Cochrane Skin Group Annual Meeting 2010

16-17 October 2010

University of Colorado Denver
Anshutz Medical Campus
Aurora, Colorado USA

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http://skin.cochrane.org

Saturday, October 16, 2010

Time	Activity/Topic	Speaker
7:00-8:15am	Breakfast @ Nighthorse Campbell Building	
8:20-8:30am	Welcome	Dellavalle
8:35-8:55am	An Introduction to the Cochrane Collaboration and the Cochrane Skin Group	Delamere
9:00-9:20am	Your Local Health Sciences Librarian: Part of the Systematic Review Team	Dudden/Protzko
9:25-9:45am	The Dermatology Clinical Effectiveness Research Network (DCERN): Early Findings for Psoriasis	Gelfand
9:50-10:10am	**Tea Break**	
10:15-10:35am	TBA	
10:40-11:00am	Mixed Treatment Comparisons	Margolis
11:05-11:25am	Commissioning Comparative Effectiveness	Williams
11:30-11:50am	Skin Conditions in the UK: A Health Care Needs Assessment	Schofield
11:50-12:55pm	Lunch @ Nighthorse Campbell Building	
1:00-1:20pm	Comparative Effectiveness Research in Pediatric Dermatology: The Hemangioma Investigator Group as a Model	Chamlin
1:25-1:45pm	A Critical Appraisal of Topical Moisturizing Devices for Atopic Dermatitis	Fleischer
1:50-2:10pm	NIH support of the Cochrane Eyes and Vision Group US Satellite: A Model for Other Fields?	Dickersin
2:15-2:35pm	Teledermatology & CER	Warshaw
2:40-3:00pm	**Tea Break**	
3:05-3:25pm	Comparative Safety Analysis: Compared to What?	Stern
3:30-3:50pm	Comparative Effectiveness Research Using Clinical Registries	Caplan
3:55-5:00pm	Panel Discussion The State of the CER: Implications for Future Research	(Moderator: Dellavalle) Dickersin, Williams, Werth, Margolis, Gelfund
6:45pm	**Dinner @ The Timbers Hotel/Peoria Grill** **Top 5 Wastes of Money Family Feud** **Local Violinist**	

Sunday, October 17, 2010

Time	Activity/Topic	Speaker
7:00-8:30am	Breakfast @ Nighthorse Campbell Building	
8:35-8:45am	Welcome	Dellavalle
8:50-9:10am	Comparative Effectiveness Research (CER) in Nigeria: The Milestones and the Millstone	Okokon
9:15-9:35am	Comparative Effectiveness Research in the Archives of Dermatology	Robinson
9:40-10:00am	Wound Healing Comparative Effectiveness Research	Kirsner
10:00-10:20am	**Tea Break**	
10:25-10:45am	Comparative Effectiveness Research in Keratinocyte Carcinoma	Chren
10:50-11:10am	Updating the Evidence Base for Treatment of Atopic Dermatitis	Nankervis
11:15-11:35am	Eczema from the Patient Perspective	Block
11:40-12:55pm	Lunch @ Nighthorse Campbell Building	
1:00-1:20pm	Acne, CER	Kimball
1:25-1:45pm	Autoimmune Skin Disease CER	Werth
1:50-2:10pm	Dermatology CER at the HMO	Asgari
2:15-2:35pm	Comparative Effectiveness Research- Perspectives from NICE	Garner
2:45-3:00pm	**Move to Library Gallery & Reading Room**	
3:05-3:25pm	Comparative Effectiveness Research	Schilling
3:30-5:00pm	Panel Discussion The State of the CER: Implications for Future Research Tea & Local Musician	(Moderator: Dellavalle) Williams, Werth, Chren
6:30pm	**Keystone Shuttle Departs from Anschutz Medical Campus**	

Saturday, October 16, 2010

An introduction to the Cochrane Collaboration and the Cochrane Skin Group

Time: 8:35 am

Speaker: Dr. Finola Delamere
Cochrane Skin Group

Abstract:

I shall give a brief introduction to the development of the international organization known as the Cochrane Collaboration and talk in particular about the work of the Cochrane Skin Group which is one of the editorial groups within the Collaboration. I will also introduce The Cochrane Library in which Cochrane systematic reviews are published electronically.

Saturday, October 16, 2010

Your Local Health Sciences Librarian:
Part of the Systematic Review Team

Time: 9:00 am

Speakers: Rosalind F. Dudden, MLA, AHIP, FMLA Director,
Library and Knowledge Services

- And -

Shandra L. Protzko, MS, AHIP Information Specialist,
National Jewish Health, Denver, CO

Abstract:

Background: Several articles have been published since 2005 on the role of the librarian in the systematic review process. While the their role as expert searchers is widely recognized, librarians also can be contracted to help with broader work flow challenges such as defining questions and record keeping. This paper gives an account of the experiences of local librarians working on systematic reviews as part of their job as a general medical librarian.

Objective: To review the contributions and roles of medical librarians at the local level for conduct of health systematic reviews and to discuss problems and barriers discovered.

Data collection and analysis: The literature was searched for articles on the librarian's participation in the systematic review process. The work of the authors in participating in reviews was examined and a list of contributions and problems was compiled.

Conclusions: Participation in the systematic review process is an expansion of the traditional role of the health sciences librarian as expert searcher and organizer of the literature. By engaging librarians at the beginning of the process, the systematic review research team can benefit from their expertise. This might include educating the researchers on the systematic review process; help with formulating the research question and exclusion criteria; doing the primary and subsequent searches on a variety of databases; documenting the searches; record keeping for the phases of the review; and writing the search methodology. As this all takes consultation time, and remuneration from the project budget can be expected in some cases. If extensive work is done, the librarian can also expect authorship status on the report of research. Problems involved include fully understanding the complicated science behind the question; irregular timing of the process with long wait times followed by short deadlines; communication about what the process is; and learning new technologies for record keeping. Rewards include working closely with a research team; expanding professional expertise; and the recognition of contributions by information professionals to health care outcomes.

Saturday, October 16, 2010

The Dermatology Clinical Effectiveness Research Network (DCERN):
Early Findings for Psoriasis

Time: 9:25 am

Speaker: Joel M. Gelfand
Assistant Professor of Dermatology and Epidemiology
Medical Director, Clinical Studies Unit, University of Pennsylvania

Abstract:

Objective: To develop an infrastructure for dermatology comparative effectiveness research and to determine the effectiveness of therapies for moderate/severe psoriasis. We report on two studies being conducted.

Data: Two data sources. 1: DCERN – a multi-center network of dermatologists. 2: Random selection of 500 physician members of the National Psoriasis Foundation and 500 members of the American Academy of Dermatology self-identified as treating psoriasis.

Methods: First, DCERN is conducting a cross-sectional study of 2000 consecutive eligible patients to determine and compare the current effectiveness of therapies for moderate-to-severe psoriasis that patients are receiving at the time of their routine evaluation. Patients are included if they have a history of ≥ 5% BSA, were treated with a biologic, systemic, or phototherapy, or are currently receiving one of these treatments. Second, we conducted a mailed survey of a nationwide sample (described above) of dermatologists, to determine their preferences for treatment and future comparative effectiveness studies. We also randomized dermatologists to $0, $5, or $10 cash that was included with the initial mailing to determine if an incentive would improve response rates.

Results:DCERN has 9 sites that include academic and private practices in Utah, Pennsylvania, New York, Colorado, and Georgia. We have enrolled 732 patients (refusal rate <2.5%) since March 2010. Current therapies include acitretin (N=43), adalimumab (N=103), cyclosporine (N=18), etanercept (N=152), infliximab (N=37), methotrexate (N=179), PUVA (N=3), ustekinumab (N=33), UVB (N=74), and topicals only (N=139). The median (IQR) DLQI and PASI are 3 (1, 7) and 3.2 (1.6, 5.8).

With respect to the nationwide dermatologist survey, the response rate was 39%, with 25%, 43% and 49% response for the $0, $5, and $10 incentive groups, respectively (P<0.001). Respondents characteristics were male (72%), private practice (70%), mean practice duration 23 years, and the median # psoriasis patients treated in the preceding three months was 30. Respondents rated the top three treatments they would like compared in an RCT; out of 10 FDA-approved psoriasis treatments, the top five were etanercept (21%), adalimumab (18%), ustekinumab (18%), methotrexate (16%) and UVB phototherapy (10%). **See GELFAND, pg. 23**

Saturday, October 16, 2010

Mixed Treatment Comparisons

Time: 10:40 am

Speaker: David J. Margolis, MD, PhD
Professor of Dermatology and Epidemiology
Departments of Dermatology and Biostatistics and Epidemiology
University of Pennsylvania

Abstract:

Cochrane are systematic reviews relying almost exclusively on using meta-analysis of randomized clinical trials (RCT) in order to inform opinions. These opinions are often on the efficacy of a therapy, the comparative efficacy of a therapy or the safety of a therapy. Unfortunately, even though clinical studies are often registered, not all RCTs are published and those that are published may not provide enough information in order to properly inform a meta-analysis. In adequate data, even of high quality, always results in inadequate conclusions. In addition, RCTs are restrictive with regards to enrollment and therefore may not provide information that generalizes to all who may receive a therapy, and randomized clinical trials are restrictive in their execution thereby measuring efficacy and not effectiveness. The purpose of this presentation is to brief describe alternative study designs such as large pragmatic studies, traditional cohort studies, as well as cohort studies using propensity scores or instrumental variables. It is likely that in the future comparative effectiveness studies will continue to favor RCT designs but will also embrace alternative designs.

Saturday, October 16, 2010

Commissioning Comparative Effectiveness

Time: 11:05 am

Speaker: Hywel Williams
Professor. Cochrane Skin Group and NIHR
Health Technology Assessment Board

Abstract:

Comparative effectiveness research (CER) is about comparing new and existing treatment against each other in order to decide "which is best" in terms of benefits and harms. CER is very much about assessing mature technologies in the settings which they are normally used in a way that informs health care decisions.

The NIHR Health Technology Assessment Programme is the UK's largest funder of Phase III clinical trials and evidence syntheses, with an annual budget of around £80 million. Most of our trials cost around £1.2 million each. Other NIHR funding bodies commission early development and mechanism work.

The HTA funds CER through four main routes. The first is the HTA Commissioning Board which identifies and prioritizes important dilemmas facing health workers that need to be resolved by commissioned research. These topics which are identified through a number of routes are then advertised for competing teams to apply for. In other words, the commissioners pull researchers to worthy but potentially unglamorous areas of research. The second funding route is through our response mode stream – the HTA Clinical Evaluation and Trials (CET) Board. CET is open to any outline application for CER that submitting teams deem to be important. Applications are prioritized and commissioned if full proposals are deemed to be useful for clinical decision making. In other words, researchers pull the funders into funding the researcher's study. The third funding route is through our themed calls on strategically broad and important areas such as obesity, medicines for children, healthcare associated infection, to areas where a rapid response is required such as H1N1 influenza. Themed calls help to provide a range of projects that answer different facets about a big problem, and they also help to build capacity in that area. Our fourth funding stream are rapid Technology Assessment Review (TARs) – typically evidence syntheses with cost effectiveness modelling that is done by ten TAR centres who are allocated work according to their capacity– in other words, paying for good teams of methodologists to "get on with it" when a requirement for a TAR arises to inform new drug purchasing or use of existing services.

Working as a healthcare research commissioner as well as researcher is a fascinating experience. The challenge is to "join up" different funding initiatives and research infrastructure, to expedite research permissions and approvals with compromising patient safety, to explore new ways of health technology assessment such as adaptive designs that reduce risks and costs, and to commission research that makes a difference to patient care.

Saturday, October 16, 2010

Skin conditions in the UK:
A Health Care Needs Assessment

Time: 11:30 am

Speaker: Julia Schofield
Consultant dermatologist, Lincoln UK
Special Lecturer, University of Nottingham UK

Abstract:

A Health Care Needs Assessment (HCNA) provides a formal assessment of the health care needs of a defined population and focuses on a particular area (in this case skin conditions). This type of assessment of need is important and should be used to underpin decisions about the planning and provision of health care services. The principle of the HCNA is that it links the scale of a healthcare problem to service provision. The first step in completing a needs assessment is to identify the healthcare burden of the defined problem. The burden of skin disease includes consideration of the epidemiology of skin conditions, their impact on quality of life and costs. The second stage is to review the services available to manage people with skin conditions within the context of the health care system and evaluate the effectiveness of those services. Recommendations are then made about how best to deliver care. In 1997 Williams published the first UK dermatology health care needs assessment. The aim of this study was to update this document.

Information about self reported skin disease in the UK was obtained from surveys performed by the Proprietary Association of Great Britain (PAGB). Data about patients presenting to their general practitioner (GP, first point of contact primary care) was provided by the Royal College of General Practitioners Research and Surveillance Unit. Specialist activity was more difficult to collect because of the lack of national data relating to outpatient activity but useful information was obtained from four dermatology departments in England. Further data was obtained from national statistical data provided by the Department of Health and the Office of Health Economics. An extensive search of the literature, including the grey literature, provided information about impact on quality of life, costs, services available and the effectiveness of services.

The report highlights some important points. Firstly, current coding systems under-estimate both the amount of skin disease in the UK and the mortality from skin conditions because skin tumours and common skin infections are not captured using the ICD 9 and ICD 10 Chapter groupings for skin conditions. When this information is included the evidence shows that skin disease is the commonest reason that people present to their GP with a new problem with around 24% of the population seeking advice about a skin condition per year. Despite this, a review of the education and training of primary care health care professionals shows that there is little emphasis on dermatology teaching. Educational programmes should be mapped to clinicalneed. Mortality from skin disease, when skin cancer is included, is about 4000 people per year (more than deaths from cervical cancer). There is very little good research evaluating the effectiveness of services although some key themes emerge and consensus statements on models of care reflect the available evidence. There has been unprecedented reform of the NHS in the UK and England in particular, between 1997 and 2010 and this has created opportunities and threats to the care of people with skin conditions.

Saturday, October 16, 2010

Comparative Effectiveness Research in Pediatric Dermatology:

The Hemangioma Investigator Group as a Model

Time: 1:00 pm

Speaker: Sarah L. Chamlin, MD
Associate Professor of Pediatrics and Dermatology
Children's Memorial Hospital and
Northwestern Feinberg School of Medicine

Abstract:

Comparative effectiveness research (CER) in the pediatric population lags behind such research in adults. This is particularly true in pediatric dermatology, a specialty that cares for many rare diseases. Many, if not most, of the clinical trials being performed in pediatric dermatology are pharmaceutical sponsored and often address common skin disorders such as acne and atopic dermatitis. While many such studies are done and the FDA has rigorous requirements of the pharmaceutical companies, it does not require comparison to alternative therapies, and few true CER studies are done in the specialty. In addition, there are many FDA regulatory changes written to protect children by requiring safety and efficacy data on drugs used in this population. Despite this, studies in pediatric dermatology comparing the clinical efficacy and cost-effectiveness of alternate therapies or procedures are lacking. This may be partially due to lack of funding and support.

The work done by the Hemangioma Investigator Group (HIG) will be presented as a framework for effective collaboration and research. The HIG was formed in 1999 by a group of pediatric dermatologists with similar interests in infantile hemangiomas (IH), and since its formation, has published 17 scientific papers. Prior to their work, little prospective research had been done on IH. The group initially performed a multicenter prospective study of more than 1000 patients with IH to define the demographic and clinical features of affected children. Next, the children with complicated subtypes of IH including large facial, multifocal and lumbosacral hemangiomas were further studied. After identifying and defining these at risk groups, clinical trials were designed. Of note, members of the HIG received an NIH Challenge grant to develop outcome measures, a severity scale and quality-of-life instrument for use in these trials. Clinical trials being performed by group members for complicated infantile hemangiomas include a Phase II clinical trial assessing the efficacy and safety of oral prednisolone vs. vincristine and a planned multi-institutional Phase III clinical trial to determine the safety and efficacy of combination therapy of prednisolone plus propranolol vs. propranolol alone for complicated infantile hemangiomas. In addition, many group members are involved in the phase II/III multicenter collaborative prospective trial comparing propranolol to placebo.

Saturday, October 16, 2010

A Critical Appraisal of Topical Moisturizing Devices for Atopic Dermatitis

Time: 1:25 pm

Speaker: Alan Fleischer
Professor and Chair of Dermatology
Wake Forest University Health Sciences

Abstract:

Objective: To review all studies which assess the therapeutic value of topical devices indicated for atopic dermatitis and to assess the comparative efficacy. Because the approval process is different for devices compared with pharmaceuticals, rigorous Phase III clinical trial results do not need to be generated prior to marketing.

Data Sources: All open and randomized controlled trials (RCT) utilizing atopic dermatitis topical devices were found using PubMed, and a single randomized controlled trial that was the author's unpublished study was included. Searches included trials for Atopiclair, Eletone, Epiceram, MimyX. Neosalus, Zenieva, and PruMyx.

Study Selection: Studies were reviewed for their methods and categorized as to results and quality. Because of the small number of studies, no studies were excluded.

Data Extraction: The majority of products had no evidence that any studies had been performed which support their efficacy, including Eletone, Neosalus, PruMyx and Zenieva. Only one product, Atopiclair, had four published randomized controlled trials compared with vehicle. MimyX had a comparative study with a commercial moisturizer; a different moisturizer was compared with Epiceram and Atopiclair; and there was a single study comparing Epiceram to fluticasone proprionate.

Data Synthesis: If one assumes that a RCT of a moisturizing device with its vehicle in which the lipid and other active elements have been removed constitutes reasonable science, then Atopiclair was found in four small RCTs to be superior to vehicle. A small, open trial found that disease severity decreased when subjects used Atopiclair. In a small RCT, a commercial moisturizer (Albolene) was found to be noninferior to MimyX. In another small RCT, a different moisturizer (Aquaphor) was found to be noninferior to both Epiceram and Atopiclair. Fluticasone proprionate cream was found superior to Epiceram at 14 days, although at 28 days the superiority of the corticosteroid was not significant.

Conclusions: These data suggest that topical moisturizing devices have some effect in reducing atopic dermatitis severity, but there is no evidence for their superiority over good moisturizing products. Since the majority of these products have never been subjected to efficacy assessments, our ability to generalize is limited. Given the great expense of these agents, their role in atopic dermatitis management remains guarded.

Saturday, October 16, 2010

Teledermatology & CER

Time: 2:15 pm

Speaker: Erin Warshaw MD MS
Chief, Dermatology
Minneapolis VAMC
Associate Professor, Dermatology
University of Minnesota

Abrstract:

Objective: To systematically review literature addressing teledermatology: 1) diagnostic accuracy/concordance, 2) management accuracy/concordance, 3) clinical outcomes, and 4) costs.

Data Sources: MEDLINE/OVID and PubMed articles from 1/1990 to 6/2009 using standard search terms.

Study Selection: Peer-reviewed controlled trials of teledermatology published in English.

Data Extraction: Study design, patient characteristics, and outcomes were extracted by trained research associates and verified by the principal investigator. We assessed quality with Quality Assessment of Diagnostic Accuracy Studies criteria.

Data Synthesis: Seventy-eight studies were included. Approximately two-thirds of studies comparing teledermatology and usual care found better diagnostic accuracy with usual care (11% and 19% difference for primary and aggregated diagnostic accuracy rates, respectively). Diagnostic concordance of store and forward with usual care was fair (weighted averages: lesion studies 64%, 62%; general studies 65%, 67%); concordance rates for live interactive and usual care (71%, 87%) were higher, but based on fewer patients. While overall rates of management accuracy were equivalent, rates for teledermatology and teledermatoscopy were inferior to usual care for malignant lesions. Management concordance rates ranged from 55 to 100%; kappa values ranged from 0.47 to 0.71. There was insufficient evidence to evaluate clinical course outcomes. Patient satisfaction and preferences were comparable. Time to treatment was shorter and clinic visits were avoided with teledermatology. Most studies found teledermatology to be cost-effective if certain assumptions were met.

Conclusions: The benefits of teledermatology (improved access, decreased travel) need to be evaluated in the context of potential limitations (inferior diagnostic and management accuracy, especially for malignant neoplasms).

Saturday, October 16, 2010

Comparative Safety Analysis:
Compared to What

Time: 3:05 pm

Speaker: Robert S. Stern, MD
Chief of Dermatology at Beth Israel Deaconess Medical Center
Harvard Medical School
Boston, MA USA

Abstract:

Comparative Effectiveness Analysis, the comparison of the relative effectiveness of competing treatments for treatment of a disease is increasingly relied upon by prescribers, regulatory agencies and insurers to determine which treatment should be preferred for the individual patient and often for reimbursement.

Most comparative effectiveness studies rely on data from relatively short-term studies. Yet, many dermatologic diseases are chronic and differences in treatments' long-term safety may be more important in determining comparative effectiveness than differences in short-term efficacy.

I will discuss the role of long term safety in determining the comparative effectiveness of psoriasis treatments. I will review briefly our knowledge concerning long-term safety of psoriasis treatments, including UVB, PUVA, cyclosporine, and biologic therapies, ongoing studies of long-term safety of biologic agents. Randomized controlled trials to assess long-term safety are not feasible. Therefore, safety assessments have often compared the incidence of adverse events in a treated population to that "expected." The potential pitfalls in calculating the observed and expected number of events will be discussed. Possible biases as a result of deletion of susceptibles, adverse selection, and latency will be discussed. The importance of completeness of follow up, duration of follow up , and assessing the relation of multiple exposures to outcome will be illustrated.

Saturday, October 16, 2010

Comparative Effectiveness Research using Clinical Registries

Time: 3:30 pm

Speaker: Liron Caplan, MD, PhD
UC Denver School of Medicine
Denver Veterans Affairs Medical Center

Abstract:

This presentation will address the role that clinical registries can play in the execution of Comparative Effectiveness Research. Various models of clinical registries will be described. As an example, we will examine the Program to Understand the Longterm Outcomes in SpondyloARthritis (PULSAR) registry in detail, which contains a clinical database and linked biologic repository. This registry includes subjects with psoriasis. The steps necessary to develop a patient registry will be articulated, and we will survey logistics aspects of running a registry.

Sunday, October 17, 2010

Comparative Effectiveness Research (CER) in Nigeria: The Milestones and the Millstone

Time: 8:50 am

Speaker: Enembe Oku Okokon
Department of Environmental Science
University of Eastern Finald

Abstract:

Objective: To provide an overview of the state and turnover CER in Nigeria and the extent to which key health problems are addressed within study imperatives.

Data Sources: Data sources were PubMed, the Cochrane Library.

Study Selection: Studies were selected by running searches in PubMed database. Search terms such as Compar*, effectiv*, research, study, and Nigeria were used. The\ Cochrane Library was searched using a listing of Nigerian authors provided by the SACC. Studies were selected both by study design; where they had to be completed systematic reviews, RCT, CCT or analytical study comparing interventions; and by study setting being within Nigeria.

Data Extraction: Data extraction was done using a questionnaire, developed by the author, which sought to capture priority areas apparent within the studies reviewed and as enunciated by the Institute of Medicine.

Data Synthesis: Simple analysis was done to produce descriptive measures and summary estimates of key variables. Microsoft Excel and EpiInfo packages were used.

Conclusion: The overall volume of intervention studies was low. A greater of the proportion of studies, 48.5%, investigated treatment options for infectious and parasitic diseases; 24.2% investigated reproductive health interventions; 62.6 % of interventions aimed to achieve cure, and 29.3% aimed for prevention. Study endpoints were efficacy (95.9%), adverse effects/tolerability (60.6%), treatment failure (28.6%) and cost (6.1%). Patterns were similar in different zones of the country. No stable funding structure could be identified for these studies. CER does reflect the pattern of need and the dominant type of healthcare in Nigeria.

Sunday, October 17, 2010

Comparative Effectiveness Research in the Archives of Dermatology

Time: 9:15 am

Speaker: June K. Robinson, MD
Professor of Clinical Dermatology
Northwestern University Feinberg School of Medicine

Abstract:

Objective: Define the role of a dermatology journal in promoting comparative effectiveness research and the scope of the effort to support this research.

Data Sources: Table of contents. Editorial policy formulated by the editors and editorial board and reported in minutes of the board and published editorials..

Selection of Data: The word files of the table of contents of each issue and the editorial board meetings from 1999-2009 were analyzed for the terms, evidence-based, or evidence-based dermatology.

Data Extraction: A quantitative assessment of evidence-based dermatology in the table of contents in all issues from 199-2010 was performed. A qualitative assessment was performed by 2 coders searching for common themes arising a priori within each board meeting and by repetition across the meetings. The responses of the 2 coders were compared and discrepancies resolved to establish inter-rater reliability. (Cohen's kappa = .97).

Data Synthesis: Since 1999, evidence-based articles have been published quarterly. In the early years of the evidence-based section, the board discussed that the evidence- based approach must be balanced by novel findings from case reports, which may be the first evidence that new therapies are efficacious or have dermatologic adverse events. In later years, this discussion ceased to be a part of the board meetings. Over the last decade, editorial support of publication of evidence-based research has been consistent. Recently. a shift in editorial priorities increased awareness of the importance of systematic review articles assessing the quality of the evidence to support recommendations. Published research identifies practice gaps, the difference between care or outcomes that should be occurring and those that are occurring. To help clinical dermatologic practice meet the challenge of efficiently delivering effective care, commentaries about practice gaps will be prepared about selected articles in each issue.

In addition, a series of editorial policy enhanced transparency of the publication process. In 2004, authors and reviewers were required to provide all fiscal relationships during the period of developing, performing, analyzing and publishing the research. Note that the disclosure is not limited to those that the authors deem to be a conflict of interest. This disclosure is placed on the title page of the manuscript to assure that it is seen by reviewers. Additional measures to enhance transparency are registration of clinical trials (2005), and definition of

See ROBINSON, pg. 23

Sunday, October 17, 2010

Wound Healing Comparative Effectiveness Research

Time: 9:40 am

Speaker: Robert S. Kirsner, MD, PhD
Vice Chairman, Professor and Stiefel Laboratories Chair
Department of Dermatology & Cutaneous Surgery
University of Miami Miller School Medicine

Abstract:

Objective: According to the Burden of Skin Disease report, wounds are the most financially costly of all skin disease. Nearly 6.5 million patients in the US are affected with chronic wounds, with an annual expenditure of nearly $25 billion for treatment alone. Unfortunately, of the common chronic wounds (diabetic foot ulcers (DFU), venous leg ulcer and pressure ulcer) less than half heal in a reasonable time with standard of care, leading to use of adjunctive agents. For diabetic foot ulcers, slow healing may result in osteomyelitis and limb amputation. To determine optimal adjunctive care and for whom, two analyses are presented: The first compared 3 adjunctive treatments (Engineered Skin, recombinant Growth Factor and autologous platelet releasate) for non healing DFU and the second, a pilot study, assessed the benefit of hyperbaric oxygen for DFU.

Data Sources: Both analyses utilized databases from large National Wound Healing Companies that administer wound centers throughout the United States. The first analysis used Curative Health Systems (CHS) Database and the second utilized National Healing Corporation (NHC) Database.

Study Selection: 1) Patients were included in this analysis if they had a primary diagnosis of neuropathic DFU; were seen at a CHS facility during a 4-year period from January 1, 2001, through December 31, 2004; were treated with at least one advanced biological therapy; and had valid visit dates along with patient and wound identifiers. 2) Patients were included in this analysis if they had a primary diagnosis of DFU; were seen at a NHC facility during a 3-year period from January 1, 2006, through August 1, 2009 and had valid visit dates along with patient and wound identifiers.

Primary Analysis: 1). The primary analysis sought to evaluate differences among advanced bi logical therapy groups regarding time to healing. 2) The primary analysis sought to evaluate the effect of HBO therapy on amputations.

Results: 1) Longer time to healing after first advanced biological therapy was associated across all treatment groups with larger wound area (P_.001), more severe wound grade (P=.001), longer duration prior to first visit (P=.003), and longer time from first visit to use of advanced biological therapy (P=.001). When adjusted for potential confounding factors, the median time to healing was faster for bilayered living cell therapy (84 days) compared with 101 days for recombinant growth factor therapy and 108 days for platelet releasate. Wounds treated with bilayered living cell therapy were 31.2% more likely to heal than wounds first treated

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Sunday, October 17, 2010

Comparative Effectiveness Research in Keratinocyte Carcinoma

Time: 10:25 am

Speaker: Meg Chren
Professor, University of California, San Francisco

Abstract:

Objective: Structured reviews have concluded that data are insufficient to permit evidence-based choices among therapies for many keratinocyte carcinomas. We aimed to compare the effectiveness of therapies for cutaneous basal cell carcinoma and squamous cell carcinoma (keratinocyte carcinoma).

Design: Prospective cohort study of 1375 consecutive patients with 1777 primary keratinocyte carcinomas diagnosed in 1999 and 2000 and followed for seven years after treatment at an American university-based private practice or a Veterans Affairs clinic. The major treatments were electrodessication and curettage (22%), excision (33%), and Mohs surgery (32%). Data were collected from patient survey, medical records, and patient examinations.

Main Outcome Measures: Tumor recurrence, skin-related quality of life, cost (in US dollars, using 2007 Medicare-approved charges).

Results: In 40% of the sample for which recurrence outcomes have been validated, 3.5% [95% CI: 2.2,5.2]) of tumors recurred: 1.6% after electrodessication and curettage 4.2% after excision, and 3.5% after Mohs surgery. With respect to quality-of-life outcomes, patients treated with excision or Mohs surgery improved in all quality-of- life domains, but quality of life did not improve significantly after electrodessication and curettage. For example, mean Skindex-16 Symptom scores improved only 3.4 [-0.9, 7.6] after electrodessication and curettage, but 9.7 [95% CI: 6.9, 12.5] after excision, and 10.2 [7.4, 12.9] after Mohs Surgery. With respect to cost outcomes, the mean total cost per tumor was $463 for ED&C, $1,182 for excision, and $2,134 for Mohs surgery. Characteristics that were independently ($p<0.000$) related to increased cost were tumor size > 10 mm, tumor location on the head or neck, and treatment with Mohs surgery.

Conclusion: ED&C did not improve skin-related quality of life, but there were few tumor recurrences after ED&C, and it was the least costly treatment. Excision and Mohs surgery may not differ substantially in quality of life and tumor recurrence outcomes, although Mohs is more costly. These comparisons are limited by differences in patients and tumors in the treatment groups, and provide a basis for targeted controlled trials of therapies for these common malignancies.

Sunday, October 17, 2010

Updating the Evidence Base for Treatment of Atopic Dermatitis

Time: 10:50 am

Speaker: Helen Nankervis
Research Associate/PhD Student
Centre of Evidence Based Dermatology
University of Nottingham, UK

Abstract:

Treating eczema (atopic dermatitis) can be very tricky as it may involve complicated and time consuming treatment regimens. With over 50 different treatments and endless treatment combinations possible, there is a great need for an up-to-date systematic review of eczema treatments.

An overarching Health Technology Assessment (HTA) systematic review of all treatments for atopic eczema was last published nearly 10 years ago by Hywel Williams and colleagues, the results of which have been used to develop guidelines for eczema care around the world. In the last decade there has been a lot of new research activity on eczema, including a large number of randomized controlled trials (RCTs).

Here we present the work on how we plan to update this review through the creation of a Global Resource of Eczema Trials (GREAT) database which contains information on all new RCTs of eczema published since 2000.

The database of randomized clinical trials for eczema treatment has already been created. The Global Resource of EczemA Trials (GREAT) database holds information on all the RCTs of treatments for eczema in one publically accessible place. The GREAT database will facilitate future research on eczema treatments by greatly speeding up the search for trials. This will avoid duplication of effort by researchers around the world searching for evidence to inform guidelines, producing systematic reviews and answering specific research questions on eczema treatment. The GREAT database can be accessed free of charge at www.greatdatabase.org.uk.

The review will include randomized controlled trials of treatments for eczema on people with established eczema which have at least one efficacy outcome. The original HTA review included 254 trials on established eczema and the update will add over 200 more. The updated review will give an overview of the evidence on benefits and harms for each type of treatment within broad treatment categories. Its design will make it easy and quickly accessible to clinicians, healthcare managers and policy makers as well as interested consumers. The findings of the original review will be presented along with an outline of the searches and data extracted for the update.

Our GREAT database, our mapping exercise of all systematic reviews of eczema http://www library.nhs.uk/skin/ and the updated systematic review will play a key role in mobilizing know edge of comparative effectiveness research to those who need it most. The work will also play a key part in helping to prioritize future research topics.

Eczema from the Patient's Perspective

Time: 11:15 am

Speaker: Julie K. Block, President & CEO, National Eczema Association

Abstract:

Why is it important to proceed with all due haste to conduct comparative effective research studies on eczema? An introduction to what it's like to live with eczema including medical, emotional, social challenges. The National Eczema Association (NEA) priorities to enhance the quality of life for children and adults with eczema, as well as conduct outreach to medical professionals, will be discussed. Accomplishments of the National Eczema Association in the areas of support, education and research will be reviewed. We will look at the research grants funded by the National Eczema Association since 2004, and research priorities for the future.

Sunday, October 17, 2010

Acne, CER

Time: 1:00 pm

Speaker: Alexa Boer Kimball, MD, MPH
Vice Chair, Dermatology
Associate Professor, Harvard Medical School

Abstract:

Objective: Comparative efficacy of the multiple treatments containing benzoyl peroxide (BPO) and clindamycin (CL) is not established. We compared the efficacy of topical 5% BPO, 1% to 1.2% CL, 5% BPO with salicylic acid (SA) preparation, and combination BPO/CL in acne lesion reduction.

Data Sources: PubMed was searched and studies were captured under search terms "acne AND benzoyl peroxide" OR "acne AND clindamycin." Limits included "clinical trials" and "publication date from 1987." In addition, studies used by the Food and Drug Administration (FDA) for medical review of combination BPO/CL products were gathered as were posters and unpublished data.

Study Selection: Each of the studies was analyzed and included in our analysis only if it met all inclusion and exclusion criteria. Studies had to have at least one treatment Arm with 5%BPO (either with or without SA-based cleanser and toner), 1% to 1.2% CL, or combination BPO/CL as part of a randomized controlled trial for acne vulgaris. Studies that used a 5% BPO 1 SA cleanser and toner regimen were separated from the other 5% BPO groups. All studies had to have efficacy end points of actual lesion reduction and/or percent lesion reduction at 2 to 4 weeks and/or 10 to 12 weeks.

Data Extraction: A total of 23 studies including 7309 patients were used in the meta-analysis.

Data Synthesis: At 2 to 4 weeks, 5% BPO + SA had statistically greater percent lesion reductions over other groups (weighted mean inflammatory lesion reduction: BPO = 33.4%, CL = 21.5%, BPO + SA = 55.2%, BPO/CL = 40.7%, placebo = 7.3%; weighted mean noninflammatory lesion reduction: BPO = 19.1%, CL = 10.0%, BPO + SA = 42.7%, BPO/CL = 26.2%, placebo = 6.7%). At 10- to 12-week end points, 5% BPO + SA and BPO/CL were similar, with overlapping confidence intervals (weighted mean inflammatory lesion reduction: BPO = 43.7%, CL = 45.9%, BPO + SA = 51.8%, BPO/CL = 55.6%, placebo = 26.8%; weighted mean noninflammatory lesion reduction: BPO = 30.9%, CL = 32.6%, BPO + SA = 47.8%, BPO/CL = 40.3%, placebo = 17.0%).

Conclusions: Trial heterogeneity, publication bias, and deficits in the reporting of individual primary studies may affect results. At early time points, 5% BPO + SA had the best profile. BPO/CL was only incrementally better than BPO alone but was superior to CL alone. At later time points, 5% BPO + SA was similar to BPO/CL.

Sunday, October 17, 2010

Medical Dermatology CER

Time: 1:25 pm

Speaker: Victoria P. Werth, M.D.
Professor of Dermatology, University of Pennsylvania and
Chief, Dermatology, Philadelphia VA Medical Center

Abstract:

Objective: To review the current state of CER in autoimmune skin disease.

Data Sources: Cochrane Database Syst Rev. 2009 Oct 7;(4):CD002954 and more recent literature related to development of disease instruments and clinical studies.

Study Selection: Original studies that advance field of CER in autoimmune skin diseases and Cochrane review.

Conclusions: There are very few controlled trials in the field of autoimmune skin diseases. The barriers for research have included lack of validated outcome measures, rare disease subsets, lack of a disease network, and lack of funding for organized studies. There have been recent efforts to develop and validate disease severity measures for cutaneous lupus, dermatomyositis, and pemphigus. These tools have been utilized in prospective disease cohorts that will facilitate evaluation of therapeutic efficacy of medications. There is a need for randomized controlled trials, as well as comparative studies to advance the evidence for therapy in these disease.

Sunday, October 17, 2010

Dermatology CER at the HMO

Time: 1:50 pm

Speaker: Maryam Asgari, MD, MPH
Research Scientist II, Kaiser Permanente
Northern California Division of Research

Abstract:

This presentation will focus on current comparative effectiveness research (CER) at Kaiser Permanente Northern California which was recently funded by a Challenge Grant from NIH. The project, currently in year 1 of 2, aims to establish the Kaiser Permanente (KP) Autoimmune Disease Registry, containing comprehensive clinical information for a large, diverse population with access to DNA for future genotyping and functional assays. This registry will be used to link clinical databases covering the 15-year period from1996-2010 in patients with psoriasis and psoriatic arthritis (as well as rheumatoid arthritis, juvenile inflammatory arthritis and ankylosing spondylitis) to measure the effectiveness of biologics for improving clinical outcomes. Currently, information is being analyzed for more than 665 patients with psoriasis who are biologics users. The Registry will provide the foundation for: (1) Measuring the many domains of effectiveness across a wide range of endpoints and throughout the patient's lifespan, (2) individualizing the determination of effectiveness to account for the patient's genetic profile, baseline risk for adverse events, and preferences, (3) estimating and comparing economic costs to the individual and society. An update of the progress of the project, as well as the data sources available in the HMO setting for research in CER will be provided.

GELFAND: The first-line treatment for moderate-to-severe psoriasis in a healthy adult patient (male or female of child-bearing potential, respectively) were phototherapy (42%, 59%), TNF-inhibitors (27%, 28%), and oral systemic (24%, 6%). Infliximab, ustekinumab, and cyclosporine were rated as the three most effective therapies, and etanercept, adalimumab, and UVB were rated as least likely to be stopped due toxicity. Additionally, 20-40% of respondents indicated that they did not know the efficacy or rate of toxicity for ustekinumab, alefacept, and infliximab.

Conclusions: DCERN can collect data for comparative effectiveness studies during routine office visits in a variety of practice settings. A modest cash incentive significantly improves response rates to surveys of dermatologists. Dermatologists who treat psoriasis generally prefer the comparison of TNF inhibitors, IL-12/23 inhibitor, and methotrexate for head-to-head trials, whereas the preferred first-line treatment for moderate-to-severe psoriasis is phototherapy. These data will be used to plan future comparative effectiveness studies in psoriasis.

ROBINSON: clinical research and need to IRB/Ethics Committee Review (2009). Each peer reviewer is graded by an editor on the quality of the review as well as the timeliness of the review. Reviewers with poor evaluations do not receive CME credit for performing the review.

Conclusions: Editors and editorial boards who demonstrate leadership can encourage authors to rise to the challenge of improving dermatologic health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision makers. Evidence-based publications in the Archives are rapidly disseminated in the lay press, thus, responding to the expressed need to inform people about which interventions are most effective for which patients under specific circumstances.

KIRSNER: with recombinant growth factor therapy (P_.001), and 40.0% more likely to heal than platelet releasate (P=.01). 2) Overall 8.2% of patients received HBO therapy including 7.5% in patients with Neuropathic DFU and 13.9% in Ischemic. Patients who had Wagner Grade 3 (Deep ulcer with abscess or osteomyelitis) neuropathic DFU experienced the greatest benefit from HBO with a 70% reduction in amputations seen in this group (OR 0.3 CI: 0.1, 0.9)

Conclusions: 1) Advanced treatment when used early had the best results. Tissue engineered skin was superior to growth factor therapy and platelet releasate. 2) HBO may reduce the risk of amputation in a defined population of patients.

NIAMS
National Institute of Arthritis and Musculoskeletal and Skin Diseases

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