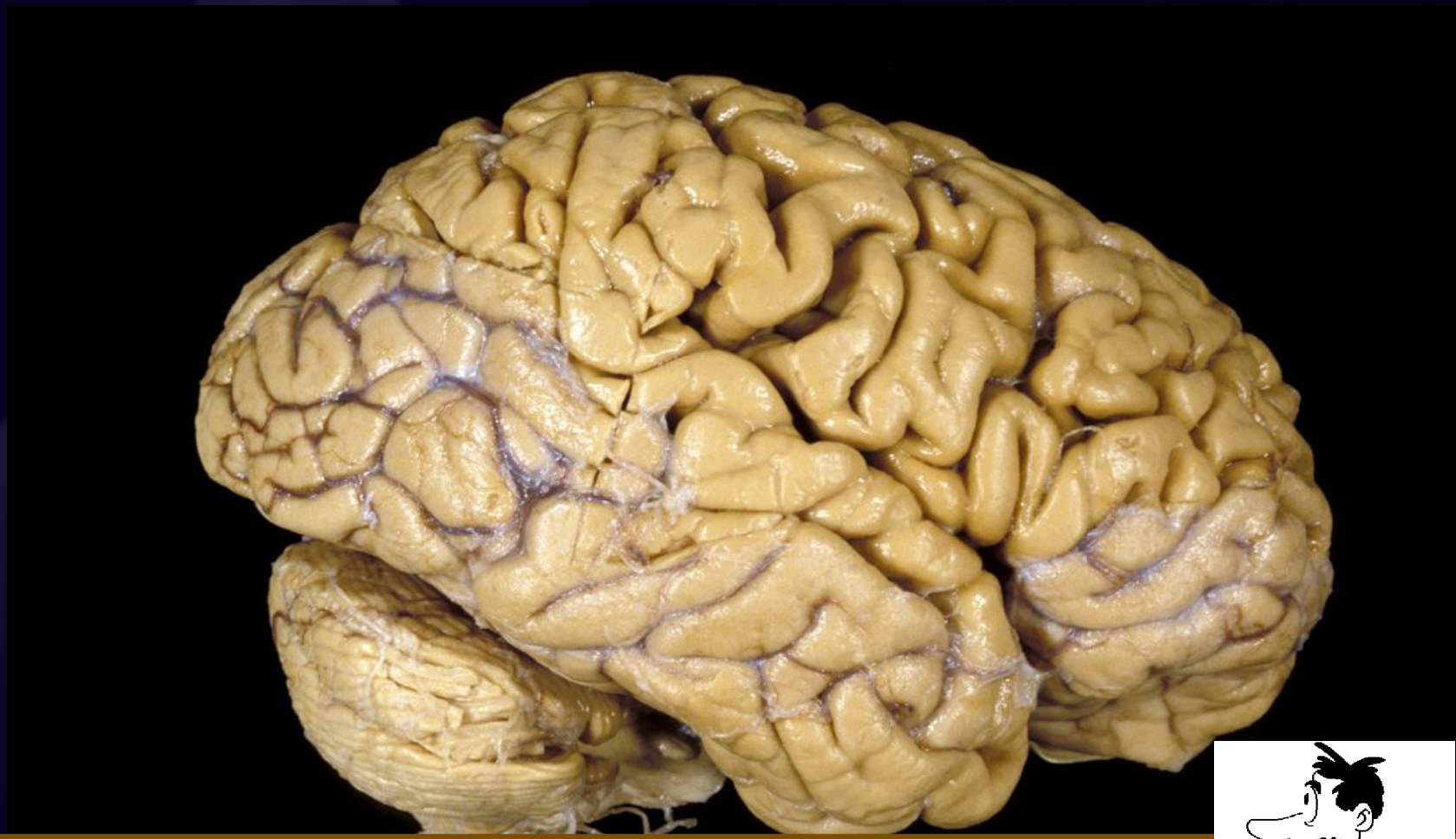
"Clinico-Biochemical correlation of serum magnesium levels in Imminent eclampsia and Eclampsia with

Single dose Mgso4-VIMS regimen- and Pritchard regimen".

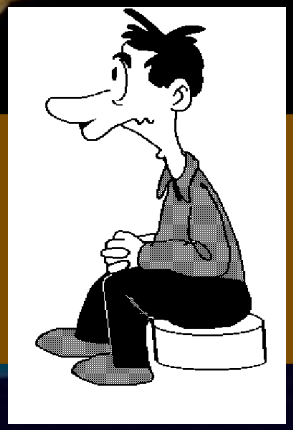
HYPERTENSIVE DISORDERS OF PREGNANCY

I.V. LABETOLOL Vs ORAL

NEFEDIPINE



Acute Treatment of Severe Hypertension in Pregnancy



Basic Management Objectives

- Termination of pregnancy with least possible trauma to the mother and the fetus
- Birth of an infant who subsequently thrives
- Complete restoration of health to the mother

VIMS Guidelines ANTI-HYPERTENSIVE Rx

GROUP 'A'

1.Persistent rise of BP in mild to moderate PE

2.Severe preeclampsia- EXPECTANT

GROUP 'B'

Hypertensive crisis

DEVIL'S DUE....

Are we neglecting HYPERTENSION in pregnancy because of the

GLAMOUR of convulsions of ECLAMPSIA ?

DIFFERENT MgSO4 REGIMENS …

- Eastman.
- Pritchard.
- Chesley & Teppers.
- Hall, Anderson, Harbert.
- Flowers.
- Zuspan.
- Cruik Shant.
- Sibai.
- Sardesai
- Leens.

JOSHI'S VIMS REGIMEN

Comparison of Outcomes in 'VIMS'

OUT COME	Joshi et al, 2003-07	Gaddi et al, 1998-03
Recurrence	9.16%	9.2%
Maternal Mortality	3.3%	5.4%
Perinatal Mortality	24.8%	39.3%
Severe Complications	11.7%	16.3%

Gaddi Suman S, Somegowda. 'Maternal & Perinatal outcome in eclampsia in a district hospital. J Obstet Gynecol Ind 2007 July;vol 57(4):324-326

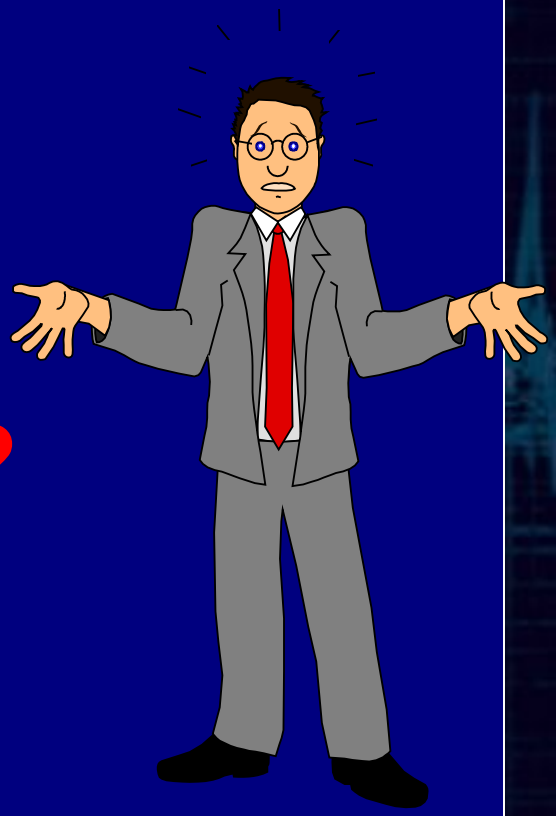
Maternal deaths....in Eclampsia

Cause		Percentage %
Intracranial hemorrhage	10	58.82%
Pulmonary edema	5	29.41%
Ante partum hemorrhage	1	5.88%
Acute renal failure	1	5.88%

MAP more than 125

WHY

I.V. LABETALOL ?



management of hypertensive emergency

Different units have their preferences for either parenteral hydralazine or labetalol, and **some use oral nifedipine**

Recent studies nifedipine and labetalol effective and safe

Combination avoided

- In severe preeclampsia with BP 160/110, can nifedipine and magnesium sulphate be given together?

Is there any additive adverse effect of giving them both together?

Abrupt hypotension is potentiated with concomitant magnesium sulfate

limitation –rare.. but scary

treated for preterm labor had an **MI** with **nifedipine**.

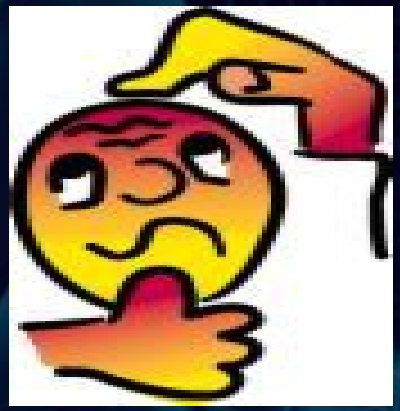
sublingual nifedipine

sudden maternal hypotension

placental hypoperfusion–

fetal distress

NIFEDIPINE



PLAYED A VERY LONG INNINGS...!

I.V. Labetalol Vs Nifedipine

1.Control of Hypertension

1.Feto- Maternal outcome

FOGSI-VIMS TRIAL

I.V. Labetalol Vs Nifedipine

PREGNANCY WITH BP

- 160/110 mmHg

Contraindications:

Asthma

Av block

I.V. Labetalol Vs Nifedipine

RULE OF

15

VIMS TRIAL

I.V. Labetalol Vs Nifedipine

LABETALOL: Initial dose
15 mg- BOLUS
Repeat dose-15 mg
every -15minutes- up to 15 times

STOP BOLUS when sBP is falling below 150 mmHg

VIMS TRIAL

Labetalol

Start oral : 200 mg twice daily when

BP starts rising

ORAL NIFEDIPINE

Initial dose-10mg

Repeat dose-10mg every 30 min.

MAXIMUM - 80 mg in 24 hours.

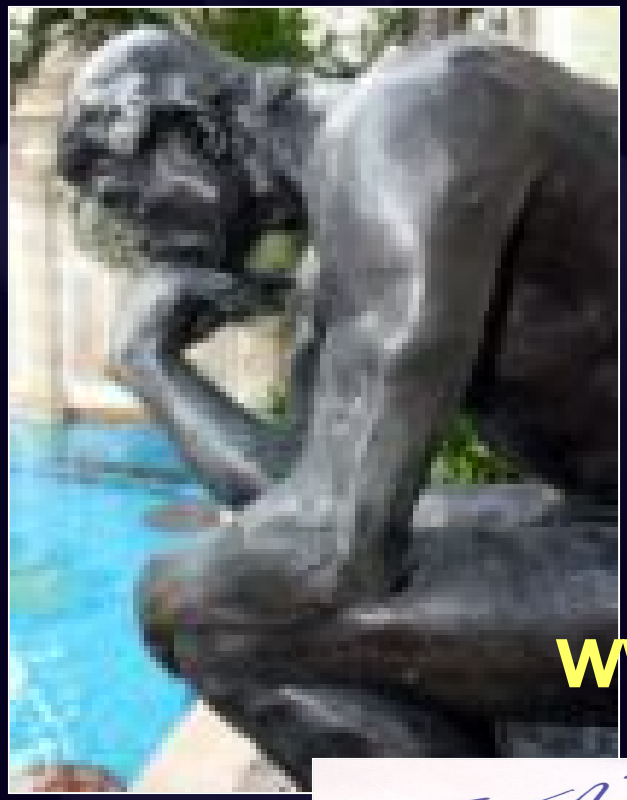
Reduce the dosage when sBP starts falling below 150 mm Hg

January 2010- VIMS

Severe PE	12
Imminent eclampsia with severe htn	4
Chronic htn (severe)	2
Eclampsia	12
Eclampsia with Severe htn	NIL

MATERNAL MORTALITY	NIL
Recurrence of convulsion	1

Safe-motherhood Committee, Bellary



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