ABSTRACTS

To summarize the efficacy/effectiveness, complications and patient follow-up reported was 7–19 months (data range: 2–30) for 8 studies. Objective anatomic success rates were 89.5% (95% CI: 88.2–90.6; n = 2614) for all GYNECARE Prolift®, and 89.5% (86.5–92.0; n = 532) for anterior, 92.0% (88.8–94.5; n = 386) for posterior and 91.3% (87.6–94.2; n = 311) for total repairs, respectively. Overall recurrence rate (any compartment) was 9.3% (8.2–10.6). Immediate repair failure rates were: overall rate of any injury (Bladder, Bowel, Vaginal or Urethral) 1.7% (1.4–2.2); n = 4,750 of which bladder injury/perforation was the highest relative to other rates; 2.3% (1.8–3.0); n = 2486. Exposure rates were 6.9% (6.0–7.8); n = 2958). Major decision resection (Figure 3B) occurred at 6.4% (5.1–8.5; n = 597). Dyspareunia rates were 6.7% (5.3–8.3; n = 1,092). Patient satisfaction was 82.3% (77.0–86.9; n = 244) and 87.5% reported they would “recommend to a friend” (81.0–92.4; n = 144).

CONCLUSIONS: The evidence for mesh-based repairs is growing. While more randomized, and appropriately powered trials are needed to treat this longer-term outcomes, current peer-reviewed data shows that the GYNECARE Prolift® kit is an effective pelvic floor repair device with limited complications and high patient satisfaction.

PH4

PERSONALIZED MEDICINE: TRENDS IN CLINICAL STUDIES BASED ON NATIONAL REGISTRY DATA

Neetan D, Parson A, Yee K, Chow A
Avanir Group Inc., Menlo Park, CA, USA

OBJECTIVES: Targeted therapies using pharmacogenomic data promise to improve the safety, efficacy, and cost-effectiveness of drug treatment significantly. To assess research progress in targeting biopharmaceutical interventions to address unmet medical need, we investigated trends in personalized medicine using data from a national clinical trial registry. METHODS: Personalized medicine (PM) is the use of a patient’s genotype or other molecular diagnostic (pharmacogenomic) data to guide a treatment decision. We queried ClinicalTrials.gov for studies using pharmacogenomic criteria for inclusion or exclusion, or for stratifying outcomes, restricting our analysis to Phase III or IV studies initiated on or before January 7, 2009. We verified the sensitivity of our search strategy using a known set of studies for which PM-related trials have been conducted. RESULTS: As a result, 1,775 (N = 151) of registered Phase III/V trials in the US (N = 9,111) used pharmacogenomic data. Over time, the number of trials using pharmacogenomic data has increased greatly and, as expected, most PM trials (55%) were in the therapeutic areas of oncology and hematology. However, we observed a marked increase in the number of PM trials for drugs targeting rare diseases, such as neurological and mental health disorders including Alzheimer’s, depression, and schizophrenia. In addition, we found that the source of funding for PM trials increasingly comes from the pharmaceutical industry rather than from public sources. CONCLUSIONS: Targeting drugs to smaller subgroups is assumed to result in treating those patients most likely to respond and least likely to experience an adverse event. These data are consistent with the idea that these gains will be experienced broadly across therapeutic areas, however, the degree of impact will vary according to our understanding of the molecular basis of disease, with associated implications for assessing relative clinical and cost effectiveness.

PH5

AN ANALYSIS OF SELECT INJURY-INCREATING ANALGESIC MEDICATIONS IN MEDICARE DUAL ELIGIBLE ENROLLEES

Blackwell SA, Montgomery MA, Baugh DK, Ciborowski G, Levy JM
Centers for Medicare & Medicaid Services, Baltimore, MD, USA

OBJECTIVES: To assess the risk of high-risk comorbidities associated with the use of select analgesics in the elderly. METHODS: Logistic regression analysis performed to examine the risk of injury-related ER visits following the use of select analgesic medications. Demographic characteristics of CMS-HCC risk score, age, gender, and origin are reported as regressors. RESULTS: Separate analyses performed to assess the likelihood of an injury-related emergency room visit when the reference group under study was morphone, methadone, and propoxyphene recipients. For morphine, all medications analyzed were found to have a higher likelihood of an injury-related ER visit as compared to morphine, except for fentanyl (p > 0.05). Coding methadone as the reference group, only ketorolac, pentazocine and meperidine recipients had a higher likelihood of having an injury-related ER visit as compared to recipients of methadone (OR 1.411, 95% CI 1.301–1.530; OR 1.183, 95% CI 1.089–1.284; and OR1.181, 95% CI 1.097–1.247, respectively). Designating propoxyphene as the reference group, only ketorolac, pentazocine, meperidine, methadone, and hydrocodone recipients had a higher likelihood (OR 1.470, 95% CI 1.144–1.837; OR 1.232, 95% CI 1.144–1.327; OR 1.231, 95% CI 1.153–1.314; OR 1.042, 95% CI 1.004–1.081; OR 1.047, 95% CI 1.038–1.057, respectively). Regarding demographics, Caucasian origin, male gender, and middle-age elderly, and high CMS-HCC risk scores were found to be factors influencing injury-related ER visits for elderly analgesic recipients. CONCLUSIONS: Morphine is a very suitable opioid for use in the elderly. Methadone, a non-Bears medication, is a problematic opioid needing further assessment by the clinical community for possible assignment to the Bears list. Propoxyphene, currently a low severity rated Bears medication, needs further assessment for possible reassignment to a high severity rating.