Psoriasis Area Severity Index (PASI) was calculated at each time. Health related quality of life forms SF-12 and Psoriasis Disability Index (PDI) were included to perform quality of life analysis. (54.67% men and 45.33% women). Mean age was 43.59 ± 15.48 years and BMI 25.07 ± 3.84. Mean affected area at inclusion was 15.97% ± 8.14. Basal PDI was 29.20 ± 14.30. Bigger values for PDI, and therefore worse quality of life, were registered in patients with PASI values between 10–50 (28.06 ± 15.26) vs. those whose PASI values were below 10 (34.18 ± 13.60 p < 0.001). After 2 months of treatment, most of patients improved their quality life index: 85.20% for PDI, 51.78% for SF-12 physical domains and 83.30% for SF-12 psychological domains. CONCLUSIONS: Tacalcitol treatment has a positive effect on health related well-being, improving quality of life measured by unspecific scales and also by dermatologic indexes such as PDI. Tacalcitol treatment increases SF-12 scores, especially those for psychological domains, resulting in improvement on patients self-esteem.

METHODOLOGICAL ISSUES

METHODOLOGICAL ISSUES—Compliance Studies

PROPERLY ADDRESSING TIME-DEPENDENCE WHEN ANALYZING THE IMPACT OF COMPLIANCE WITH MEDICATION IN CHRONIC ILLNESSES

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OBJECTIVES: A common problem in outcomes research is translation of enhanced tolerability or convenience to higher compliance and better effectiveness. This is particularly tricky for chronic illnesses where time-dependent factors act in tandem. The objective was to develop an approach to this problem for administrative database analyses. METHODS: Data on women with osteoporosis who received medication (1996–2001) were obtained from Saskatchewan Health. Using dispensing records, each subject’s compliance pattern was derived; hospitalization/physician service records were used to determine fracture occurrence. Patients were highly compliant if dispensings covered a minimum portion (e.g., 80%) of their follow-up time. RESULTS: The common approach is to compare event rates among compliance categories, using Cox regression to adjust for confounders and relaxing the assumption of constant rates. Our rates were 8.3% and 11.1% for high and low compliance, respectively (RR = 0.75); the effect estimated from a Cox regression was RR = 1.24, and RR = 1.29 when adjusted for confounders, suggesting a detrimental effect for increased compliance. This analysis is inherently biased, however, since the timing of compliance measurements in the risk sets of the Cox model are not concurrent; the compliance of the survivors in the risk set is defined over a longer period and so is prone to be lower than the compliance of the subject who suffered the fracture. Thus, poor compliance becomes correlated with longer survival and produces contradictory findings. This can be resolved by measuring compliance based on medication use only up to the time of the fracture for all members of a given risk set. This analysis produced a crude RR = 0.81, and 0.84 when controlling for other risk factors. CONCLUSIONS: It is feasible to obtain population-based estimates of the impact of compliance on outcomes using an administrative database, but the analysis techniques should properly account for the time dependencies of all pertinent variables.

METHODOLOGICAL ISSUES—Clinical Outcomes Studies

DISABILITY IN STROKE OUTCOMES RESEARCH: CLINICAL MEANING OF THE BARTHEL INDEX, THE FUNCTIONAL INDEPENDENCE MEASURE AND THE MODIFIED RANKIN SCALE

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OBJECTIVES: Residual disability after stroke presents a major economic and humanistic burden. To quantify disability in patient, three disability instruments are globally used: the Barthel Index (BI), Motor component of Functional Independence Measure (M-FIM), and Modified Rankin Scale (MRS). Study objectives are: 1) to develop a crosswalk among these measures by categorizing scores presenting clinical significance; and 2) to examine the variation of the categorization scheme over time from stroke onset. METHODS: The Kansas City Stroke Study (KCSS) data was utilized for the current study. Disability measures at baseline (stroke index date), one, three and six month after index date were collected by trained clinicians. Polytomous logistic regression analysis was applied to produce probabilistic distributions of BI or M-FIM scores, representing clinically distinct disability states, which were defined by the six levels of the MRS. Model fit statistics were examined to verify logistic model appropriateness. A categorization scheme, which minimized the false positive response rate, was selected as the optimal categorizing system. RESULTS: BI and M-FIM differentiated disability well in lower ADLs than higher ADLs. For BI, 4 clinically distinct disability levels were differentiated with the following categorization scheme: 0 £ MRS5 < 15, 15 £ MRS4 < 70, 70 £ MRS3 < 95, and 95 £ MRS(0 + 1 + 2) £100. For the M-FIM, 3 stages were