
# EVIDENCE BASED MEDICINE

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# The Big Question????

Are scientific methods used to determine which drugs and procedures are best for treating diseases?

# Evidence Based Medicine (EBM)

- 1980s:It started in Canada, applying basic rules of evidence.
- Term: Scientific medicine was suggested.
- 1991: Term “Evidence Based Medicine” appeared.
- In 1992, the UK government funded the establishment of the **Cochrane** Centre in Oxford.

# الطب المبنى على الدليل

# DERMATOLOGY POSTGRADUATE COURSE

**Course aims:**

- To build up dermatologists who are skilled and competent in the diagnosis and management of all aspects of diseases of the skin and its appendages, capable of applying national and international standards of patient care and **scientific research, using evidence based medicine competently in practice**, together with the ability to respond to the changing health needs of the Egyptian community.

# Definition

**Evidence-based medicine (EBM)** is the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.

# Why Evidence Based Medicine?

- In practice we need information about diagnosis, treatment and harm.

Q:

- What is the best diagnostic modality to ask for?
- What is the best treatment that I should prescribe?
- What are the harms that might affect this patient from certain treatment?

# Why Evidence Based Medicine?

- Answer should be based on solid research evidence rather than on opinion, or past untested experience.
- **Clinicians should:**
- A- Adopt a life-long learning process to stay up to date with current literature.
- B- Provide the scientifically proven best diagnostic or treatment modality to your patient.

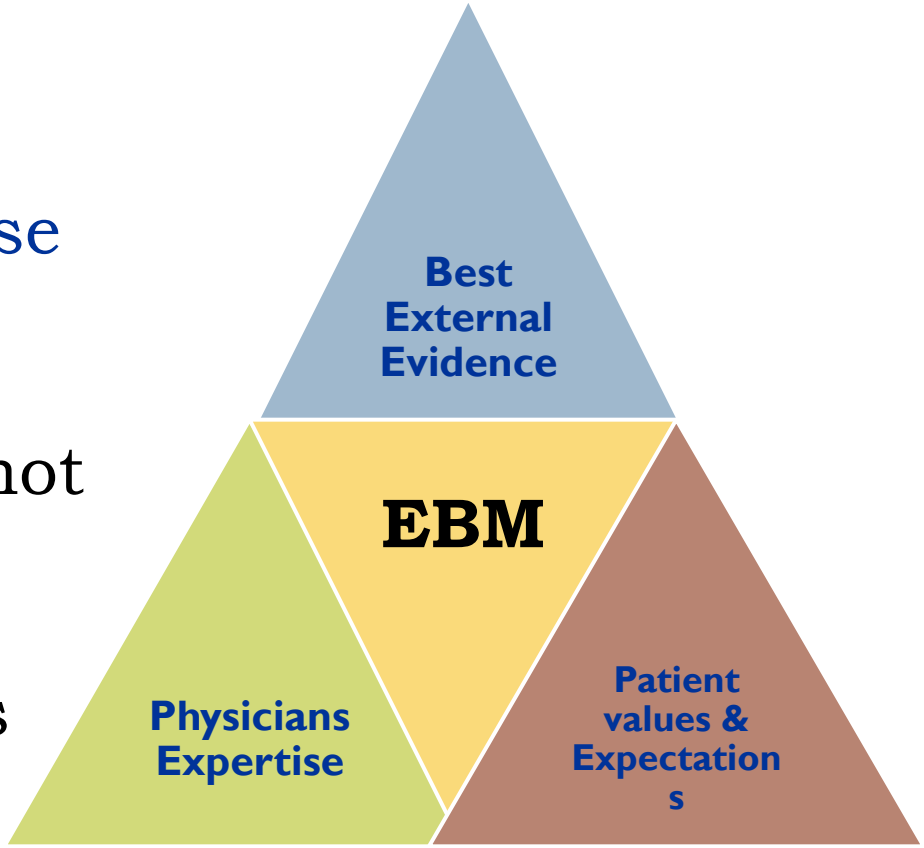
# EBM forms part of a multistep process:

1. Production of evidence through research and scientific review.
2. Production and dissemination of evidence-based clinical guidelines.
3. Implementation of evidence-based, cost-effective practice through education and management of change.
4. Evaluation of compliance with agreed practice guidance through clinical audit and outcomes-focused incentives.

- الدليل
- المبادىء التوجيهية
- التطبيق
- التقييم

# What is Evidence Based Medicine?

- Defined as:
  Integration of best research evidence with clinical expertise and patient values.
- EBM complements experience; it does not replace it.
- EBM integrates patients preferences and concerns into clinical decisions.



# How to practice Evidence Based Medicine?

- Assessment of the patient.
- Basic computer and internet searching skills to acquire best available evidence.
- Application of **critical appraisal rules** in evaluating clinical literature.
- Applying results of appraised evidence to the patient.

# CRITICAL APPRAISAL

Def: Assessment of research evidence.

Evaluate this research is telling the truth (valid), suitable to your patient (relevant), and the results worth to be used in clinical practice.

# CRITICAL APPRAISAL

**WHY**

Published research is not always reliable, we cannot take its conclusions for granted.

Published research is not always relevant, we have to read article to judge its applicability.

# Hierarchy of EBM

- Evidence Based Medicine presents a priority pyramid of evidence to guide clinical decision making.
- Meta-analyses and systematic reviews are at the top of the pyramid, with the least possible deviation of errors.


**SRs :** Systematic reviews
**RCTs:** Randomized control trials

# EBM Resources

- Preappraised: ready-made answers for Questions: but limited topics!!

Cochrane library

http://www.Cochrane.org

- Non-appraised resources: you need to appraise:

http://www.pubmed.gov

# Basic Study Designs

- Investigator manipulates a variable and examines effect on an outcome

- Designs
  - randomized controlled trial
  - Controlled clinical trial

- Investigator observes outcome of naturally occurring difference in a variable

- Designs
  - Cohort study
  - Case control study
  - Case series study

# Cohort Studies

- Two groups of people followed over time
- One group has received an intervention or exposure (e.g. smoking)
- Groups otherwise closely matched
- Groups followed over time
- Can be used for causation, diagnostic, harms and therapeutic studies

# Case-Control Studies

- Used mainly for **causation** studies
- Patients with outcome matched to controls
- Investigations made into possible causes in both patients and controls.

# Randomised Controlled Trials

- Treatment group and ‘control’ group
- Random assignment to groups
- May involve ‘blinding’ of participants and researchers
- Used for therapeutic or diagnostic interventions
- Some interventions unsuitable for RCTs

# Other Types of Clinical Research

- These are lesser forms of evidence, but for some interventions, exposures or conditions they may be the only form available

- Case studies / Case series

# Exercise

- What Type of clinical research is this?
- Two groups of doctors, one group smokers, the other non-smokers are followed over the course of 20 years to see whether which group are more likely to develop lung cancer

# Answer

- Cohort study

# Exercise

- What Type of clinical research is this?

- Two groups of patients are studied, one group given physiotherapy for low back pain, the other given advice only. Patients are randomly assigned to either group and followed up after six months.

# Answer

- Randomised controlled trial

# Quiz

- What Type of clinical research is this?
- One hundred sets of twins, where one had developed melanoma and the other had not, were studied for possible causation factors

# Answer

- Case-control study

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Pediatr Dermatol. 2013 Nov 14. doi: 10.1111/pde.12240. [Epub ahead of print]

# Narrowband Ultraviolet B Light in Langerhans Cell Histiocytosis: A Case Report.

Ness MJ, Lowe GC, Davis DM, Hand JL.

Department of Pediatric and Adolescent Medicine, Mayo Clinic, Rochester, Minnesota.

## Abstract

Langerhans cell histiocytosis (LCH) (previously called eosinophilic granuloma, Hand-Schüller-Christian syndrome, Letterer-Siwe disease, and Hashimoto-Pritzker disease) is a rare, heterogeneous disorder with highly variable presentation. LCH commonly affects the skin, as well as internal organs. Because the skin lesions appear benign, and LCH is unfamiliar to most physicians, diagnosis is often delayed. Treatment is controversial, with further clinical study needed. For persons with extensive, skin-limited disease, the existing topical therapies are impractical. We present a child with cutaneous LCH lesions that responded to ultraviolet light phototherapy with minimal adverse effects or patient discomfort.



PMID: 24224945 [PubMed - as supplied by publisher]

JAMA Dermatol. 2013 Oct 2. doi: 10.1001/jamadermatol.2013.5098. [Epub ahead of print]

# A 3-Year Follow-up of Sun Behavior in Patients With Cutaneous Malignant Melanoma.

Idorn LW, Datta P, Heydenreich J, Philipsen PA, Wulf HC.

Dermatological Research Department D92, Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark.

## Abstract

IMPORTANCE UV radiation (UVR) exposure is the primary environmental risk factor for developing cutaneous malignant melanoma (CMM). OBJECTIVE To measure changes in sun behavior from the first until the third summer after the diagnosis of CMM using matched controls as a reference. DESIGN, SETTING, AND PARTICIPANTS Three-year follow-up, observational, case-control study performed from May 7 to September 22, 2009, April 17 to September 15, 2010, and May 6 to July 31, 2011, at a university hospital in Denmark of 21 patients with CMM and 21 controls matched to patients by sex, age, occupation, and constitutive skin type participated in the study. Exposure to UVR was assessed the first and second summers (n = 20) and the first and third summers (n = 22) after diagnosis. Data from 40 participants were analyzed. MAIN OUTCOMES AND MEASURES Exposure to UVR was assessed by personal electronic UVR dosimeters that measured time-related UVR in standard erythema dose (SED) and corresponding sun diaries (mean, 74 days per participant each participation year). RESULTS Patients' daily UVR dose and UVR dose in connection with various behaviors increased during follow-up (quantified as an increase in daily UVR dose each year; all days: mean, 0.3 SED; 95% CI, 0.05-0.5 SED; days with body exposure: mean, 0.6 SED; 95% CI, 0.07-1.2 SED; holidays: mean, 1.2 SED; 95% CI, 0.3-2.1 SED; days abroad: 1.9 SED; 95% CI, 0.4-3.4 SED; and holidays with body exposure: mean, 2.3 SED; 95% CI, 1.1-3.4 SED). After the second year of follow-up, patients' UVR dose was higher than that of controls, who maintained a stable UVR dose. No difference was found between groups in the number of days with body exposure or the number of days using sunscreen in the second and third years of follow-up. CONCLUSIONS AND RELEVANCE Our findings suggest that patients with CMM do not maintain a cautious sun behavior in connection with an increase in UVR exposure, especially on days with body exposure, when abroad, and on holidays.

PMID: 24080851 [PubMed - as supplied by publisher]

# Comparative Research

- **Experimental**
- Investigators assign the intervention, & compare the effect against a control.
- Non- Randomized CT: Groups are selected.
- RCT: Participants are randomly distributed (e.g. sealed envelopes) in 2 or more groups.

J Drugs Dermatol. 2013 Mar;12(3):300-6.

# A multicenter, randomized, double-blind study of the efficacy and safety of calcipotriene foam, 0.005%, vs vehicle foam in the treatment of plaque-type psoriasis of the scalp.

Feldman SR, Mills M, Brundage T, Eastman WJ.

Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem, NC, USA. sfeldman@wakehealth.edu

## Abstract

**BACKGROUND:** Calcipotriene ointment and cream are effective treatments for psoriasis, but many patients with scalp psoriasis prefer lighter, less messy vehicles.

**OBJECTIVES:** To evaluate the efficacy and safety of calcipotriene foam, 0.005%, for plaque-type psoriasis of the scalp.

**METHODS:** Subjects (n=363) were randomized into an 8-week, multicenter, double-blind, vehicle-controlled, parallel-group, phase 3b study of calcipotriene foam, 0.005% (NCT01139580). Primary end point was the proportion of subjects with an Investigator's Static Global Assessment (ISGA) score of 0 (clear) or 1 (almost clear) at week 8 for scalp involvement. Body involvement, target lesion score, and improvement for erythema, scaling, and plaque thickness were also assessed.<BR>

**RESULTS:** At week 8, more subjects in the calcipotriene foam, 0.005% group (40.9%) met the primary end point vs the vehicle foam group (24.2%; intent-to-treat [ITT] population; P <.001); a significant difference between groups was also observed at weeks 2 (P = .041) and 4 (P <.001). No significant difference was observed between treatment groups for ISGA of body psoriasis (ITT population; P = .544). In the per-protocol population, but not the ITT population, more subjects in the calcipotriene foam, 0.005%, group than the vehicle foam group met the secondary end points for scaling (P = .019) and plaque thickness (P =.027). Incidence of adverse events in both treatment groups was low; calcipotriene foam, 0.005%, was associated with erythema. Limitations: An 8-week study provides limited safety and efficacy data.<BR>

**CONCLUSION:** Calcipotriene foam, 0.005%, was more effective than vehicle foam for improving scalp psoriasis

# RANDOMIZED CONTROLLED TRIALS (RCT)

- Randomization ensures balancing study groups and eliminating bias.
- One group to receive studied intervention, other to receive control intervention.
- Both groups are followed up prospectively, results are finally compared.

**Gold Standard of clinical research**

# SYSTEMATIC REVIEW

- Review article: summary of many articles, without appraising them.
- Systematic Review: Selects relevant research, collects and analyses data from studies included in this review. Statistical methods may be used to analyze these results: Meta-Analysis.

J Dermatol Sci. 2009 May;54(2):76-87. doi: 10.1016/j.jdermsci.2009.02.002. Epub 2009 Mar 20.

# Topical calcineurin inhibitors in atopic dermatitis: a systematic review and meta-analysis.

El-Batawy MM, Bosseila MA, Mashaly HM, Hafez VS.

Department of Dermatology, Faculty of Medicine, Cairo University, Egypt.

## Abstract

**OBJECTIVES:** To build a critical appraisal of the available literature to evaluate the effectiveness of topical calcineurin inhibitors in treatment of atopic dermatitis (AD), in comparison to topical corticosteroids (TCs) and/or placebo.

**REVIEW METHODS: DESIGN:** systematic review and meta-analysis.

**DATA SOURCES:** electronic search of MEDLINE Pubmed along the last 10 years (1997-2006).

**STUDY SELECTION:** randomized control trials of TCIs reporting efficacy outcomes, in comparison to TCs or vehicle (placebo) or both. Data synthesis: of 210 articles, 19 studies were included, 10 for tacrolimus and 9 for pimecrolimus, involving 7378 patients of whom 2771 applied tacrolimus, 1783 applied pimecrolimus, and 2824 were controls. Both drugs were significantly more effective than a vehicle. However, two long-term trials comparing demonstrated the value of pimecrolimus in reduction of flares and steroid-sparing effect after 6 months. Compared to TCs, both 0.1% and 0.03% tacrolimus ointments were as effective as moderate potency TCs, and more effective than a combined steroid regimen. Tacrolimus was more effective than mild TCs.

**CONCLUSIONS:** TCIs in AD are more effective than placebo. Although less effective than TCs, pimecrolimus has its value in long-term maintenance and as a steroid-sparing agent in AD, whenever used early enough, at first appearance of erythema and/or itching. In treatment of moderate to severe AD, topical tacrolimus is as effective as moderately potent TCs, and more effective than mild preparations. Chronic AD lesions of the face and flexures are the most justified indication for topical calcineurin inhibitors.

PMID: 19303745 [PubMed - indexed for MEDLINE]

# CONCLUSION

- We may make **Strong** or **Weak recommendations** on further criteria:

A. Balance between desirable and undesirable effects (not considering cost)
B. Quality of the evidence
C. Values and preferences
D. Costs (resource utilization).

# REFERENCES


- EBM workshop in MEDC, Kasr El-Aini.
- Essentials of Evidence-Based Medicine, Editors: Prof Dr Abdelhamid Atteya & Prof Dr Eman Abdel-Raouf.
- What is evidence-based medicine. Jonathan Belsey (2009).

# THANK YOU