

Patient Expectations as Predictors of Outcome In Patients with Acute Low Back Pain

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BACKGROUND: Few studies have evaluated the association between patient expectations for recovery and clinical outcomes, and no study has evaluated whether asking patients to choose their therapy modifies such an association.

OBJECTIVE: To evaluate the association between patients' expectations and functional recovery in patients with acute low back pain (LBP), and to determine whether that association is affected by giving patients choice of therapy.

DESIGN AND PARTICIPANTS: A secondary analysis of a randomized controlled trial comparing usual care alone to usual care plus choice of chiropractic, acupuncture, or massage in 444 adults with acute LBP, lasting less than 21 days.

MEASUREMENTS AND MAIN RESULTS: Primary outcome was functional disability (Roland score) at 5 and 12 weeks. Patients' general expectations for improvement were associated with improvement in functional status ($\beta=0.96$, 95% CI=0.56, 1.36). A 1-point increase in general expectations was associated with a 0.96-point improvement in Roland score. The association of expectation with outcome was 2–3 times greater in the usual care group than the choice group. However, these differences did not reach statistical significance.

CONCLUSIONS: In patients with acute LBP, higher expectations for recovery are associated with greater functional improvement. Eliciting patient expectations for improvement may be a simple way to identify patients with the highest (or lowest) likelihood of experiencing functional improvement. Incorporating questions about patient expectations in future trials may clarify the role of this important correlate of clinical outcomes.

KEY WORDS: expectations; preference; choice; low back pain; randomized controlled trial.

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BACKGROUND

Prior research has documented intriguing associations between patients' expectations for recovery and their clinical outcomes.^{1–8} A systematic review of the literature on expectations of recovery found that 15 of 16 studies reported that positive patient expectations were associated with better health outcomes.⁹

Most studies evaluating the association between expectations and clinical outcomes have focused on relatively subjective outcomes. Patients with high expectations that acupressure bands would provide relief from chemotherapy-induced nausea reported more relief than those with low expectations,¹⁰ and patients with benign prostatic hypertrophy who had positive expectations for surgery reported feeling better after surgery than patients with more negative expectations.²

Regarding functional outcomes, investigators found that general expectations for recovery were associated with functional ability after total joint arthroplasty.¹¹ Higher expectations of specific therapies, but not general expectations for improvement, were associated with functional improvement in patients with persistent low back pain.⁴

Because of its clinical relevance, and its relevance to future study design, it is important to expand our understanding of this association. Are patients who are generally optimistic about their recovery more likely to get better than patients who are more pessimistic? Are there sociodemographic or clinical factors associated with having high expectations? Are there other factors that modify the effect of expectations on outcome?

In this context, we performed a secondary analysis to evaluate whether there was an association between patients' general expectations for recovery from acute low back pain (ALBP) and their functional outcomes. We also evaluated whether patients' expectations of specific therapies were associated with their outcomes. In addition, we took advantage of a unique element of the parent study's design to examine

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whether the effect of expectation on outcome was modified by asking patients to choose their therapy. Because one possible explanation for an association between expectation and outcome is that expectation is a component of the placebo effect, we hypothesized that this effect might be different among patients who chose their own therapy versus those who were prescribed therapy by their clinicians. To our knowledge, this question of a differential effect of expectations based on giving patients choice of therapy has never been studied.

METHODS

We performed a secondary analysis of data from a randomized controlled clinical trial comparing usual care alone to usual care plus patient choice of adjunctive complementary and alternative medical (CAM) therapy (consisting of acupuncture, chiropractic, or massage) for acute low back pain (ALBP). We recruited patients from 4 clinical practice sites of Harvard Vanguard Medical Associates (HVMA), a large multispecialty group practice in the greater Boston area. Full details of recruitment have been previously described.¹²

PARTICIPANTS

English-speaking patients age 18 and above were considered for the study if they were presenting for initial evaluation of low back pain and scored greater than 3 on a 0–10 pain scale. We excluded patients whose pain was not in the low back or had lasted longer than 21 days. Other reasons for exclusion have been described.¹²

RANDOMIZATION

We randomized eligible participants at each clinic using a stratified permuted-block design by clinical site. Randomization assigned one-third of participants to the usual care arm.

TREATMENTS

Clinics provided usual care to all participants according to their standard treatment algorithm, which included NSAIDs, muscle relaxants, limited bed rest, education, and activity alterations. Participants randomized to choice continued to receive usual care at HVMA clinics, but were also given a choice of adjunctive acupuncture, chiropractic, or massage therapy. CAM treatments took place at the private offices of participating credentialed CAM providers. Further details about treatments provided have been described.¹²

DATA COLLECTION

At baseline interviews, we obtained data on patient demographics including age, gender, education, income, marital status, employment status, and smoking. We collected data on patient expectations as described below. We assessed baseline functional status using the modified Roland–Morris Disability Questionnaire^{13–15} that includes 23 yes–no ques-

tions about difficulties with daily activities such as difficulty getting dressed and climbing stairs. The overall score is a sum of positive responses, ranging from 0 to 23, with a higher score signifying more disability. The instrument has been extensively validated. A change in score of 2 points or greater is considered clinically significant.¹³ We also evaluated clinical status, disability, history of back pain, general health, and depressive symptoms as previously described.¹² Our primary outcome was change in functional status from baseline to 5 and 12 weeks.

We analyzed 2 measures of patient expectation, collected at baseline. The first was the participants' general expectation based on the question: "Using a scale from 0 to 10, with 0 being no improvement and 10 being complete recovery, how much improvement do you expect in six weeks?" The second expectation variable was a participant's specific expectation of the CAM therapy that they chose. Before randomization, patients were asked: "Using a scale from 0 to 10 (where 0 is not at all helpful and 10 is extremely helpful), how helpful do you believe that _____ [a specified CAM therapy] would be for your current episode of back pain or sciatica?" For each participant, the number they assigned to the therapy that they ultimately chose was used as their measure of specific expectation. General expectation was measured for all participants, whereas specific expectation was limited to those randomized to the choice group.

DATA ANALYSIS

In the main study comparing usual care (UC) with choice of CAM therapy for ALBP, the choice group showed no difference in functional status at week 5.¹² For our initial analysis, we pooled data from the UC and choice groups to maximize power.

We used linear regression to determine whether expectations were independently associated with a 5-week or 12-week change in Roland score. We first tested the continuous expectation variables for an association with change in Roland score using unadjusted linear regression. We also tested each of the sociodemographic, clinical, and historical covariates for an association with the primary outcome using unadjusted analysis. Because our primary focus was the unadjusted analysis, we only ran adjusted models if a relationship was seen in the unadjusted analysis.

In the adjusted analysis, we included those covariates found to have an association with the outcome with a p value of $\leq .10$ in the unadjusted analysis. We attempted to build a parsimonious model by using a forward selection algorithm followed by backward elimination to remove variables no longer significant at $p < .05$. We individually tested those covariates excluded from the model for confounding, and would have reincluded any covariates whose inclusion produced a change of 10% or more in the estimated coefficient for the expectation variable of interest. However, none of the covariates produced such an effect in either model. We performed all analyses with SAS 9.1.3 (2002–2003 by SAS Institute Inc., Cary, NC, USA).

If we found an association between either expectation measure and outcome, we stratified that expectation variable into 4 categories: low (0–2), medium (3–6), high (7–9), and very high (10). We evaluated the distribution of sociodemographic and clinical covariates by expectation category to see if there were any significant differences in distribution. For ordinal variables,

we tested for significance using a Kruskal–Wallis test. For binary variables, we used a Cochran–Armitage test for trend. For continuous variables, we tested for a trend across the different means using a linear contrast within linear regression.

In a secondary analysis, we stratified participants according to whether they were in the usual care or choice groups to see if there was any difference in the association between expectation and outcome in these two groups. We used the same adjusted linear regression models we constructed for the general study population and analyzed the association between general expectation and primary outcome in the usual care and choice groups separately. To test for effect modification we introduced an interaction term (the product of the usual care vs choice variable with the expectation variable) in our models.

RESULTS

As shown in Table 1, our population tended to be white, well-educated, and employed. Thirty-four percent of our patients

were seeing a physician for ALBP for the first time. Mean pain and Roland scores represented moderate to high levels of pain and dysfunction. Over a 5-week period, mean Roland score dropped more than 50%. Attitudes toward CAM therapies appeared to be similar to attitudes toward conventional physical therapy. On the 0–10 scale, patients, on average, rated the probable helpfulness of chiropractic at 6.1 (± 2.96), acupuncture 6.1 (± 2.52), and massage 7.2 (± 2.27). They rated physical therapy 6.9 (± 2.51).

In the unadjusted analysis, general expectation, but not specific expectation, was strongly and significantly associated with improvement in Roland scores at 5 and 12 weeks. For each 1-point increase in general expectation, there was a 0.96-point improvement in Roland score at 5 weeks. In the adjusted models, general expectation retained statistical significance (see Table 2).

As seen in Table 1, patients' general expectations tended to be high. When we stratified patients according to level of general expectation, no participants fell into the low category. Thirteen percent of participants (58) reported their general

Table 1. Demographic and Clinical Characteristics by Level of General Expectation

Patient Characteristics	Study Group* n=442	Level of General Expectation			p value
		Medium n=58	High n=186	Very High n=198	
Demographics					
Mean Age [†]	43.0	40.9 \pm 13.1	42.8 \pm 12.9	43.9 \pm 12.3	0.12
Female	53%	56.9%	55.9%	50.0%	0.24
Annual Income > \$75,000?	34%	37.7%	30.0%	39.7%	0.33
Education Beyond High School	97%	98.3%	95.7%	97.0%	0.93
White	65%	65.5%	63.6%	67%	0.66
Married or living with someone	65%	55.2%	63.4%	69.2%	0.04
Employed (currently working)	85%	80.7%	85.5%	86.9%	0.33
Clinical Factors General Health					
Weeks worked in past year	43.2 \pm 13.2	43.7 \pm 11.2	42.5 \pm 14.2	43.8 \pm 12.7	0.96
Self-rating of general health [‡]	2.3 \pm 0.9	2.5 \pm 1.0	2.5 \pm 0.9	2.1 \pm 0.9	0.002
Physical SF12 Subscale	36.7 \pm 7.5	38.6 \pm 8.0	36.6 \pm 7.5	36.2 \pm 7.2	0.03
SF12 [§]	4.7 \pm 1.3	4.7 \pm 1.6	4.8 \pm 1.2	4.7 \pm 1.3	0.94
Current Episode Baseline					
Baseline Roland Score	16.4 \pm 4.7	15.2 \pm 5.5	16.3 \pm 5.0	16.8 \pm 4.1	0.02
Pain Score [¶]	7.1 \pm 2.2	6.4 \pm 2.5	7.0 \pm 2.1	7.3 \pm 2.1	0.007
Days in bed in past wk	0.94 \pm 1.5	0.8 \pm 1.4	1.1 \pm 1.7	0.9 \pm 1.3	0.71
Days/wk exercise [#]	4.1 \pm 1.7	4.3 \pm 2.0	3.9 \pm 1.7	4.3 \pm 1.6	0.91
First Time MD**	34%	24.1%	27.4%	43.2%	0.0006
Leg pain or numbness?	38.2%	41.4%	39.5%	36.4%	0.44
5 Week Follow Up					
5 Week Roland Score	7.5 \pm 6.9	9.9 \pm 7.2	8.5 \pm 6.9	5.9 \pm 6.5	0.0003
Prior Episode(S)					
Hospitalized for LBP in past?	2.3%	3.5%	3.8%	0.5%	0.06
Prior helpfulness PCP ^{††}	5.8 \pm 3.0	4.0 \pm 3.2	5.8 \pm 2.7	6.5 \pm 3.0	<.0001
Prior helpfulness PT ^{‡‡}	6.5 \pm 2.7	4.6 \pm 3.0	6.4 \pm 2.7	7.7 \pm 1.8	<.0001
Chosen CAM therapy in past?	31%	15.4%	37.1%	28.9%	0.92
Prior helpfulness CAM ^{§§}	8.1 \pm 2.1	8.5 \pm 1.3	7.9 \pm 2.5	8.2 \pm 1.8	0.81

*For nearly all variables, more than 90% of data were available; however, data were missing at a higher rate for the following variables: days/week of exercise (n=313), helpfulness of PCP for past episodes (n=269), helpfulness of PT for past episodes (n=148), treatment by chosen CAM therapy in past (n=185), and helpfulness of CAM therapy in past (n=84).

[†]Means are followed with \pm standard deviation

[‡]1=Excellent, 5=poor

[§]Amount of time during past week feeling blue: 1=all time, 6=none of time

^{||}0=No disability, 23=worst disability

[¶]0=No pain, 10=worst pain ever

[#]Prior to current LBP episode

**Patient seeing MD for LBP for first time

^{††}Helpfulness of PCP for prior LBP (0=not helpful, 10=extremely helpful)

^{‡‡}Helpfulness of PT for prior episode of LBP (0=not helpful, 10=extremely helpful)

^{§§}Helpfulness of CAM therapy for prior episode of LBP (0=not helpful, 10=extremely helpful)

Table 2. Results of Linear Regression Analysis for Primary Outcomes and Predictors

Expectation Variable	Change in Roland at 5 Weeks β -Coefficient (confidence interval)	Change in Roland at 12 Weeks β -Coefficient (confidence interval)
General (unadjusted)	0.96 (0.56, 1.36) ($p < .0001$; $n = 400$)	0.87 (0.46, 1.29) ($p < .0001$; $n = 387$)
General (adjusted)*	0.80 (0.43, 1.16) ($p < .0001$; $n = 376$)	0.59 (0.21, 0.98) ($p = .0027$; $n = 365$)
Specific (unadjusted)	0.12 (-0.35, +0.60) ($p = 0.61$; $n = 245$)	0.14 (-0.63, +0.36) ($p = 0.59$; $n = 239$)
Specific (adjusted)	Not performed	Not performed

*General expectations in model are adjusted for factors including age, race, income, baseline Roland score, depression, history of sciatica, 1st time seeing MD for back pain, and baseline pain score.

expectations for improvement in the medium range, 42% (186) reported expectations in the high range, and 45% (198) reported expectations for improvement as 10 on a 0–10 scale. The mean general expectation was 8.6 (standard deviation [SD] = 1.7).

There were no significant differences in the distribution of age, sex, income, education, race, or employment status by general expectation category. However, married patients or those with a partner had higher expectations. Other factors associated with higher general expectations included: worse pain or function at baseline; better general health; seeing a health care provider for ALBP for the first time; or finding one’s primary care physician or physical therapist to have been helpful for a prior episode of ALBP.

In the adjusted models, in addition to general expectation, age, race, income, depressive symptoms, baseline Roland score, sciatica, and first time seeing an MD for back pain were independent correlates with functional status at both 5 and 12 weeks (see Table 3).

In a secondary, stratified analysis, we found that the magnitude of the association between general expectation and change in Roland score at 5 weeks (β -coefficient) was nearly twice as large in the usual care group (0.95) as the choice group (0.55) (Table 4). At 12 weeks, this difference was even more pronounced between usual care (0.80) and choice (0.29). When an interaction term (treatment group by expectation) was entered into the model, however, it did not reach significance for a 5-week Roland score ($p = 0.27$) and was just short of significance for a 12-week Roland score ($p = 0.068$).

DISCUSSION

We found that participants’ general expectations for improvement, but not their specific expectations of chosen therapies, were significantly associated with changes in disability at 5 and 12 weeks. We also found that the association between general expectations and outcome appeared to be substantially higher in the usual care versus the choice group (see Table 4).

We are aware of only 1 prior study that has evaluated the effect of patient expectations on their low back pain outcomes. In that study, *general* expectations for improvement were not found to be associated with improvement in Roland score at 10 weeks, whereas *specific* expectations were associated with improvement.⁴ The studies, however, had important differences. Whereas our population suffered from *acute* back pain, the prior study evaluated patients with *chronic* back pain. The prior study was limited to 135 patients and used a 7-point Likert scale (where patients rated their expectation for recovery in 1 month from 1 [complete recovery] to 7 [much worse]) to measure general expectation. A final, fundamental difference was that the prior study randomly assigned patients to acupuncture or chiropractic, whereas our study asked patients to choose between three CAM therapies. In this light, the possible mediating effect of choice on the association between expectation and outcome (discussed below) may be relevant.

The different measures of general expectation in these 2 studies highlight the need for a more standardized approach to studying the association between patient expectations and

Table 3. Adjusted Models

Covariate	β -Coefficient	P value	Interpretation
Factors Independently Associated with Change in Roland Score at Week 5			
General Expectation	-0.80 (-1.16, -0.43)	<.0001	Higher expectation, more improvement
Age	+0.07 (0.02, 0.11)	.0068	Younger, more improvement
Nonwhite vs. White	+2.1 (0.80, 3.41)	.0016	White, more improvement
Income > \$75,000	-1.62 (-2.90, -0.35)	.013	Wealthier, more improvement
Are you depressed?	-0.84 (-1.29, -0.38)	.0003	Less depressed, more improvement
Baseline Roland score	-0.60 (-0.73, -0.47)	<.0001	Worse baseline, more improvement
1st time seen MD for LBP	-1.53 (-2.81, -0.25)	.019	1st time seeing MD, more improvement
Leg pain or numbness	-2.44 (-3.66, -1.21)	.0001	No sciatica, more improvement
Factors Independently Associated with Change in Roland Score at Week 12			
General Expectation	-0.59 (-0.98, -0.21)	.0027	Higher expectation, more improvement
Age	+0.05 (0.0002, 0.10)	.049	Younger, more improvement
Nonwhite vs. White	+2.44 (1.12, 3.76)	.0003	White, more improvement
Income > \$75,000	-1.37 (-2.66, -0.08)	.037	Wealthier, more improvement
Are you depressed?	-0.47 (-0.94, -0.003)	.048	Less depressed, more improvement
Baseline Roland score	-0.61 (-0.74, -0.47)	<.0001	Worse baseline, more improvement
1st time seen MD for LBP	-1.98 (-3.26, -0.69)	.0027	1st time seeing MD, more improvement
Leg pain or numbness	-2.38 (-3.62, -1.13)	.0002	No sciatica, more improvement

Table 4. Stratified Analyses

	β -Coefficient*	p value†
Stratified Analysis Showing Differences in the Association Between General Expectation and Change in Roland Score in Usual Care versus Choice Groups at 5 Weeks		
Usual Care	0.95	.0016
Choice	0.55	.03
Interaction Term‡	N/A	.27
Stratified Analysis Showing Differences in the Association Between General Expectation and Change in Roland Score in Usual Care versus Choice Groups at 12 Weeks		
Usual Care	0.80	0.007
Choice	0.29	0.30
Interaction Term‡	N/A	0.068

*The β -coefficient is measuring the magnitude of the association between general expectation and the outcome (Roland score).

†The p value is a measure of the significance of the association between general expectation and the outcome (Roland score).

‡The interaction term is the product of the usual care versus choice variable with the general expectation variable.

clinical outcomes. In the systematic review performed by Mondloch and colleagues, only 2 of the 16 studies reviewed shared a common question regarding patient expectations.⁹ To develop a more comprehensive understanding of the complex associations between patient expectations and recovery, we need to develop validated instruments for assessing expectations and take a more uniform approach in our study designs, asking study subjects about expectations before randomization.

Whereas the differences between studies on patient expectations are noteworthy, the similarities are even more striking. In the vast majority of studies, investigators have consistently shown strong, statistically and clinically significant associations between patients' expectations and clinical recovery.

The reason for this association remains unexplained. It could be that patients are good judges of their own illnesses and are able to accurately identify their likelihood of improving over several weeks. An alternative explanation is that there is a reporting bias such that patients who have predicted they will have significant improvement are more likely to report improvement several weeks later so as to be self-consistent. A third possibility is that higher expectations are associated with better compliance with a medical regimen that is responsible for greater improvement. It is also possible that there is something about the expectation itself that is therapeutic, akin to the placebo effect.

One of the more intriguing, albeit speculative, findings of our study is the possible differential effect of expectation on outcome in the choice versus the usual care groups (see Table 4). To our knowledge, no study has ever looked at this type of effect modification. Whereas it is possible that such a difference could result from patients having strong negative associations with CAM (and thereby having their expectations dampened after being randomized to choice), this does not appear to have been the case. On average, we found that patients rated CAM therapies similar to conventional physical therapy in terms of their likely helpfulness for their current episode of back pain.

The stratified analysis could shed light on the possible etiologic scenarios outlined above. It is unlikely that the first 3

explanations—patients' self-awareness, reporting bias, or compliance—would be dramatically different in the choice versus the usual care groups. However, it is certainly possible that the act of choosing one's own therapy might have an impact on the 4th scenario (i.e., that the expectation itself is therapeutic). A component of positive expectation may be confidence that a health care provider will choose the appropriate intervention to heal the patient. Perhaps placing that choice entirely in the hands of the patient reduces the overall effect of the expectation. (As discussed below, patients in our study were not provided with the information, support, and dialog critical to shared decision making). Whereas this line of argument can only be conjectural based on our own research, it is worth further study.

One limitation of our study is that it did not have adequate power to evaluate whether the association between expectation and outcome was different in the choice versus usual care groups. Because an interaction term is needed to evaluate this type of effect modification, and because the interaction term is the product of 2 variables, we would have required 4 times as many subjects to maintain the same power to evaluate this question. Despite dramatically different β -coefficients for choice versus usual care (0.27 vs 0.80) even the week 12 interaction term was just short of statistical significance.

A second limitation was that the general and specific expectation questions were formatted somewhat differently, which makes a direct comparison of the responses problematic.

IMPLICATIONS/CONCLUSIONS

Given the relatively strong association between expectation and outcome, one implication of this research is that clinicians who wish to estimate their patients' prognoses may wish to assess general expectations for improvement as part of their initial evaluation of ALBP. This study did not evaluate whether changing a patient's expectations leads to improved outcomes, but it does suggest that patients with higher expectations for speedy recovery are likely to show more improvement. For example, on average, a patient who rated his general expectation for recovery a 6 would have nearly a 3-point lower Roland score at 5 weeks than a patient with the same functional status who rated his expectation a 9 on the 0–10 scale. This large a difference in the Roland score is clinically significant. In fact, it represents a larger difference in outcome than the difference between patients with and without sciatica.

It has often been assumed that allowing patients to choose the therapy for which they have greater preference confers a therapeutic advantage.¹⁶ Whereas this has been studied to some extent, particularly in depression, no consistent therapeutic advantage has been shown in giving patients their choice of therapy.^{17,18} It may be that the type of choice offered to patients and the amount of support that patients receive in making informed decisions play important roles in determining the impact of the choice itself. It cannot be overemphasized that in our study we did not use a shared decision-making model within which patients are assisted in making choices that are optimized to their particular preferences and are informed by interaction with health care providers.^{19,20} Instead, patients were left on their own to make decisions about which they may, or may not, have been well-informed.

Our study raises several questions about the effect of patient expectations on clinical outcomes. Why is it that patients' expectations appear to be consistently associated with their clinical outcomes? Do changes in the therapeutic intervention, including giving patients unassisted choice, modify the effect of expectations? Does altering patients' expectations alter their outcomes? The answers to these questions are relevant to clinical practice and to the design of future trials. Priorities for increasing our understanding of these complex associations include designing validated and uniform instruments for assessing patient expectations and developing optimal study designs. Including questions about patient expectations in future trials would be an inexpensive but potentially valuable way to increase our understanding of these associations and may also prove important in preventing confounding by this poorly understood, but significant, correlate of clinical outcomes.

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Conflict of Interest: *None disclosed.*

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