NEUROLOGICAL DISORDERS – Clinical Outcomes Studies

PND1

MIXED TREATMENT COMPARISON OF ADVERSE EVENTS FOR BG-12, GLATIRAMER, AND TERIFLUNOMIDE FOR THE TREATMENT OF RELAPSING FORMS OF MULTIPLE SCLEROSIS

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OBJECTIVES: Clinical trials of two new oral treatments (Teriflunomide and BG-12) for relapsing-remitting multiple sclerosis (RRMS) have been recently published. As efficacy is similar between these products and glatiramer, a comparison of their relative safety is relevant to physicians, patients, and providers. Our objective was to conduct a mixed treatment comparison of adverse event (AEs) in placebo-controlled randomized clinical trials of BG-12 240mg BID and TID, Glatiramer 20mg SID, and Teriflunomide 7mg and 14 mg SID in RRMS. **METHODS:** Articles were selected and reviewed following Cochrane guidelines. Placebo-controlled phase III RRMS clinical trials were eligible for inclusion. Data collected were the total number of patients experiencing at least one AE. The odds ratio (OR) of AEs, Credible Interval (CrI), and confidence in OR >1 for all drug pairs were estimated using a Bayesian random effects network meta-analysis with placebo as baseline comparator, and multi-arm adjustment. The mean rank (1-5) and probability of ranking lowest (PrL) of all treatments were calculated. The Surface Under Cumulative Ranking (SUCRA) summarized overall strength of evidence of the ranking of each treatment (best 100%, worst 0%). **RESULTS:** A total of 384 studies were identified and reviewed, and 3 studies (3737 patients) were included for analysis. Preliminary results are reported. Glatiramer exhibited the lowest AEs of all treatments (OR >1 for all comparisons with ≥ 90% confidence), except for borderline non-significantly lower AEs vs. placebo (OR=.73;95%CrI=.18-1.98;PL=89.6%). Patients receiving glatiramer had the lowest AEs (rank=1.4,PrL=80.3%,SUCRA=91.7%), followed by placebo (rank=2.9,PrL=4.2%,SUCRA=62.6%), BG-12 240mg TID (rank=3.2,PrL=4.8%,SUCRA=56.8%), Teriflunomide 7mg (rank=4.2,PrL=5.5%,SUCRA=35.3%), BG-12 240mg BID (rank=4.7,PrL=1.2%,SUCRA=26.9%), and Teriflunomide 14mg (rank=4.7,PrL=4.0%,SUCRA=26.7%). **CONCLUSIONS:** Preliminary results suggest that RRMS patients treated with Glatiramer have the lowest risk of experiencing AEs, while patients taking Teriflunomide 14mg have the highest AEs risk. This evidence may be useful to perform net clinical benefit analyses on alternative RRMS treatments.

PND2

EPIDEMIOLOGY AND ECONOMIC STUDIES ON PATIENTS DIAGNOSED WITH INSOMNIA: A REVIEW OF THE LITERATURE

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OBJECTIVES: To conduct a systematic review of literature in peer-reviewed journals on epidemiology and economic studies on patients diagnosed with Insomnia. **METHODS:** The initial search strategy was developed in the PubMed/MEDLINE database, and was then translated for the Cochrane and Embase database searches. Search strings for epidemiology and economics studies for Insomnia were constructed using varied approaches that included the use of MeSH terms, as well as keywords that would afford the best retrieval. Additional parameters were placed on the final search strategy to limit the retrieval to articles written in English, involving human subjects and published between 2000 and 2010. **RESULTS:** The initial search identified 225 articles for epidemiology and 144 articles for economic studies on Insomnia from PubMed/Medline/Embase/Cochrane databases. After removing duplicates and non-relevant articles, 40 articles for epidemiology and 13 for economic studies were included in the study. Twenty-three studies were focused on the prevalence of insomnia and the estimates among all of the studies ranged from 6.6% to 56%. Two studies focused on one year incidence rates of insomnia; one in Canada and the other in the UK. There were 4 studies each on burden of illness and cost effectiveness and 5 studies on retrospective claims analysis. The average annual direct and indirect per-person costs were $5,010 for individuals with insomnia syndrome, $1,431 for individuals presenting with symptoms, and $421 for good sleepers. **CONCLUSIONS:** There was a significant variation in the prevalence rates of Insomnia across different studies and in different countries. Insomnia results in significant direct and indirect costs and indirect costs in comparison to patients who were not diagnosed with Insomnia.

NEUROLOGICAL DISORDERS – Cost Studies

PND3

NATALIZUMAB FOR 2ND LINE TREATMENT IN RELAPSING-REMITTING MULTIPLE SCLEROSIS PATIENTS: 5-YEAR BUDGET IMPACT ANALYSIS (BIA) FROM THE BRAZILIAN PUBLIC PAYER PERSPECTIVE

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OBJECTIVES: Multiple sclerosis (MS) is a neurodegenerative disease associated with long-term disability and economic impact. With the addition of new agents for the MS treatment (e.g. natalizumab), there is a need to evaluate the relative value of newer therapies in terms of cost, given health care resource constraints in Brazil. Natalizumab is an effective therapeutic option for RRMS patients. Compared to other drug options, it shows better efficacy in terms of disease progression and relapse rates. Although natalizumab is indicated for 2nd line, the Ministry of Health public guidelines recommend natalizumab only in 3rd line treatment for MS. Therefore, a BIA has been created to analyze the impact of introducing natalizumab in 2nd line treatment in the public system. **METHODS:** BIA was based in a Markov model with monthly cycles and 5-year time horizon and MS epidemiological data were obtained from DATASUS. The model compared current MS treatment options reimbursed by the Brazilian government - interferon, glatiramer acetate and natalizumab (3rd line) with an alternative scenario with natalizumab in 2nd line. **RESULTS:** Number of Brazilian patients eligible for Relapsing-Remitting Multiple Sclerosis (RRMS) treatment was estimated to be around 7,098, 2,397 and 498 patients (1st, 2nd and 3rd line treatment, respectively) in the first year. Compared to the current scenario, the inclusion of natalizumab in the reimbursement protocol for 2nd line shows an additional budget through the 5 years consecutively as: 124.9K, 365.7K, 652.3K, 912.8K and 1.0M (USD). It is expected that during the 5-year analysis, the inclusion of natalizumab as 2nd line will increase the budget for MS by 4% with average cost per MS patient of USD50.60 (USD13.061 vs USD13.112 per patient/year). **CONCLUSIONS:** The estimated budget impact to include natalizumab as a 2nd line treatment option was USD3.1M in five years (increment of 4.0% of the current budget) for MS treatment.

PND4

ANÁLISIS DE COSTO-EFECTIVIDAD DE DOS FORMULACIONES DE TOXINA BOTULÍNICA TIPO A (TBA) EN COLOMBIA PARA EL TRATAMIENTO DE LA PARÁLISIS CEREBRAL INFANTIL (PCI)

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OBJECTIVOS: La incidencia de PCI es de 1.5 a 5/1000 nacidos vivos, esta representa la mayor causa de discapacidad infantil con un alto impacto en salud pública y la TBA hace parte del tratamiento integral. Los objectivos de este estudio son de comparar la costo-efectividad e impacto presupuestal del tratamiento con TBA Dysport 500U y Botox 100U en pacientes pediátricos con PCI, bajo la perspectiva del sistema de salud colombiano en un horizonte temporal de un año. **METODOLOGÍAS:** Para valorar la efectividad y seguridad se realizó revisión sistemática de la literatura; para la estimación de costos se utilizó la metodología de caso tipo, validado por tres fisiatras. Se estimó el costo de tratamiento anual basados en la "Circular 04 de Noviembre de 2012 de la Comisión Nacional de Precios". El análisis de sensibilidad incluye una variación entre el 25% y 30% de las dosis y escenarios sin optimización de unidades. Se calculó y comparó el costo promedio de tratar un paciente con PCI durante 1 año y el impacto presupuestal en una cohorte 1000 pacientes con cada medicamento. **RESULTADOS:** Las dos alternativas son equivalentes en términos de respuesta clínica y seguridad de acuerdo a lo encontrado en la evidencia científica. El costo promedio de tratamiento por paciente con TBA 500U es USD 2592 vs USD 3888 con TBA 100U, lo que representa un ahorro anual del 33% con el uso de TBA 500U. Si se considera una cohorte de 1000 pacientes, la elección de tratar PCI con TBA 500 proyecta un ahorro de USD 1,296,000 para el sistema de salud colombiano. En el 83% los escenarios del análisis de sensibilidad el uso de TBA 500U se mantuvo costo-ahorrativa. **CONCLUSIONES:** Desde la perspectiva del sistema de salud Colombiano el tratamiento de la PCI con TBA 500U resulta costo-ahorrativo vs el tratamiento con TBA 100U.

PND5

ANÁLISIS DE COSTOS MEDIANTE UN MODELO LINEAL GENERALIZADO DE PACIENTES MEXICANOS CON SINDROME DE WEST

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OBJECTIVOS: Realizar un análisis de costos del Síndrome de West (SW) mediante un modelo lineal generalizado desde la perspectiva institucional del Sector Salud de México. **METODOLOGÍAS:** Se identificaron los costos médicos directos de la atención de pacientes con SW (CIE-10 G40X) en el período comprendido entre 2000 y 2010, en el Hospital Infantil de México Federico Gómez (HIMFG). Los costos de recursos se obtuvieron del tabulador de cuotas de recuperación del HIMFG ajustados por el índice de precio del Sector Salud al 2011, los costos se reportan en MxP.Se realizó un modelo lineal generalizado para conocer la distribución de los valores de cada concepto evaluado y con estos resultados se realizó un análisis de sensibilidad Bootstrap para observar el comportamiento en los costos y la variabilidad de los mismos, además de una simulación de Monte Carlo con los intervalos de confianza generados. **RESULTADOS:** Se revisaron 86 expedientes de pacientes con SW, 60,7% de sexo masculino, la edad de inicio de los espasmos fue en promedio 4.9 meses, el tiempo promedio de seguimiento de los pacientes fue de 2.67 años. El costo total promedio del seguimiento fue de $45.425,73 correspondiendo el 73,79% del gasto a uso de fármacos antiepilépticos, 24,39% a estudios de extensión y el 2,2% restante a atención ambulatoria, hospitalizaciones y consulta de urgencias. En relación al tiempo de seguimiento, el medicamento con mayor costo durante el seguimiento fue la vigabatrina (media $21.924,24, rango $1.051,27 - $101.347,70), seguida del valproato de magnesio (media $6.914,75, rango $50,41 - $108.176,50). El análisis de sensibilidad realizado mostró que el modelo de costos es robusto y eficaz. **CONCLUSIONES:** La mayor proporción del coste de tratamiento en pacientes con SW correspondió al tratamiento antiepiléptico, lo que coincide con otros reportes de la literatura en relación al costo generado por el tratamiento farmacológico en pacientes epilépticos.

PND6

BURDEN OF MULTIPLE SCLEROSIS AND UNMET NEEDS IN BRAZIL: COST OF ILLNESS STUDY

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OBJECTIVES: To assess both direct medical and non-medical costs of Brazilian multiple sclerosis (MS) patients. **METHODS:** This was a cross-sectional, multicenter study conducted in 8 Brazilian major MS treatment sites. Costs due to MS treatment were calculated based on the resource utilization related to inpatient days, outpatient visits, laboratory and imaging tests, disease modifying therapies (DMTs), co-medication, OTC medications, aids and/or home modifications, and professional caregiver. Unit costs derived from Brazilian official price lists were applied to the