What's New in Intravascular Devices

Dr. Mark Rupp, University of Nebraska Medical Center

A Webber Training Teleclass

What's New in Intravascular Devices

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Hosted by Martin Kiernan
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www.webbertraining.com May 16, 2013

Potential Conflict of Interest Disclosure

In past 5 years:

- Research contracts to UNMC:
  - Cubist, Becton Dickinson, 3M, Molynlcke, Sanofi, Cardinal Healthcare Foundation
- Consultant:
  - Semprus, Microbiotix, Bard, Baxter, 3M
- Honoraria:
  - Baxter, 3M, Care Fusion

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Objectives

- Clinical Significance of CLA-BSI
- Pathogenesis of CLA-BSI
- Prevention of CLA-BSI
  - Practice Measures
  - Technologic Innovations
    - Coated/Impregnated CVCs
    - Antimicrobial Dressings
    - Needleless Connectors and Coated Valves
    - Caps
    - Antimicrobial Locks/Flushes

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Clinical Significance of CLA-BSI

- 78,000 central line-associated bloodstream infections (CLA-BSI) are estimated to occur yearly in United States hospitals and dialysis units.
- 2010 NHSN report from 3029 US hospitals, mean CLA-BSI rate in critical care units ranged from 0.6 – 3.5/1000 CVC d.
- CLA-BSI are associated with an estimated mortality rate of 12.3% and excess healthcare costs between $7,288 and $29,156 per episode.

Srinivasan A, et al. MMWR 60: 2011; CDC BHSN 2010 Data Summary; Umscheid CA, et al. Infect Control Hosp Epidemiol. 2011; 32:101-114. Scott RD. Division of Healthcare Quality Promotion, CDC, 2009.

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Clinical Significance of CLA-BSI

- Europe
  - EPIC II Study (Vincent, et al. JAMA 2009). 1 day point prevalence survey of 13,796 adult ICU patients. 51% had an infection, 15.1% BSI, 4.7% CLA-BSI
  - Germany KISS
    - 2008, 26 ICUs mean CLA-BSI rate 2.63/1000 CVC d
  - Hansen et al. (J Hosp Infect, 2009)
    - 5 countries, 288 ICUs, median CLA-BSI rate 1.5/1000 CVC d

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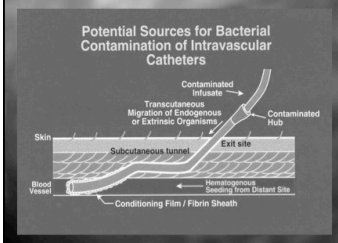
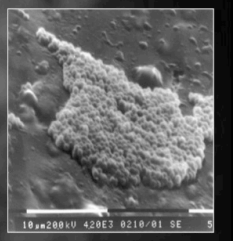
Pathogenesis of CVC-Associated BSI





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Prevention of CLA-BSI
Practice Interventions

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The NEW ENGLAND JOURNAL of MEDICINE

DECEMBER 28, 2006

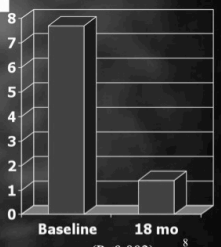
An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

Intervention in 108 ICUs:
- Daily Goals Sheet
- Hand Hygiene
- Full Sterile Barrier Precautions
- Chlorhexidine Antiseptic
- Avoidance of the Femoral Site
- Removal of CVCs asap

Compliance? Use of Technologic Innovations? Surveillance and Validation?

Mean BSI/1000 CVC d



(P<0.002)

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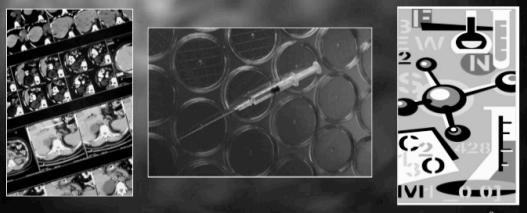
Prevention of CLA-BSI
Technologic Interventions



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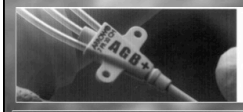
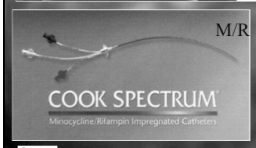
Commercially Available Antimicrobial Central Venous Catheters



CHG/SS

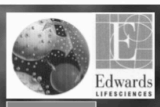
ARROWg'ard Blue PLUS® Central Venous Catheters



M/R

COOK SPECTRUM

Minocycline/Rifampin Impregnated Catheters



Silver/Platinum/ Carbon (Silver Iontophoretic; Vantex)

Hydrocath Assure (BD)
Benzalkonium
AMC Thromboshield (Edwards)
Benzalkonium Heparin

Multistar
Miconazole/Rifampin
(Vygon)

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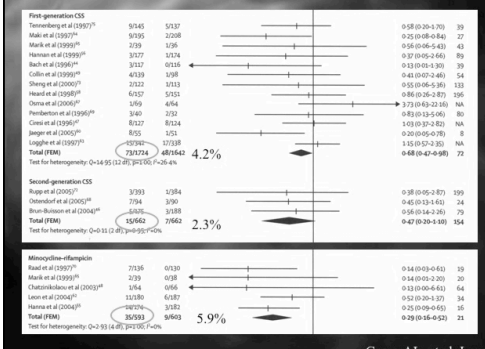
Do antimicrobial-coated catheters prevent BSI?



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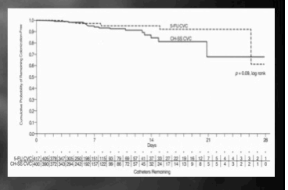
Casey AL, et al. Lancet ID, 2008

Novel Antimicrobial Catheter Treatments (5-FU)

- 5-Fluorouracil
  - Multi-center, RCT of 5-FU vs 1st gen CH/SS CVC in ICU pts
  - Colonization 5.3% vs 2.9% (P=0.09)
  - CR-BSI 0.7/1000 CVC d for CH/SS vs 0.0/1000 d CVC d (NS)



Kaplan Meier analysis of colonization

Walz, et al. Crit Care Med, 2010

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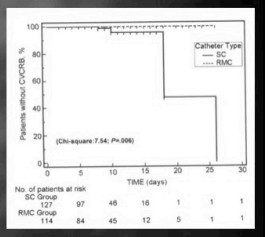
Novel Antimicrobial Catheter Treatments (Rifampicin-Miconazole)

- Lorente L, et al. Clin Infect Dis 2008
- Single center, controlled, non-blinded, non-randomized study
- 241 CVCs at IJ site, 184 femoral site
- CR-BSI/1000 CVC d:
  - IJ: 4.93 vs 0 (P=0.03)
  - Femoral: 8.62 vs 0 (P=0.04)



CR-BSI/1000 d for IJ Site

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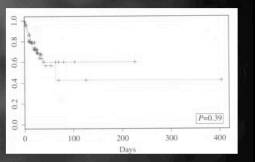
Novel Antimicrobial Catheter Treatments (Silver Nanoparticles (AgTive)

- Antonelli M, et al J Hosp Infect, 2012
- Prospective, randomized, controlled, study in 5 ICUs; 338 pts
- Results:
  - Colonization: 32.6% vs 30%
  - CR-BSI: 3.36/1000 CVC d in each group



CR-BSI; P=0.39

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Novel Antimicrobial Catheter Treatments

- Chlorhexidine/Minocycline/Rifampin
  - Raad, et al. AAC 2012:
- Gendine (Gentian violet & Chlorhexidine)
  - Hanna, et al. AAC 2006
  - Broad spectrum activity vs GPC, GNR, Fungi; Duration of activity > 3 weeks; Outperformed M/R, CH/SS CVCs

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Cost effectiveness of antimicrobial catheters in the intensive care unit: addressing uncertainty in the decision

Kate A Halton[1,2], David A Cook[3], Michael Whitby[4], David L Paterson[1,5] and Nicholas Graves[1,2]

"Current evidence suggests that the cost effectiveness of using antimicrobial CVCs within the ICU is highly uncertain. Policies to prevent CR-BSI amongst ICU pts should consider the cost effectiveness of competing interventions… Decision makers would do well to consider the current gaps in knowledge and the complexity of producing good quality evidence in this area."

Crit Care, 2009

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Chlorhexidine Impregnated Dresssings

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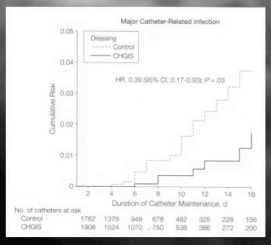
Chlorhexidine-Impregnated Sponges and Less Frequent Dressing Changes for Prevention of Catheter-Related Infections in Critically Ill Adults

A Randomized Controlled Trial

Timsit, et al. JAMA, 2009



- CR-BSI: 1.3/1000 CVC d vs 0.4/1000 CVC d (P<0.005)
- No significant difference between 3d and 7d dressing changes
- Full sterile barrier precautions used
- Site prep with 4% povidone iodine soln & PI/Etoh

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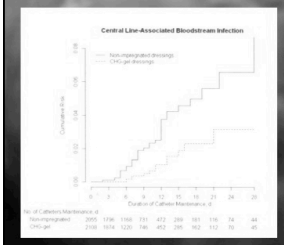
Randomized Controlled Trial of Chlorhexidine Dressing and Highly Adhesive Dressing for Preventing Catheter-Related Infections in Critically Ill Adults

Timsit JF, Mimoz O, Mourvillier B, et al. Amer J Resp Crit Care Med, 2012



- 12 ICUs, 4163 catheters
- CR-BSI: 1.3/1000 CVC d vs 0.5/1000 CVC d (P=0.0006)
- Highly adhesive dressings decreased detachment rate, but increased catheter colonization rate
- Full sterile barrier precautions used & Site prep PI/Etoh or CHG/Etoh

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Chlorhexidine Patient Bathing

Effectiveness of Chlorhexidine Bathing to Reduce Catheter-Associated Bloodstream Infections in Medical Intensive Care Unit Patients

Susan C. Bleasdale, MD; William E. Trick, MD; Ines M. Gonzalez, MD; Rosie D. Lyles, MD; Mary K. Hayden, MD; Robert A. Weinstein, MD

Arch Intern Med 2007

Daily CHG baths in ICU patients decreased BSI from 16.8 to 6.4/1000 CVC d.

Effectiveness of Routine Patient Cleansing with Chlorhexidine Gluconate for Infection Prevention in the Medical Intensive Care Unit

Kyle J. Popovich, MD; Bala Hota, MD, MPH; Robert Hayes, BA; Robert A. Weinstein, MD; Mary K. Hayden, MD

ICHE 2009

Daily CHG baths in ICU patients decreased CLA-BSI from 6.99 to 4.1/1000 CVC d

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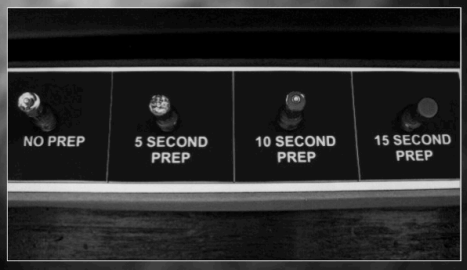
Scrub the Hub!



Slide courtesy Kristina Bryant, Kosair Children's Hosp

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Not All Mechanical Valves are Created Equal

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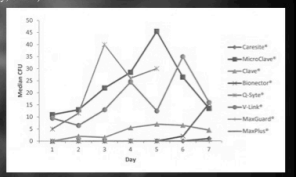
Needleless Connector Valves Linked to Increased CLA-BSI

(Figure from Jarvis, Infect Control Today, 2010)

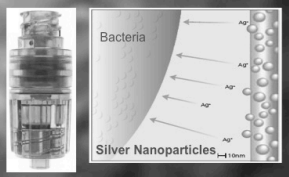
- Maragakis: ICHE, 2006
- Rupp: Clin Infect Dis, 2007
- Salgado: ICHE, 2007
- Field: ICHE, 2007
- Toscano: AJIC, 2009
- Jarvis: Clin Infect Dis, 2009



Median CFU *S. aureus* recovered from eluate over 7 days of simulated clinical use

(Casey et al, IDWeek, 2012)

Silver coated connector valves



- 2 silver coated IV connector valves on the market. Very little clinical data re: effect on colonization of catheters or Bloodstream infection

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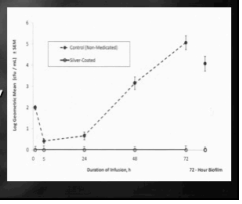
In Vitro Studies of a Novel Antimicrobial Luer-Activated Needleless Connector for Prevention of Catheter-Related Bloodstream Infection

Dennis G. Maki — Clin Infect Dis, 2010

- 1) Control vs coated connectors challenged with direct inoculation of 10^5 organisms into valve:
  - 5.2-6.8 log reduction of 5 species of bacteria and 3 log reduction of *C. albicans.*
- 2) Simulated clinical use: septum inoculated with 10^3 *E cloacae*, allowed to dry, connector actuated, infusion x 72 h, down stream fluid sampled and biofilm in valves assessed



Microbiological comparison of a silver-coated and a non-coated needleless intravascular connector in clinical use

A.L. Casey, T.J. Karpanen, P. Nightingale, M. Cook, T.S.J. Elliott*

University Hospitals Birmingham NHS Foundation Trust, The Queen Elizabeth Hospital, Edgbaston, Birmingham, UK

J Hosp Infect, 2012

- 25 pts with haematologic malignancy randomized to have silver coated connector or control. Following 4 days of use, connectors evaluated for colonization

Rate and level of microbial presence on and within the silver-coated and non-coated connectors following clinical use

	Non-coated	Silver-coated	OR (95% CI)	*P*-value
No. of connectors cultured	117	119		
No. (%) of connectors with micro-organisms present on the external silicone compression seal	41 (35)	36 (30.3)	0.8 (0.47–1.39)	0.49
Median no. of cfu isolated from the external silicone compression seals (lower and upper quartiles)	0 (0–2)	0 (0–2)		0.50
No. (%) of connectors with micro-organisms present within the internal fluid pathway	55 (47)	31 (26.1)	0.40 (0.23–0.69)	0.001
Median no. of cfu isolated from the internal fluid pathway (lower and upper quartiles)	0 (0–4)	0 (0–2)		0.001

OR, odds ratio; CI, confidence interval; cfu, colony-forming units.

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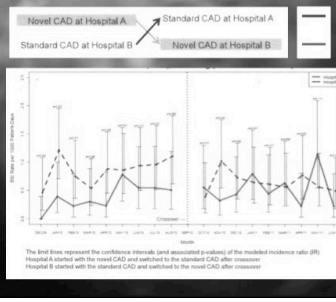
Comparison of a Novel Silver-Coated Catheter Access Device and a Standard Catheter Access Device: A Dual Center Cross-over Study

JT Jacob, et al. IDSA Annual Meeting 2012



- Crude CLA-BSI incidence rate 0.54/1000 pt d (silver) vs 0.73/1000 pt d (control) (p = 0.02)

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Anti-Infective Catheter Lock Solutions

	No. CRBSI/No. IVDs Control	VHLS	RR (95% CI)	
Schwartz et al	8/29	3/24	0.45 (0.14-1.38)	
Rackoff et al	10/31	10/32	0.97 (0.47-1.98)	
Daghistani et al	3/34	2/30	0.76 (0.16-3.56)	
Carratala et al	17/60	15/57	0.84 (0.47-1.5)	
Henrickson et al	31/80	6/35	0.08 (0.04-0.18)	
Garland et al	18/43	7/42	0.4 (0.19-0.82)	
Barriaga et al	26/44	18/39	0.78 (0.50-1.18)	
Overall	**113/321**	**61/259**	**0.49 (0.26-0.95)**	**P=0.03**

Conclusion: Anti-Infective Lock solutions are useful in certain circumstances. Additional study to assess optimal solution (antibiotics, alcohol, taurolidine, trisodium citrate, EDTA, etc) and populations

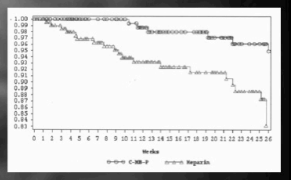
Safdar & Maki, CID, 2006

A novel antimicrobial and antithrombotic lock solution for hemodialysis catheters: A multi-center, controlled, randomized trial*

Dennis G. Maki, MD; Stephen R. Ash, MD; Roland K. Winger, BS, PE; Philip Lavin, PhD; for the AZEPTIC Trial Investigators

Crit Care Med, 2011

- Lock solution of 7% sodium citrate, 0.15% methylene blue, 0.30% parabens
- 25 HD centers, randomized, open-label study



CR-BSI: 0.82 vs 0.24/1000 CVC d; RR 0.29, P=0.005

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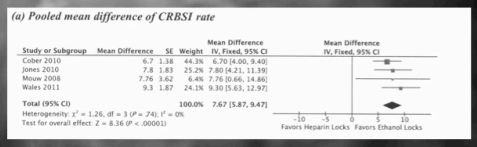
Ethanol Locks to Prevent Catheter-Related Bloodstream Infections in Parenteral Nutrition: A Meta-Analysis

Oliveira C, et al. Pediatrics, 2012



- Risk ratio for CR-BSI: 0.19 (95% CI 0.12-0.32)
- Risk ratio for catheter replacement: 0.28 (95% CI 0.06-1.23)

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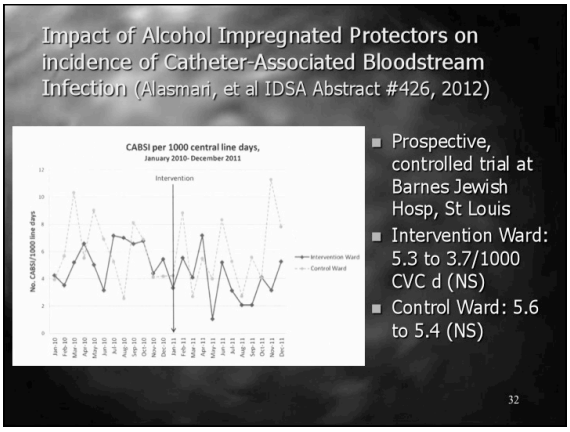

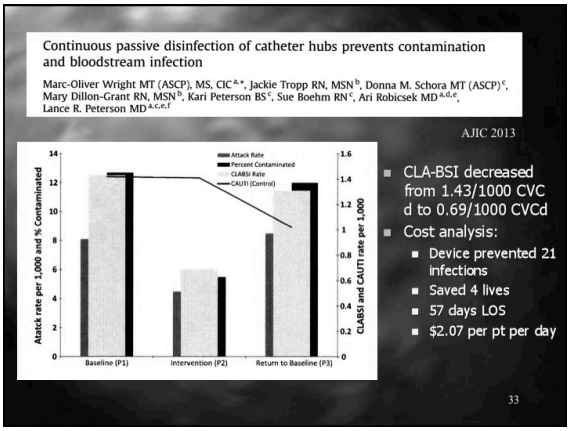

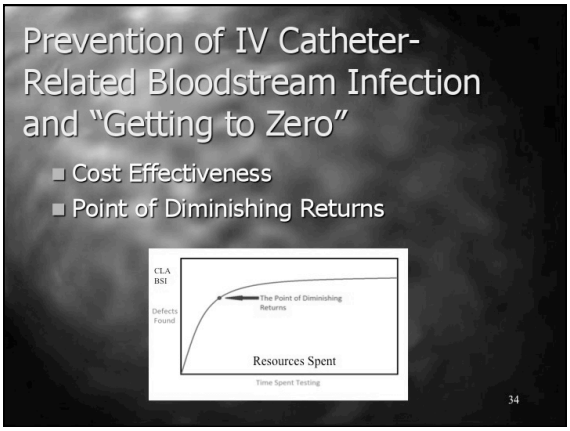

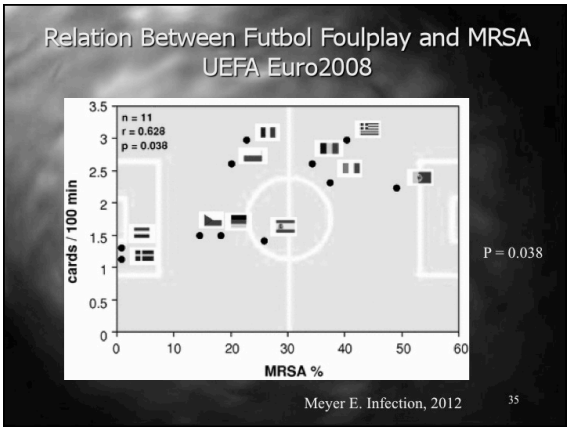

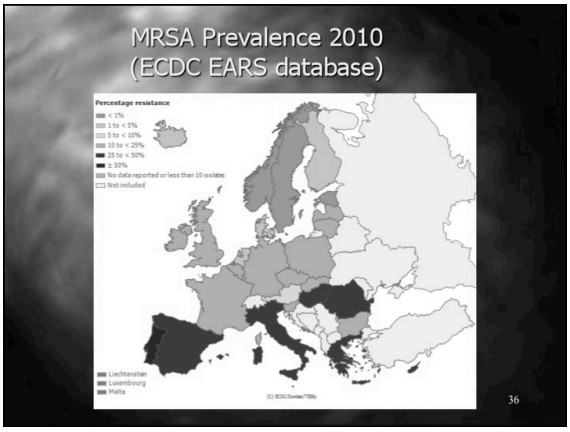

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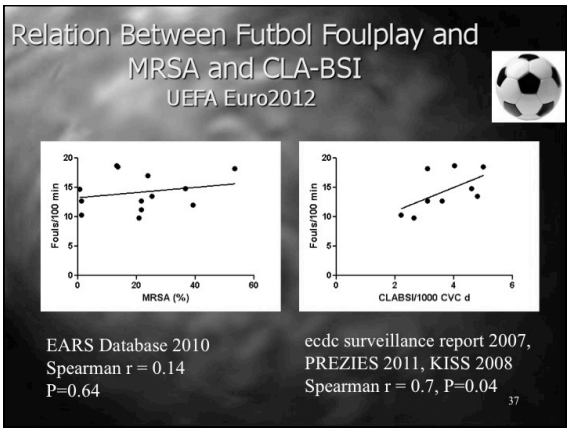

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