authorities to recommend that NSAIDs be prescribed at the lowest dose. SoluMatrix diclofenac is approved for the management of mild to moderate acute pain and osteoarthritis (OA) pain in adults. Based on previous studies that examined the efficacy and safety of SoluMatrix diclofenac, we evaluated the pooled safety of SoluMatrix diclofenac in older patients (≥65 years of age) across two phase 3 studies.

Methods: A 12-week randomized, multicenter, double-blind, parallel-group study enrolled 305 chronic NSAID and/or acetaminophen users, 41 to 90 years of age with symptomatic and radiographically documented (Kellgren-Lawrence grade II or III) OA of the hip or knee. Patients had baseline Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale scores ≥40 mm at baseline and a documented OA pain "flare" (increase in WOMAC pain subscale ≥15 mm) following NSAID/acetaminophen discontinuation. Patients received either SoluMatrix diclofenac capsules 35 mg two or three times daily (BID or TID) or placebo. A 12-month open-label, multicenter study treated 601 chronic NSAID/acetaminophen users, aged 40 to 86 years, with knee and/or hip OA. Patients initially received SoluMatrix diclofenac 35-mg capsules BID; that could be increased to TID and reduced as needed.

Results: Similar proportions of patients reported AEs in the ≥65 years of age group (157/205 [76.6%]) compared with the <65 years of age group (365/500 [73.0%]). In patients ≥65 years of age treated with SoluMatrix diclofenac, the most commonly reported AEs included nausea (18/205, 8.8%), diarrhea (17/205, 8.3%), and upper respiratory tract infection (17/205, 8.3%). In patients <65 years of age treated with SoluMatrix diclofenac, the most commonly reported AEs were headache (40/500, 8.0%), upper respiratory tract infection (34/500, 6.8%), and diarrhea (32/500, 6.4%). Forty-six of the 205 patients ≥65 years of age (22.4%) withdrew from the study due to any AE, whereas 73/500 patients <65 years of age (14.6%) withdrew from the study due to an AE. Few SoluMatrix diclofenac-treated patients experienced AEs reported in class labeling for NSAIDs, including stroke, myocardial infarction, gastrointestinal ulcers, perforation or hemorrhage, or liver function abnormalities and occurred with no major differences among the two age groups (Table). Two patients (<65 years of age) reported myocardial infarctions, which were not considered to be treatment-related; there were no deaths.

Table. Summary of Selected Adverse Events of Special Interest by Organ System

	≥ 65 Years of Age	< 65 Years of Age	Overall
	SoluMatrix diclofenac 35 mg Combined (n = 205)	SoluMatrix diclofenac 35 mg Combined (n = 500)	SoluMatrix diclofenac 35 mg Combined (N = 705)
Gastrointestinal Disorders			
Gastrointestinal ulcer	1 (0.5)	0	1 (0.1)
Perforation or Hemorrhage	0	1 (0.2)	1 (0.1)
Renal Disorders			
Serum creatinine elevation	6 (2.9)	5 (1.0)	11 (1.6)
Hypertension	9 (4.4)	12 (2.4)	21 (3.0)
Blood pressure increase	3 (1.5)	4 (0.8)	7 (1.0)
Renal failure	0	1 (0.2)	1 (0.1)
Hepatic Disorders			
Alanine aminotransferase elevation	4 (2.0)	21 (4.2)	25 (3.5)
Aspartate aminotransferase elevation	2 (1.0)	14 (2.8)	16 (2.3)
Abnormal liver function test	3 (1.5)	6 (1.2)	9 (1.3)
Hepatic enzyme increased	0	3 (0.6)	3 (0.4)
Transaminases increased	0	2 (0.4)	2 (0.3)
Hepatic enzyme abnormal	0	1 (0.2)	1 (0.1)
Cardiovascular Disorders			
Myocardial infarction	0	2 (0.4)	2 (0.3)
Stroke	0	0	0

Data presented as n (%).
AE = adverse event.
The denominator for the percentages is the number of patients in the safety population within each category. AEs were recorded from the time the patient signed the informed consent until the patient completed or withdrew from the clinical trial.

Conclusions: In pooled 12-week and 12-month phase 3 studies, a comparable proportion of SoluMatrix diclofenac-treated patients ≥65 years of age and <65 years of age experienced similar AEs. These data add to the growing SoluMatrix diclofenac safety experience.

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BMI, PAIN AND FUNCTION IN PATIENTS WITH KNEE OSTEOARTHRITIS

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Purpose: To evaluate the relationship between BMI and pain and function in patients with knee osteoarthritis (KOA) undergoing multiprofessional clinical treatment.

Methods: Thirty-eight patients (four men and 34 women) aged 47-83 years old (mean 63.2 years) in usual treatment for knee OA for more than three months, i.e. oral diacerhein and analgesics (according to pain), orthotics (when indicated) were selected for a two-days two months apart multiprofessional (medical, nutritional, psychological, physical and occupational therapy, physical educator and social workers) educational program on Ostearthritis. X-rays were performed to classify the OA degree (Kelgreen & Lawrence – K&L). All patients were evaluated at baseline (one month prior to first class) and at 6 months (3 months after the second class) with height, weight (BMI estimation), and asked to complete WOMAC, Lequesne, and visual analogue pain scale questionnaires.

Results: Eight patients had grade I (K&L), eleven, grade II, thirteen, grade III and six, grade IV. The results regarding change in VAS, WOMAC-pain, WOMAC and Lequesne did not correlate to the initial degree of osteoarthritis. There was no significant BMI variation in this study (average -0.2, SD= 0.22, range -4.9, 2.7). The higher the initial BMI, the lower the improvement in pain (Spearman test, $p = 0.03$). Pain did not improve significantly ($p = 0.2$). Function improved ($p < 0.001$) in inverse ratio to the initial BMI. However, the group that decreased BMI tended to improve pain and function and the group that increased BMI tended to improve pain and function (Kruskal-Wallis test, not significant).

Conclusions: BMI determines how patients will improve pain and function.

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GENDER DIFFERENCES IN THE RELATIONS BETWEEN CLINICAL QUESTIONNAIRES AND RADIOGRAPHIC GRADES IN KNEE OSTEOARTHRITIS. A CROSS-SECTIONAL EVALUATION OF 518 PATIENTS

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Purpose: To evaluate the correlations between common clinical OA diagnostic tools in order to determine the value of each. A secondary goal was to investigate the influence of gender differences on the findings.

Methods: Five hundred and eighteen patients with knee OA were evaluated using the Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire, short form 36 (SF-36) Health Survey and plain radiographs. Analysis of variance (ANOVA) was used to compare the different domains of the WOMAC and SF-36 questionnaires between genders and the radiographic scale.

Results: Higher knee OA x-ray grade were associated with worse clinical outcome: for women – higher scores for the WOMAC pain, function and final scores and lower scores in the SF-36 final score; in men: lower SF-36 overall and Physical domains scores. Gender differences were found in all clinical scores that were tested, with women having worse clinical scores for similar radiographic grading (p values< 0.001).

Conclusions: Knee radiographs for OA have an important role in the clinical evaluation of the patient. Patients with higher levels of knee OA in x-ray has a higher probability of having a worse clinical score in the WOMAC and SF-36 scores. The gender differences suggest that for similar knee OA x-ray grade women's clinical scores are lower.