TRIAL-AND-ERROR PRESCRIBING BEHAVIOR IS MODIFIED BY A PSORIASIS PRECISION MEDICINE TOOL: PRELIMINARY CLINICAL UTILITY FINDINGS FROM THE MATCH STUDY

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ABSTRACT

In the United States, psoriasis affects >3% [1] of the population, leading to healthcare costs of >$110 billion annually. [2] There are currently 11 approved biologics for healthcare practitioners to consider in psoriasis patient treatment plans which contributes to trial and error behavior. Real world response rates to these drugs are estimated to be approximately 50%, further compounding the problem that matching the optimal biologic to a given patient the first time can be difficult. According to Joint AAD/NPF guidelines, predictive biomarkers for the appropriate biologic agent for patients are needed. [3] A machine learning-based test (Mind.Px) has been introduced that predicts patient response to biologic drug class with a positive predictive value >91%.[4] This test uses a dermal biomarker patch that allows for rapid and painless extraction of mRNA. This 16-week randomized study (MATCH) was designed to assess the test utility in physician decision making and patient outcomes.

To date, 188 patients from 28 sites have been enrolled in the study; of these, 94 patients were randomized to the test informed arm and physicians were provided test results prior to biologic selection. After reviewing test results, 92.3% of the physician therapeutic choices were concordant with test results, despite formulary restrictions or physician preference. In contrast, only 62.9% of physician therapeutic choices were concordant with test results in the treatment as usual arm. Furthermore, interim analysis of those patients who have completed the study showed improved clinical outcomes in those patients whose treatment was concordant with Mind.Px test results. Specifically, this cohort reached PASI75 faster than those who were not provided with test results (p = 0.036). These results provide an interim measurement of the clinical utility of Mind.Px by showing that physicians will utilize this test in psoriasis biologic decision making and by doing so, this leads to improved patient outcomes

1 Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057
2 Pilon D, Teeple A, Zhdanava M, et al. The economic burden of psoriasis with high comorbidity among privately insured patients in the United States. *J Med Econ*. 2019;22(2):196-203. doi:10.1080/13696998.2018.1557201
3 Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. JAAD. VOLUME 80, ISSUE 4, P1029-1072, APRIL 01, 2019.
4 Bagel J, Wang Y, Montgomery P III, et al. A machine learning-based test for predicting response to psoriasis biologics. *SKIN The Journal of Cutaneous Medicine*. 2021;5:621- 638.

MATCH STUDY DESIGN

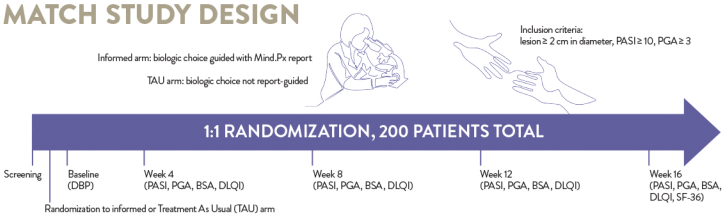

FIGURE 1. Design of MATCH clinical utility study.

FIGURE 2. Dermal Biomarker Patch (DBP) workflow.

Assessments	Visit 1 Screening 1-4 Weeks	Visit 2 Baseline/ Randomization	Visit 3 Week 4 ±3 Days	Visit 4 Week 8 ±3 Days	Visit 5 Week 12 ±3 Days	Visit 6 Week 16 ±3 Days
Informed Consent	X					
Inclusion/Exclusion Criteria	X					
Demographics	X					
Clinician Demographics	X					
Mind.Px Dermal Patch	X					
Medical History	X					
Biologic Treatment History (previous & current; including response and questionnaires)	X					
Current Biologic Treatment & Biologic Treatment Trials Since Last Visit (including response and questionnaires)		X	X	X	X	X
Medication History (other than biologics)	X					
Physical Exam	X					
Vital Signs	X					
Randomization		X				
PASI	X	X	X	X	X	X
PGA	X	X	X	X	X	X
BSA	X	X	X	X	X	X
DLQI		X	X	X	X	X
SF-36 (patient reported)		X				X
Clinician Utility Questionnaire*		X *(after)*				
Adverse Events (AEs)	X	X	X	X	X	X
IP accountability	X					
Dose Changes		X	X	X	X	X
Switching		X	X	X	X	X
Regimen Augmentation		X	X	X	X	X
Discontinuation		X	X	X	X	X
Biologic Compliance		X	X	X	X	X

TABLE 1. Schedule of activities for MATCH study.
** Performed at the baseline visit for subjects in the MND group only after receipt of Mind.Px report.*

RESULTS

Previously, we reported that physicians are willing to utilize molecular information such as that provided by Mind.Px in their psoriasis biologic treatment paradigm.[2] Indeed, we found that physicians reported a desire to utilize Mind.Px results even if this differed from their initial clinical choice. We have initiated a prospective study aimed at conclusively proving the clinical utility of this test in a blinded patient cohort. Presently, we have enrolled 188 patients from 28 sites into this study; of these, 94 patients were randomized to the test informed arm and physicians were provided test results prior to biologic selection. Statistical analysis of concordance between the Mind.Px-informed and Mind.Px-uninformed groups (92.3% vs 62.9%, respectively) showed that when given access to Mind.Px results, physician behavior was significantly altered (p = 1.4 x 10-6). Furthermore, in the Mind.Px informed arm, of the seven discordant cases, six of the seven were the result of physicians being unable to align with Mind.Px results due to insurance formulary restrictions.

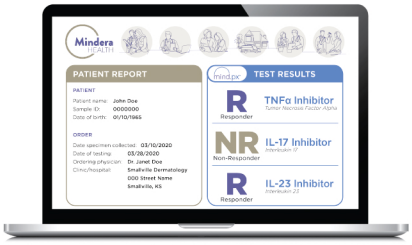

FIGURE 3. Sample Mind.Px test report received by physicians during the MATCH study.

	Mind.Px Informed	TAU
Concordant (%)	84 (92.3%)	61 (62.9%)
Discordant (%)	7 (7.7%)[a]	36 (37.1%)

[a] Four of the five patients were discordant due to insurance formulary restrictions.

TABLE 2. Concordance of physicians with Mind.Px results.

We have also performed an interim analysis on patients who have completed the MATCH study to determine if those patients showed improved clinical outcomes relative to patients who did not receive Mind.Px test results in decision making. Importantly, a statistically greater proportion of patients reached PASI75 by week 4 in the concordant arm relative to either the MATCH TAU arm or our historic STAMP data set[4] (p=0.036 and p=0.002, respectively). Fisher's exact test). Furthermore, while the comparison of concordant arm versus MATCH TAU arm is not currently statistically significant, the trend observed in STAMP and MATCH TAU arms are highly similar, suggesting that future analyses will reach statistical significance.

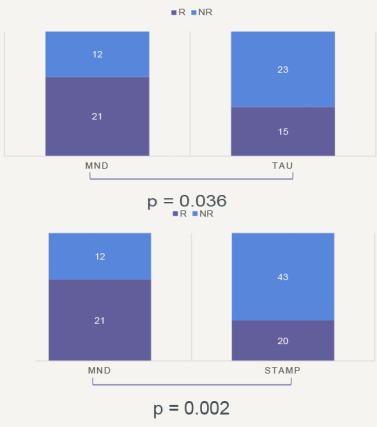

FIGURE 4. Interim analysis of patients who have completed the MATCH study shows that by using Mind.Px results, patients reach clinical endpoints faster than patients in treatment as usual arms.

CONCLUSION

These results provide an interim validation of the clinical utility of Mind.Px by showing that physicians will utilize this test in psoriasis biologic decision making and by doing so, lead to improved patient outcomes. Barring any restrictions from payer formularies, physicians choose to utilize and align with Mind.Px results in their clinical decision making 97% of the time, in alignment with our previously reported survey study.[2] In the concordant cohort, interim analysis shows a statistically significant clinical improvement where patients reach clinical endpoints faster than those who do not receive test results. Improved patient outcomes such as this can potentially translate into tremendous cost savings for healthcare systems. Mind.Px can effectively minimize the trial-and-error approach to psoriasis treatment, and provide physicians, patients, and payers with a powerful tool for re-envisioning psoriasis patient management.

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