Méthode.– Enquête prospective sur une durée de quatre mois (juin 2010 à septembre 2010) par échantillonnage aléatoire au niveau des trois villes de la région de l'Orientale du royaume du Maroc (Oujda, Berkane et Taourirt), par le biais d'un questionnaire anonyme auprès des pharmaciens d'officine.
Résultats.– L'étude a concerné 121 pharmaciens dont 72,2 % au niveau des quartiers populaires et 27,8 % au niveau des quartiers résidentiels. Selon eux la moyenne des médicaments dispensés en automédication était 54,75 %, et 51,2 % des pharmaciens ont déclaré que les femmes s'automédiquent plus que les hommes. Selon 43 % des pharmaciens, la majorité des médicaments dispensés sans ordonnance par jour sont sous forme de médication officinale. Les adultes représentent la tranche d'âge qui s'automédique le plus. Pour 43 % des pharmaciens, l'automédication est en augmentation et 52 % d'entre eux précisent que les patients de l'automédication sont des patients habituels de la pharmacie. Les antalgiques, les orexigènes, les AINS et les vitamines constituent les classes les plus utilisées en automédication. Les pathologies gastriques occupent la première place, et 38 % des pharmaciens déclarent qu'ils ont reçu au moins un cas soufrant de troubles liés à l'automédication, avec une fréquence de très rare à rare. Les effets indésirables rapportés étaient l'hypersensibilité aux médicaments, les troubles digestifs et les troubles métaboliques.
Conclusion.– La fréquence de l'automédication reste élevée dans la région orientale du Maroc. Elle reste est en augmentation selon les pharmaciens interrogés compte tenu de la facilité de l'obtention des médicaments sans ordonnance, d'où l'intérêt de sensibiliser les pharmaciens et les patients par rapport à cette pratique.

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Ethical submission issues in international pharmaco-epidemiological studies

Y. Bourhis, F. Logette, D. Bayle
Registrat-MAPI, Lyon, France

Objectives.– Principles of patients' individual rights are a constant concern of research ethics and were subject to international agreements (such as the Helsinki Declaration). Besides, an important harmonization process was carried out by the International Conference on Harmonization (ICH), through Good Clinical Practices (GCP), in order to define the principles and rules of clinical research and facilitate its internationalization. These guidelines were transposed into national regulations and adapted in Europe by the Directive 2001/20/EC. Nevertheless, these guidelines do not apply to pharmaco-epidemiological studies. Guidelines and general recommendations were specifically developped by the Council for International Organizations of Medical Sciences (CIOMS) or the International Society of Pharmaco Epidemiology (ISPE) for pharmaco-epidemiological studies (International Guidelines for Ethical Review of Epidemiological Studies and Good Pharmaco-epidemiology Practices (GPP)). However, the specific national regulations implemented for applying these main principles differ drastically from one country to another, with a broad range of mandatory national ethics and/or regulatory submissions, depending on the design and characteristics of the study. The aim of this communication is to present various issues encountered with national submissions of pharmaco-epidemiological studies.
Method.– We focus on 2 examples of international pharmaco-epidemiological studies (retrospective and prospective), taking into account several specificities (children, patient reported outcomes, direct to patient contact. . .), and compare the mandatory submissions in different countries.
Results.– In the case of an international non-interventional study, timelines and submission processes greatly vary from one country to another and have an important impact on budgets and timelines. Therefore, it has to be anticipated before the study implementation. For example, to conduct a prospective NIS in Europe, neither ethics nor regulatory approvals are needed in Austria (an adaptation of the Informed Consent Form is sufficient), while in Spain, a complex review process involving competent authority for classification (AEMPS), central, regional and also local ethics committees over a 5 month period approximately have to be undergone.
This only concerns ethics aspects but data protection and safety aspects can also greatly jeopardize the ability to start the study in some countries. As an example, direct to patients contacts are a mean to collect precious information directly from the source and are particularly helpful in pathologies where patients are not seen regularly by their healthcare providers. This system is feasible and generally well accepted as long as you are able to provide some proof elements that in no case a breach in confidentiality can occur. But in some rare cases, such as in Hungary, this kind of contacts are completely prohibited. In Portugal, where a data protection committee has recently been nominated, authorities are still conservative and may not accept such program.
Conclusion.– Regulatory and/or IRB/EC submissions are an important step of any pharmaco-epidemilogic study that requires utmost attention to ensure the greatest chance for approval. Our purpose is to highlight the variety and complexity of national regulations in the framework of international pharmaco-epidemiological studies and the need to clearly define the regulatory requirements and anticipate their impacts in terms of study documentations, timelines and financial considerations.

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Caractéristiques et réponses aux traitements dans le mélanome stade III non opérable et stade IV : étude rétrospective longitudinale MELODY

C. Bedane[a], M.-T. Leccia[b], B. Sassolas[c], S. Mansard[d], B. Guillo[e], L. Mortier[f], C. Robert[g], P. Saiag[h], F. Truchetet[i], A. Oukessou[j], B. Bregman[j], C. Lebbé[k]
[a] *Hôpital Dupuytren, CHU de Limoges, Limoges, France*
[b] *Hôpital Michallon, CHU de Grenoble, Grenoble, France*
[c] *Hôpital Morvan, CHU de Brest, Brest, France*
[d] *Hôtel-Dieu, CHU de Clermont-Ferrand, Clermont-Ferrand, France*
[e] *Hôpital Saint-Éloi, CHU de Montpellier, Montpellier, France*
[f] *Hôpital Claude-Huriez, CHRU de Lille, Lille, France*
[g] *Institut Gustave-Roussy, Villejuif, France*
[h] *Hôpital Ambroise-Paré, Boulogne-Billancourt, France*
[i] *Hôpital Beauregard, CHR de Metz-Thionville, Thionville, France*
[j] *Bristol-Myers Squibb, Rueil-Malmaison, France*
[k] *Hôpital Saint-Louis, Paris, France*

Introduction.– Le mélanome demeure la première cause de mortalité par cancer de la peau. Le dépistage précoce a permis de dissocier la prévalence et la mortalité, cependant le pronostic des stades les plus avancés reste sombre. L'étude MELODY avait pour objectifs la description des caractéristiques de la maladie, des modalités de prise en charge ainsi que des réponses aux traitements chez les patients atteints de mélanome de stades III non opérables et stades IV (SIIINO-SIV).
Méthodes.– MELODY est une étude observationnelle, rétrospective, longitudinale, multinationale sur trois pays (France, Italie, Royaume-Uni), portant sur une population atteinte de mélanome SIIINO-SIV. Dans la cohorte française, 10 services de dermatologie experts dans la prise en charge des cancers cutanés (9 CHU + 1 CLCC) devaient constituer un registre de la file active de tous les mélanomes vus dans ces centres entre juillet 2005 et juin 2006. Dans cet effectif, les cas SIIINO-SIV avec un suivi de deux mois minimum étaient extraits en vue d'un descriptif détaillé des caractéristiques de la maladie, des traitements reçus (systémiques, locaux, soins de support) et de leur réponse, ainsi que des ressources de soin utilisées, jusqu'au 1er mai 2008 ou jusqu'au décès.
Résultats.– En France, parmi les centres sélectionnés, une file active de 1224 patients (pts) a été identifiée pendant la période d'étude, d'où ont été extraits 278 cas SIIINO-SIV, âgés de 57 ± 17 ans en moyenne. Au moment du diagnostic initial du mélanome, 34/1224 pts (2,8 %) étaient SIIINO-SIV. En termes de traitement, 253/278 pts (91 %) ont reçu un traitement systémique, dont 230 (91 %) une chimiothérapie, toutes lignes confondues, alors que 129/278 pts (46,4 %) ont eu un traitement chirurgical et 96/278 (34,5 %) une radiothérapie. En première ligne de traitement systémique ($n = 249$), 198 pts (80 %) ont été traités hors essai clinique, dont 119 (60 %) sous dacarbazine et 35 (18 %) sous fotémustine en monothérapie ; la médiane de survie sans progression était de 2,8 mois [2,6 ; 3,5]. En seconde ligne de traitement systémique, 159/278 pts (57 %) ont été traités dont 139 (87 %) hors essai clinique, avec 75 (54 %) sous fotémustine, et 16 (12 %) sous dacarbazine ; la médiane de survie sans progression était de 2,5 mois [2,1 ; 2,9]. La médiane de survie globale, calculée sur l'effectif européen, était de 16,4 mois [15,1 ; 18,2] à

compter de la date de diagnostic du SIIINO-SIV, de 13,3 mois [12,3 ; 14,9] à partir de la date de traitement systémique de première ligne et de 8,0 mois [7,0 ; 9,8] à partir de la date de traitement systémique de deuxième ligne (6,8 mois [5,5 ; 7,8] chez les diagnostiqués en SIIINO-SIV pendant la période d'inclusion). Dans ce dernier cas, le taux de survie était respectivement de 28,8 % [22,1 ; 35,9] et de 14,7 % [9,0 ; 21,8] à 1 et 2 ans.

Conclusion.– Sur l'effectif étudié, les traitements systémiques administrés donnent, comme décrits dans la littérature, des résultats modestes en termes de survie globale et de survie sans progression. Dans le mélanome à un stade avancé, il existe clairement un besoin thérapeutique non couvert.

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Economic analysis of cataract surgery in Europe: An analysis of hospital databases available in 11 countries

M. Doz [b], G. Berdeaux [a], A. Lafuma [b]
[a] *Alcon France, Rueil-Malmaison, France*
[b] *Cemka-Eval, Bourg-la-Reine, France*

Objectives.– Cataract surgery is one of the most efficacious medical strategy and one of the most frequently performed operation in developed countries. EOCD [1] is supposed collecting information on this topic but data is not often updated. The aim of this survey was to estimate the number and costs of cataract surgery performed in 14 European countries and the potential costs associated with astigmatism.

Method.– Cataract surgery numbers were estimated from available databases. Costs associated with cataract surgery were based on official tariffs of local health care systems. Ratios of number of surgeries and costs per 100,000 people were also estimated for each country to allow comparisons. Astigmatism related costs were also explored. This survey was carried out in 14 European countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, and the UK.

Results.– Information was fully available in 10 countries and partly available in 1. Cataract surgery rates were in the range of 444 to 1006 operations per 100,000 people in the countries with complete information. All the countries were using a Disease Related Group (DRG) system for costs and tariffs. Costs of operations were highly variables according to the consideration of potential complications and to the type of surgery, outpatient or complete hospitalisations. Average cost of surgery ranged across the countries from 875 € to 2000 €. Average cost per inhabitant was estimated between 5 and 15 € per year. Astigmatism associated costs are never taken into account.

Conclusion.– Cataract surgery is performed in a large part of the European population with variations across countries that cannot be explained by epidemiological parameters.

Reference

[1] http://ec.europa.eu/health/ph_information/dissemination/echi/echi_fr.htm.

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Blood pressure responses to eprosartan-based therapy and trends in cognitive function in patients with initially resistant hypertension: Subanalysis of the OSCAR study

R.J. Petrella [a], E. Shlyakhto [b], O.A. Conrady [b], A. Sedefdjian [c], F. Sevenier [c], P.R. Hughes [d], A. Pathak [e]
[a] *Lawson Health Institute, University of Western Ontario, London, Canada*
[b] *VA Almazov Federal Center for Heart, Blood and Endocrinology, St Petersburg, Russia*
[c] *Evidence Based Communication, Fovea Group, Rueil-Malmaison, France*
[d] *Hughes associates, Oxford, UK*
[e] *Unité 858, Inserm, Toulouse, France*

Objective.– In the OSCAR study (Observational Study on Cognitive function And SBP Reduction), 6 months of antihypertensive therapy based on eprosartan was associated with a significant reduction in mean systolic blood pressure (SBP) and a significant improvement in mean Mini-Mental State Examination (MMSE) score ($P < 0.0001$ for both outcomes) in a very large community-dwelling population of patients with arterial hypertension recruited in 28 countries and managed in routine primary care. In this study, cognitive function was demonstrated to be independently and inversely correlated with SBP. The size of the ITT cohort of OSCAR ($n = 25,745$) enables us to identify large subgroups for further investigation, with the intention of adding to what is still sometimes limited epidemiological data on these specific types of patients.

Method.– We report our findings in a cohort of 2948 patients considered to have had resistant hypertension (RH) at the start of OSCAR because meeting this definition of RH: SBP/DBP $\geq$ 140/90 mmHg despite $\geq$ 3 antihypertensive drugs (AHD) $\leq$ 4 weeks of baseline visit. We then compared RH and non-RH sub-groups. Such observations may be instructive to the better management of this form of arterial hypertension.

Results.– RH patients' mean age was 66.9 ± 9.5 y (74.8% $\geq$ 60 y); 1474 were women. Mean BMI was 28.8 ± 4.6 kg/m^2; 1171 (40.1%) had diabetes mellitus (DM); other markers of cardiovascular risk were widely prevalent. Mean systemic blood pressure (BP) was 164.8 ± 14.5/93.3 ± 9.8 mmHg; pulse pressure (PP) was 71.5 ± 14.2 mmHg; 2,108 RH patients (71.5%) had systo-diastolic hypertension (SDH); 827 (28.1%) had isolated systolic hypertension (ISH). Mean MMSE was 26.5 ± 3.6 (range 12.0–30.0). Significant ($P < 0.001$) differences vs non-RH patients included greater age, BMI, SBP and PP, and lower MMSE.

After eprosartan-based therapy for 6 months (EBT; 600 mg/d) BP in RH was 138.8 ± 12.2/81.9 ± 7.4 (ΔSBP–26 ± 15.7; ΔDBP–11.4 ± 9.8); PP was 57.0 ± 10.8 (ΔPP–14.5 ± 13.8) (all $P < 0.001$ vs. baseline and non-RH group). Two thousand five hundred and seventy-six patients (87.4%) responded to EBT (i.e. SBP < 140 mmHg and/or ΔSBP $\geq$ 15 mmHg, or DBP < 90 mmHg and/or ΔDBP $\geq$ 10 mmHg); 1426 RH patients (48.4%) achieved normalized BP (i.e. SBP < 140 mmHg and DBP < 90 mmHg). ΔPP in RH-ISH was–18.0 ± 13.3 mmHg ($P = 0.003$ vs RH-SDH).

End-of-EBT mean MMSE was 27.5 ± 3.0 ($P < 0.001$ vs. baseline; n.s. vs non-RH). MMSE increased from 26.1 ± 3.7 to 27.1 ± 3.2 in RH-DM and from 26.5 ± 3.4 to 27.4 ± 3.0 in RH-ISH (n.s. vs subgroups RH-non-DM and RH-other hypertension subsets).

Blood pressure responses after EBT coincided with stabilization/improvement of MMSE in RH patients. EBT effects on PP may be relevant to the evolution of MMSE in RH-ISH patients.

Conclusion.– Use of eprosartan-based therapy in a large group of patients considered to have RH was associated with a substantial reduction in mean systemic BP and an increase in the average MMSE score. These observations are compatible with the premise that use of eprosartan may delay or prevent cognitive decline in people with treatment-resistant high BP.

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Cost of glaucoma in the United Kingdom according to the UK General Practice Research Database (GPRD)

J.F. Salmon [a], A. Lafuma [b], J. Robert [b], G. Berdeaux [c]
[a] *Oxford Eye Hospital, Oxford, United Kingdom*
[b] *Cemka-Eval, Bourg-la-Reine, France*
[c] *Alcon France, Rueil-Malmaison, France*

Objectives.– The objective of this analysis was to estimate the total budget dedicated to glaucoma care according to the UKGPRD and to identify factors associated with high costs.

Method.– Data were extracted on patients treated on the National Health Service (NHS) with a diagnosis of ocular hypertension or glaucoma, or treated with topical intraocular lowering treatment, surgery or laser for glaucoma. The budget was estimated from resources consumed in 2008 and included glaucoma drugs, laser, surgery, hospitalization, specialist and general practitioner (GP) visits. In-patient resources were estimated from the Hospital Episode Statistics. Results were expressed in Great Britain Pound, 2008. Factors associated with high cost were identified using linear stepwise regression. National extrapolation was performed according to the relative size of the GPRD to the UK general populations.

Results.–Details of 33,441 patients were extracted, which suggests that about 510,000 patients were treated in the NHS in UK in 2008. The mean age was 74.2 years, and 47.3% were male. The initial diagnosis was made at 67.8 years. Older patients, longer time since diagnosis, a higher number of previous treatments, a higher number of treatment switches in the previous one year