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The Role of Gender in Moderating Treatment Outcome in Collaborative Care for Anxiety

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Objective: The aim of this study was to test whether gender moderates intervention effects in the Coordinated Anxiety Learning and Management (CALM) intervention, a 12-month, randomized controlled trial of a collaborative care intervention for anxiety disorders (panic disorder, generalized anxiety disorder, posttraumatic stress disorder, and social anxiety disorder) in 17 primary care clinics in California, Washington, and Arkansas.

Methods: Participants (N=1,004) completed measures of symptoms (Brief Symptom Inventory [BSI]) and functioning (mental and physical health components of the 12-Item Short Form [MCS and PCS] and Healthy Days, Restricted Activity Days Scale) at baseline, six, 12, and 18 months. Data on dose, engagement, and beliefs about psychotherapy were collected for patients in the collaborative care group.

Results: Gender moderated the relationship between treatment and its outcome on the BSI, MCS, and Healthy Days

measures but not on the PCS. Women who received collaborative care showed clinical improvements on the BSI, MHC, and Healthy Days that were significantly different from outcomes for women in usual care. There were no differences for men in collaborative care compared with usual care on any measures. In the intervention group, women compared with men attended more sessions of psychotherapy, completed more modules of therapy, expressed more commitment, and viewed psychotherapy as more helpful.

Conclusions: These findings contribute to the broader literature on treatment heterogeneity, in particular the influence of gender, and may inform personalized care for people seeking anxiety treatment in primary care settings.

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Collaborative care interventions involve care managers in proactive, time-limited, patient follow-up to track outcomes, identify intervention nonresponders, and facilitate engagement in evidence-based psychotherapy and pharmacotherapy. Collaborative care interventions improve clinical outcomes for anxiety and depression with minimal incremental cost (1–9). However, a substantial proportion of patients receiving collaborative care do not improve. Understanding which factors influence treatment heterogeneity is essential to continued quality improvement efforts.

Moderation analysis can highlight which patient characteristics influence intervention effects and can be used to personalize care and improve treatment effectiveness (10,11). For example, demographic characteristics, such as race-ethnicity, age, and socioeconomic status, have been identified as moderators of collaborative care interventions for anxiety and depression (12). In two studies, minority status predicted greater effects of collaborative care intervention with regard to access, treatment adherence, and symptoms (1,13) for depression but not for anxiety (14). In another study, older age

predicted longer engagement in collaborative care and higher rates of adequate pharmacotherapy (15). In a study of collaborative care for anxiety, lower socioeconomic status did not moderate the intervention effect (16).

The moderating effect of gender has received little attention in studies of collaborative care. Patients and care managers in collaborative care work together to determine the composition of care, including amount and type of psychotherapy, medication, or both. It is likely that patients' views on treatment could influence the decision-making process and subsequent intervention effect. Gender is well studied as a moderator of outcomes in efficacy trials of cognitive-behavioral therapy (CBT) (17,18) and pharmacotherapy (19). After receiving a comparable number of CBT sessions for anxiety and depression, men and women have shown similar clinical outcomes (17). However, prior research has indicated that there are gender differences in engagement in CBT (20), treatment preference (21), therapeutic alliance (22), self-efficacy (23), and outcome expectancy (24), which could all affect the effectiveness of CBT delivered within the context of

a collaborative care trial. The impact of gender on outcome of pharmacotherapy for anxiety and depression is inconsistent, with some studies suggesting that women respond more favorably and drop out less often during medication trials (19).

To date, evidence about the moderating effect of gender on collaborative care for depression has been mixed, and no evidence exists in regard to collaborative care for anxiety (4,12,25–27). Five large effectiveness trials of collaborative care evaluated whether gender is predictive of intervention effects. Two studies, each with increased resources for pharmacotherapy and psychotherapy, found that gender had no association with depression (12,25). A third study reported that collaborative care for depression (with increased resources for pharmacotherapy only) was more cost-effective for women than for men, resulting in a greater number of quality-adjusted life-years (4). A fourth reported that women undergoing collaborative care with increased resources for pharmacotherapy were more likely than men to achieve remission from depression (27). The Partners in Care Project found that the effect of gender on outcomes was mixed, varying by intervention arm (increased resources for pharmacotherapy and increased resources for psychotherapy) and outcome measure (26,28). In Partners in Care, pharmacotherapy-focused collaborative care reduced depression burden and improved the mental health quality of life among women but not among men. Psychotherapy-focused collaborative care reduced the depression burden for both men and women and improved the mental health–related quality of life for men but not women. Thus increased resources for pharmacotherapy seem to be more effective for women than men, whereas the effectiveness of psychotherapy-focused collaborative care appears to be mixed.

No previous studies have examined gender as a moderator of collaborative care for anxiety. We tested gender as a moderator of treatment outcome in the Coordinated Anxiety Learning and Management (CALM) intervention, a 12-month collaborative care intervention for anxiety (6). We hypothesized that gender would moderate the relationship between intervention and clinical outcomes over the course of treatment (measured at six months, 12 months, and 18 months) and that women would report more positive responses to collaborative care compared with men. We also explored whether there were gender differences in dose, engagement, and beliefs about the core elements of the intervention.

METHODS

Participants (N=1,004) ranged in age from 18 to 75 and had diagnoses of panic disorder, generalized anxiety disorder, posttraumatic stress disorder (PTSD), or social anxiety disorder and were referred by physicians from 17 clinics at four sites (Little Rock, Los Angeles, San Diego, and Seattle). All sites provided institutional review board approval, and all participants provided written informed consent. Details about the intervention and the evaluation methodology are described elsewhere (6,29).

Study Arms

Patients were referred to the study, and after initial screening between June 2006 and April 2008, they were randomly assigned to receive either usual care (N=501) or collaborative care (N=503).

Usual care. Usual care participants were treated by their primary care physician, who prescribed medications or referred patients to specialty mental health providers. At baseline, many usual care participants reported that they used psychotropic medication (62%, N= 311) or attended counseling (47%, N=234). There were low rates of adequate pharmacotherapy (31%, N=153) and CBT usage (5%, N=23).

Collaborative care. The collaborative care intervention tested in this study was based on the IMPACT (Improving Mood–Promoting Access to Collaborative Treatment) depression intervention (30). Participants worked with care managers to choose the best treatment approach. Patients could select medication, CBT, both, or neither. Care managers monitored the pharmacotherapy or delivered CBT face to face. Most of the care managers had master's degrees in social work or nursing. Those delivering CBT were supervised by licensed clinical psychologists, and those monitoring medication usage were supervised by study psychiatrists, who interacted with patients' primary care physicians either in writing or in person (29). The psychotherapy was computer-assisted, modularized CBT. The patient and the care manager worked together during the session using the computer-guided protocol. Modules included psychoeducation, breathing retraining, cognitive restructuring, and exposure. Completing eight sessions of CBT was considered a full course of psychotherapy. A few participants experienced interruptions in CBT because of life events or emerging substance dependence. Participants could also opt to receive monthly relapse prevention sessions by telephone after they completed the CBT course.

Measures

Using telephone surveys, the RAND Survey Research Group assessed outcomes of all participants at baseline, six, 12, and 18 months. Interviewers were blind to treatment condition.

The Brief Symptom Inventory (BSI [31]) is a shortened version of the Symptom Checklist–90 and is a 53-item measure of a range of symptoms in nine subscales and three global scales. Only the anxiety and somatization subscale outcomes are reported here. Items assessed degree of distress rated on a 5-point Likert scale, with responses ranging from 0, not at all, to 4, extremely (32). The BSI has good internal consistency ($\alpha=.71-.85$) and test-retest reliability ranging from .68 to .91 on all scales. Subscales demonstrate construct and criterion validity in a variety of settings (31,33–35).

Version 2 of the 12-Item Short Form (SF-12 [36]) is a brief version of the SF-36 Health Survey, which comprises the mental component summary (MCS) and physical component summary (PCS). Composite scores (range 0–100) are computed for all items

on the scale, with each item weighted such that the MCS and PCS are oblique (37), and higher scores represent better functioning.

The Healthy Days, Restricted Activity Days scale (38) is a one-item estimate of number of days in the previous 30 days in which activities were restricted by general medical or mental health problems. Higher scores represent more restricted activity.

For the subset of patients randomly assigned to collaborative care, beliefs about mental health and CBT were assessed in seven domains: intention to seek treatment, comfort talking to a mental health professional, stigma, helpfulness of treatment, potential for spontaneous recovery, outcome expectancy, and self-efficacy. For intention to seek treatment, participants were asked, "If you had a serious emotional problem, would you go for professional help?" For comfort talking to a mental health professional, participants were asked, "How comfortable would you feel talking about personal problems with a professional?" The stigma item asked participants "How embarrassed would you be if your friends knew you were getting professional help for an emotional problem?" These three items were rated on 4-point scales. Participants gauged helpfulness of treatment by responding to the following question: "Of the people who see a professional for serious emotional problems, what percentage do you think are helped?" Beliefs about spontaneous recovery were probed with the question "Of those who do not get professional help, what percentage do you think get better even without it?" Participants indicated expectations about outcomes by answering, using a 9-point scale, "How likely is it that your anxiety can be successfully treated?" Finally, participants were asked to rate, using a 9-point scale, "How likely is it that you will be able to do what is necessary to make your anxiety treatment successful?"

Data on amount of CBT and engagement in CBT were entered by the care manager after each clinical encounter for the subset of patients randomly assigned to collaborative care. Amount of CBT included number of sessions, participation in relapse prevention calls, interruption of treatment, number of CBT modules completed, and total number of exposure exercises completed. At the completion of each session, clinicians assessed engagement, which included homework adherence (4-point scale on proportion of total assignments completed) and commitment to CBT (a scale from 0 to 10).

Data Analysis

All analyses were conducted with SAS 9.3 (39). Chi square tests for categorical variables and nonparametric Wilcoxon's rank-sum tests for continuous variables were used to compare demographic and baseline clinical characteristics. Using the MacArthur Moderation model (11), we examined whether gender moderated the effect of collaborative care on clinical outcomes to test the main hypothesis. The dependent variables included scores on the BSI, PCS, MCS, and Healthy Days measure at six-, 12-, and 18-month follow-ups. Mixed models were used to account for the repeated measures. A generalized

linear model for repeated measures using a restricted maximum likelihood approach was used to fit the models that used PROC MIXED in SAS. A strength of this approach is that it can be used when data are missing at random (40,41).

Each regression model was specified to include group, gender, and the two-way interaction of group \times gender plus covariates. For each model, covariates included baseline score on the target measure, site and case-mix demographic variables (education, race, age, and income), and clinical variables (chronic conditions, generalized anxiety disorder, PTSD, and major depressive disorder) to adjust for baseline differences. We chose not to center for gender or intervention because we were interested in estimating the specific effect of the intervention for women rather than the average effects for both genders.

Predicted least-squares means (LSMEANS in SAS) were calculated for the intervention and control groups by gender, with continuous covariates set at their mean values and categorical covariates set at 1 divided by the number of categories. Type III tests of significance were used to determine the effect of a given variable after all other variables in the model were controlled for and are analogous to the F statistic in logistic regression.

For collaborative care participants only, CBT amount (number of CBT modules completed and total number of exposure exercises completed during the course of treatment), CBT engagement (homework adherence and commitment to CBT), and beliefs about CBT (outcome expectancy, self-efficacy, and five items on beliefs about treatment) were compared between men and women; statistical techniques appropriate for the distribution for each item were used. Three items had a normal distribution (outcome expectancy, self-efficacy, and commitment to CBT for treatment of anxiety), two had a binomial distribution (interrupted treatment and relapse prevention), three variables had a negative binomial distribution (total number of CBT sessions, number of CBT exposure sessions, and total number of CBT modules completed), one had a gamma distribution (CBT homework adherence), and five beliefs variables had a multinomial distribution (intention to seek treatment, comfort talking to a provider, stigma, helpfulness of treatment, and spontaneous recovery). For each analysis we also controlled for baseline differences in site; education; race-ethnicity; number of chronic conditions; presence of generalized anxiety disorder, PTSD, or major depressive disorder; age; and income.

RESULTS

Demographic and Baseline Data

As shown in Table 1, a majority of the sample (71%) was female. Demographic and baseline clinical characteristics indicated that a lower proportion of women were white and earned less than men, even though men and women were employed at similar rates. Compared with men, women were more frequently diagnosed as having generalized anxiety disorder, and they had poorer health status on the SF-12 PCS.

TABLE 1. Baseline characteristics of participants assigned to collaborative or usual care across 17 clinics, by gender

Variable	Women (N=714; 71%)				Men (N=290; 29%)				Total (N=1,004; 100%)		p
	Control (N=355)		Intervention (N=359)		Control (N=146)		Intervention (N=144)		N	%	
	N	%	N	%	N	%	N	%			
Race-ethnicity											<.001
Hispanic	71	20	85	24	21	14	19	13	196	20	
African American	58	16	46	13	7	5	5	4	116	12	
Other	37	10	47	13	18	12	22	15	124	12	
White	189	53	181	50	100	68	98	68	568	57	
Education (years)											.15
<12	21	6	23	6	5	3	6	4	55	5	
12	65	18	64	18	22	15	14	10	165	17	
>12	269	76	272	76	119	82	124	86	784	78	
Currently working	244	69	253	71	106	73	105	73	708	71	.74
Insurance	309	87	308	86	128	88	116	81	861	86	.32
N medical conditions											.11
0	59	17	69	19	34	23	41	28	203	20	
1	82	23	82	23	29	20	26	18	219	22	
≥2	214	60	208	58	83	57	77	53	582	58	
Panic disorder	166	47	167	47	74	51	68	47	475	47	.85
Generalized anxiety disorder	268	75	284	79	98	67	106	74	756	75	.04
Social anxiety disorder	137	39	151	42	58	40	59	41	405	40	.82
Posttraumatic stress disorder	70	20	69	19	19	13	23	16	181	18	.27
Major depression	232	65	243	68	86	59	87	60	648	65	.19
N anxiety disorders											
1	151	43	139	39	69	47	62	43	421	42	.61
2	135	38	142	40	55	38	55	38	387	39	
3 or 4	69	19	78	22	22	15	27	19	196	20	
Any substance use disorder	3	1	3	1	3	2	1	1	10	1	.58
Age (mean±SD)	43.30±13.83		42.86±13.52		44.53±13.44		44.34±12.29		43.47±13.44		.43
Income (mean±SD) ^a	3.94±7.66		4.06±3.82		5.46±5.37		5.67±13.51		4.45±7.53		<.001
Sheehan Disability Scale (mean±SD) ^b	17.3±7.18		16.88±7.62		16.69±6.90		16.52±6.96		16.96±7.27		.57
PCS (mean±SD) ^c	48.88±11.68		48.00±11.36		50.43±11.23		51.64±11.10		49.19±11.47		<.001
MCS (mean±SD) ^d	31.88±9.83		31.51±9.83		32.47±10.80		32.00±10.36		31.85±10.04		.80
BSI (mean±SD) ^e	16.17±8.81		16.90±9.13		16.42±9.28		15.11±8.48		16.32±8.96		.25
Healthy Days (mean±SD) ^f	11.06±9.81		11.58±9.51		11.40±10.18		11.10±10.54		11.30±9.85		.65

^a The income variable is the adjusted income by age, family size and number of children.
^b Possible scores range from 0 to 30, with higher scores indicating greater functional impairment from symptoms.
^c Physical component summary score of 12-Item Short Form. Possible scores range from 0 to 100, with higher scores indicating better functioning.
^d Mental component summary score of 12-Item Short Form. Possible scores range from 0 to 100, with higher scores indicating better functioning.
^e Brief Symptom Inventory. Possible scores range from 0 to 48, with higher scores indicating more symptoms.
^f Healthy Days, Restricted Activity Days Scale, measuring number of days in past 30 in which activities were restricted by general medical or psychiatric problems

Clinical Outcomes

The results for BSI showed a two-way interaction effect of intervention and gender (F=8.24, df=1 and 890, p=.004). Women’s case-mix-adjusted predicted means were significantly lower (meaning better) for collaborative care than for usual care, whereas for men, there were no significant differences between collaborative care and usual care (Table 2).

For the MCS, there was also a significant two-way interaction between intervention and gender (F=8.13, df=1 and 889, p=.005). As shown in Table 2, women’s case-mix-adjusted predicted means were higher than for those in usual care (indicating better mental health functioning). For men, there were no significant differences between collaborative care

and usual care. For the PCS, no significant main effect or interaction effects were found for men or women.

On the Healthy Days scale, the two-way interaction between intervention and gender was significant (F=5.03, df=1 and 884, p=.03). Women in collaborative care had significantly lower case-mix-adjusted predicted means (restricted activity days) than those in usual care. For men there were no significant differences at any time point between collaborative care and usual care.

Amount of CBT, Engagement in CBT, and Beliefs About CBT

A majority (87%) of the intervention group received CBT. A third (33%) received CBT alone, 54% received CBT and

TABLE 2. Adjusted mean outcome scores on three measures, by gender^a

Measure	Men					Women				
	Intervention	Control	df	F	p	Intervention	Control	df	F	p
Brief Symptom Inventory ^b	9.78	10.32	1, 890	.49	.48	8.45	11.57	1, 890	42.40	<.001
MCS score ^c	43.62	41.75	1, 889	2.80	.09	45.54	39.90	1, 889	64.27	<.001
Healthy Days ^d	5.60	6.16	1, 884	.53	.46	4.63	7.23	1, 884	28.63	<.001

^a Mean outcomes refer to mean outcomes across time points (6, 12, and 18 months).

^b Possible scores range from 0 to 30, with higher scores indicating more symptoms.

^c Mental component summary score of 12-Item Short Form. Possible scores range from 0 to 100, with higher scores indicating better functioning.

^d Healthy Days, Restricted Activity Days Scale, measuring number of days in past 30 in which activities were restricted by general medical or psychiatric problems

pharmacotherapy, 9% received pharmacotherapy only, and 4% received no services. Parameter estimates for CBT dose, engagement, and belief scores for the subset of patients randomly assigned to collaborative care for women, with men as the reference group, are reported in Table 3. On average, women attended a greater number of CBT psychotherapy sessions than men (7.3 versus 6.5; odds ratio [OR]=1.18, $p=.01$), although the mean number of sessions for each group was within the recommended range (six to eight sessions). There were no differences in frequency of interrupted treatment or participation in relapse prevention; however, the total number of CALM CBT exposure modules completed was greater for women (OR=2.44, $p=.02$). The clinician-rated measure of commitment was significantly higher for women (OR=1.26, $p=.04$), and women estimated that a larger proportion of people who seek professional help for a serious emotional problem would benefit (63% versus 59%; OR=.64, $p=.02$).

DISCUSSION

This is the first study to evaluate gender as a moderator in collaborative care for anxiety and contributes to the growing literature on treatment heterogeneity and personalized medicine. Women had less access to economic and social resources (with lower income) and a poorer health-related quality of life than men had but benefited more from the intervention. These findings support our hypotheses that women would respond more favorably to the collaborative care intervention. Women who received collaborative care showed larger reductions in anxiety than women who received usual care. Likewise, women who received collaborative care showed greater improvements in mental health functioning and larger reductions in days of restricted activity than women who received usual care, whereas men who received collaborative care did not show any differences compared with collaborative care.

In order to understand the relative differences in response between men and women receiving collaborative care, while controlling for gender differences in baseline characteristics, we focused on gender differences in attitudes about mental health among patients who received collaborative care. Compared with men, women reported a higher commitment to therapy and a stronger belief in the helpfulness of psychotherapy. These dimensions are thought

to partially predict motivation and effort in treatment and have been found to be predictive of more positive clinical outcomes in CBT (42). With regard to dose of psychotherapy, women attended approximately one more session of CBT than men and completed more exposure activities. Exposure activities are highly predictive of treatment outcome across studies of CBT for anxiety (20). Women were also judged by their providers to have a greater commitment to CBT, which is also associated with better responses (20). It is possible that any one of these dose, engagement, or belief factors could have contributed to the overall positive effect of collaborative care for women or that the cumulative effect of several factors influenced the observed positive clinical outcomes.

There may also be unmeasured factors that contribute to the positive response among women. Prior work has found

TABLE 3. Parameter estimates for amount of cognitive-behavioral therapy (CBT), engagement, and beliefs among participants receiving collaborative care

Variable ^a	OR ^b	F	df	p
Amount of CBT				
Number of CBT sessions attended	1.18	6.31	1, 481	.01
Interrupted treatment ^c	1.04	.01	1, 481	.92
Relapse prevention ^d	1.38	1.82	1, 481	.18
Completed CALM CBT modules ^e	1.17	3.24	1, 481	.07
CALM CBT exposures ^f	2.44	5.96	1, 481	.02
Engagement				
CBT homework adherence	.93	3.34	1, 387	.07
CBT anxiety commitment	1.26	4.36	1, 481	.04
Beliefs				
Outcome expectancy	1.20	2.51	1, 479	.11
Self-efficacy	1.20	3.13	1, 479	.08
Intention to seek treatment	1.42	2.94	1, 480	.09
Comfort talking to provider	1.15	.49	1, 480	.48
Stigma	.78	1.59	1, 480	.21
Helpfulness of treatment	.64	5.37	1, 480	.02
Spontaneous recovery	1.04	.03	1, 480	.85

^a The reference group was men for all comparisons.

^b Odds ratios were adjusted for significant case-mix variables.

^c Number of participants with interruptions in CBT treatment because of life events or substance use

^d Number of participants who received relapse prevention phone calls after completion of CBT

^e Mean number of Coordinated Anxiety Learning and Management (CALM) modules completed during the course of treatment with the care manager

^f Mean of the total number of exposure modules in the CALM intervention completed during the course of treatment

that women are responsive to social relationships and respond positively to therapy environments that foster empowerment and collaboration (43). In collaborative care, the relationship with care managers is collaborative, with sessions focused on treatment decision making. This may have reduced the complexity of the treatment environment, which has been shown to create barriers for women in treatment (44), and may have increased the patient's commitment to CBT (20). Women have reported that empowerment and assistance navigating the health care system are instrumental in achieving a positive treatment response, whereas men have not found these features to be salient (43,45).

A major implication for continued improvement of collaborative care interventions is to more effectively engage men in treatment beyond simply increasing attendance. One example of this is the Real Men, Real Depression campaign of the National Institute of Mental Health; this public media campaign is designed to communicate directly with men about their experiences of depression. The approach acknowledges that men in Western culture are more likely to value their own self-reliance and are less likely to ask for help when they experience problems (46). The goal of Real Men, Real Depression is to decrease stigma and to increase mental health treatment utilization by directly addressing the cultural barriers males face in choosing whether to get help (47). Relatively little attention, however, has focused on adapting psychotherapy protocols to incorporate strategies to address cultural barriers that interfere with dose, engagement, and beliefs about mental health treatment. On the basis of focus group data on male attitudes about mental health treatment, some potential adaptations could include discussion of typical male symptom profiles (such as fatigue, irritability, and anger), strategies to reduce apprehension about help seeking and to combat mental health stigma, and efforts to reduce apprehension about disclosure of distress during psychotherapy (46).

The following limitations should also be considered. This study was a secondary analysis and was not originally designed to test our specified hypotheses; therefore, the risk of a type I error was somewhat elevated as a result of multiple comparisons. Randomization was not stratified by gender. Many of the questions assessing attitudes and behavior were limited to a single, face-valid item. Furthermore, gender was constrained to male and female and did not account for the fluidity of gender and other dimensions of gender and sexual identity (including transgender, bisexual, lesbian, or gay). Although we controlled for income, education, race-ethnicity, and diagnostic variables, we likely did not capture all of the gender-based inequities (48). Last, belief, dose, and engagement data were limited to the treatment group and therefore unavailable for moderation analysis.

CONCLUSIONS

Our findings contribute to the field of personalized medicine for both women and men. Future research will need to investigate which features of collaborative care facilitate

improvement among women. More important, future work is needed to identify ways to tailor collaborative care to meet the needs of men. For example, it would be beneficial to identify ways to increase men's confidence in the efficacy of psychotherapy and to develop strategies that increase engagement in therapy. Mixed-methods studies involving quantitative and qualitative research could explore in greater detail the determinants that influence response to collaborative care among genders.

AUTHOR AND ARTICLE INFORMATION

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Dr. Stein reports that he has consulted for Janssen Pharmaceuticals. Dr. Roy-Byrne reports having stock options with Valant Medical Solutions. The other authors report no financial relationships with commercial interests.

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