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Patient-Reported Outcomes for Low-Risk Ductal Carcinoma In Situ
A Secondary Analysis of the COMET Randomized Clinical Trial

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IMPORTANCE Active monitoring (AM) for low-risk ductal carcinoma in situ (DCIS) has been considered as a potential alternative to guideline-concordant care (GCC; inclusive of surgery with or without radiation). Reported data comparing patient-reported outcomes (PROs) between GCC and AM for DCIS are lacking.

OBJECTIVE To compare PROs at baseline and over time in patients with low-risk DCIS randomized to receive either AM or GCC.

DESIGN, SETTING, AND PARTICIPANTS This prespecified secondary outcome analysis used prospectively collected validated questionnaires at baseline, 6 months, 1 year, and 2 years from participants enrolled from June 2017 to January 2023 in the Comparing an Operation to Monitoring, With or Without Endocrine Therapy (COMET) study for low-risk DCIS, which randomized participants to receive GCC or AM.

INTERVENTION Randomization to GCC or AM.

MAIN OUTCOMES AND MEASURES Context-relevant PROs, including health-related quality of life, anxiety, depression, and symptoms measured by validated survey instruments. Mixed models, including sensitivity analyses, with group, point, and group-by-point effects were used to compare PROs between groups.

RESULTS Of the 957 participants in COMET, 225 (24%) were younger than 55 years at enrollment, 325 (34%) were aged 55 to 65 years, and 403 (42%) were older than 65 years, and 953 (99.5%) completed questionnaires at some point within the first 2 years, with a completion rate of more than 83% at all points. Quality of life, anxiety, depression, worries about DCIS, and symptom trajectories were comparable between groups, with modest fluctuations over time of limited clinical significance. Physical functioning was the only specific Medical Outcomes Study 36-item short-form health survey (SF-36) domain for which changes in the score trajectory differed by group over time, with mean scores ranging from 50 (baseline) to 48 (6, 12, and 24 months) in the GCC group and 50 (baseline) to 47 (12 months) and 48 (6 and 24 months) in the AM group (pooled SD, 9.9; $P = .01$), although these were also of limited clinical significance.

CONCLUSIONS AND RELEVANCE In this prespecified secondary analysis of the COMET prospective randomized trial, the overall lived experience of women randomized to undergo AM for low-risk DCIS was similar to that of women randomized to GCC during the 2 years following diagnosis.

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Supplemental content

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For the more than 50 000 women with a diagnosis of ductal carcinoma in situ (DCIS) annually in the US alone, controversy exists regarding optimal management for this precursor condition, which exhibits variable potential progression to invasive cancer.[1-3] The Comparing an Operation to Monitoring, With or Without Endocrine Therapy (COMET) study for low-risk DCIS randomized women with low-risk DCIS to either guideline-concordant care (GCC; surgery on diagnosis, with or without radiotherapy) or active monitoring (AM; surgery only if progression to invasive cancer).[4] The primary outcome demonstrated that AM was noninferior to GCC at a median follow-up of 2 years, with the 2-year cumulative rate of ipsilateral invasive cancer of 5.9% in the GCC group vs 4.2% in the AM group.[5] This article focuses on the prespecified secondary end point to compare participants' general health-related quality of life (QOL), anxiety, depression, and specific symptoms associated with treatment of DCIS by group using prospectively collected validated questionnaires at baseline, 6 months, 1 year, and 2 years.

Prior research had demonstrated relatively favorable QOL overall for women treated for DCIS, although some studies have found declines in vitality and mental health, and demonstrated heightened anxiety and fear of recurrence among women with DCIS similar to the levels for women with invasive breast cancer history.[6,7] Women treated for DCIS are also at risk of developing persistent pain after breast surgery, with estimates ranging from 25% to 68%, which may lead to disability and psychological distress for patients with breast cancer in general.[8-13] Fearing these potential long-term, late effects of treatment, and recognizing that not all DCIS will progress to invasive breast cancer with potential for metastasis, women with DCIS and their health care clinicians have been interested in AM as an alternative management strategy.[14] However, to our knowledge, no prior published prospective randomized studies have compared AM with conventional management with surgery (± radiation therapy) (GCC) regarding QOL and symptoms at baseline and longitudinally. Thus, women face a substantial burden of uncertainty when considering the trade-offs of surgery (± radiotherapy) or AM for low-risk DCIS.[6,15] In this article, we present the prespecified analysis of patient-reported outcomes (PROs) from the COMET study comparing GCC with AM over 2 years of follow-up.

Key Points

Question Are there differences in health-related quality of life, anxiety, depression and worries, and symptoms associated with the treatment of ductal carcinoma in situ (DCIS) between individuals who undergo surgery vs active monitoring for low-risk DCIS?

Findings In this prespecified secondary analysis of 957 participants in the COMET randomized clinical trial, overall health-related quality of life, anxiety, depression, worries, and symptom trajectories were comparable between groups during 2 years of follow-up.

Meaning The results of this secondary analysis suggest that the lived experiences of individuals with low-risk DCIS are similar during early follow-up regardless of treatment allocation in a study comparing surgical management with active monitoring.

Methods

Study Oversight

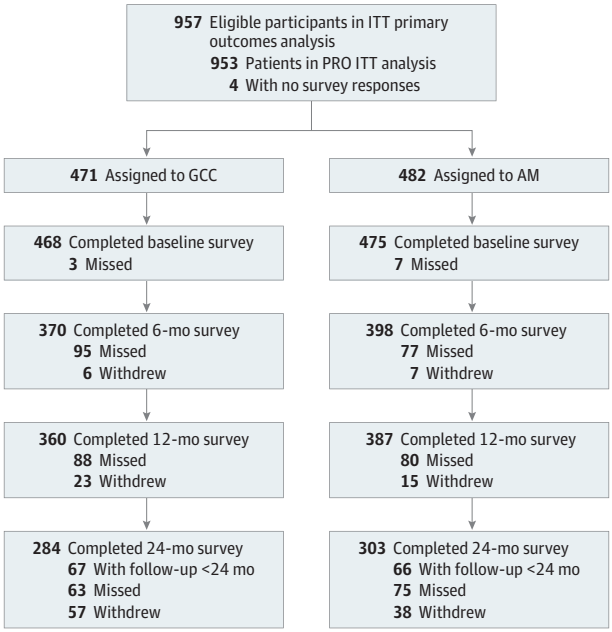
COMET was a large, pragmatic randomized noninferiority trial that compared oncologic and PROs between participants randomized to receive GCC or AM. The study has been described previously,[4] and the full protocol, including the statistical analysis plan, have been provided (eAppendix in Supplement 1). The trial was coordinated across 100 Alliance for Clinical Trials in Oncology Foundation Trials member sites between June 2017 and January 2023; 83 sites accrued at least 1 patient to the study. Institutional review board approval of the study protocol was obtained at each site, and all participants provided written informed consent to participate in the study. The Alliance for Clinical Trials in Oncology Foundation Trials data and safety monitoring board provided ongoing oversight for conduct of the study and allowed release of the data for this first planned analysis on March 31, 2024. The dataset was locked for the first planned analysis on June 30, 2024. This report follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines for reporting PROs in randomized clinical trials.[16]

Study Design, Setting, and Participants

Details of the recruitment methods of COMET have been published previously (eAppendix in Supplement 1).[4] Between June 2017 and January 2023, 997 eligible women 40 years or older with a diagnosis of low-risk DCIS (nuclear grade 1 or 2, hormone recepter–positive disease) enrolled to the study, 957 of whom were randomized 1:1 to 1 of 2 groups: GCC or AM. Randomization was stratified by age at diagnosis (<55, 55-65, or >65 years) maximum diameter of microcalcifications (<2 cm, 2-5 cm, or >5 cm), and DCIS nuclear grade (1 or 2).

Participants randomized to GCC had standard-of-care treatment for their diagnosis, including surgery consisting of either mastectomy or breast-conserving surgery. Participants choosing breast-conserving surgery were offered adjuvant radiotherapy treatment according to standard practice. Diagnostic mammograms were required every 12 months for the affected breast (if not treated with mastectomy) and unaffected breast. Participants in the AM group did not undergo surgery at the time of diagnosis and were scheduled for diagnostic mammograms every 6 months for the affected breast and every 12 months for the unaffected breast. Further evaluation, including biopsy, was recommended if participants developed physical examination or had imaging findings concerning for disease progression. Surgical intervention was recommended if the biopsy demonstrated invasive cancer. For participants whose biopsy results showed benign breast changes, atypia, or DCIS, continued AM was recommended. Participants who preferred to undergo surgery at any time, for any reason, proceeded to surgery. Participants in both arms were offered the choice for endocrine therapy in consultation with their treating physician, although this was not a protocol requirement. All participants were asked to complete PRO

Figure 1. CONSORT Diagram of COMET Study Accrual, Randomization, and Patient-Reported Outcome (PRO) Follow-Up



AM indicates active monitoring; GCC, guideline-concordant care; ITT, intention-to-treat.

questionnaires as part of study participation. To be eligible for this analysis, participants had to have responded to at least 1 PRO questionnaire. PRO surveys were administered at prespecified points during the study, including baseline before randomization, 6 months, 1 year, and annually thereafter. They were administered in print or electronic form, either in clinic or remotely, and were available in English and Spanish versions based on participant preference. Race and ethnicity classifications were investigator observed for this analysis.

PRO Measures

The PRO instruments used in this study were selected and piloted in collaboration with the COMET Study patient leadership team to optimize elucidation of potential differences between management strategies and minimize participant burden.[4] PROs were prespecified secondary outcomes assessed using validated measures germane to the potential effect of diagnosis and treatment of DCIS based on previous literature on 3 domains (see eAppendix in Supplement 1 for instruments).

The first domain was health-related QOL. The Medical Outcomes Study 36-item short-form health survey (SF-36)[17] was used to measure health-related QOL, which was separated into 8 domains (general health, physical functioning, role physical, role emotional, social functioning, bodily pain, vitality, and mental health) that comprise physical component scores (PCS) and mental component scores as well as EuroQol 5-Dimensions 5-Levels (EQ-5D-5L)[18,19] to evaluate health status for use in evaluating health and health care that includes 5 functional dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) plus a visual analog scale (EQ-VAS) that asks participants to assess how good or bad their health is today. For the SF-36, changes as few as 2 points were considered clinically significant, whereas the minimally important differences for the EQ-5D-5L index scores ranged between 0.037 and 0.069.[20,21]

The second domain was emotional/psychological (anxiety, depression, worries about breast cancer). The State Trait Anxiety Inventory scale[22] was used to measure general anxiety, for which a cut point of 39 to 40 can detect clinically significant symptoms. The Center for Epidemiologic Studies Depression scale (CES-D-10)[23-25] was used to measure depressive symptoms, for which a score of 10 or greater demonstrates good predictive accuracy, and 4 items were adapted from the Quality of Life in Adult Cancer Survivors (QLACS)[26] scale to evaluate frequency (1 = never; 7 = always) of worries about DCIS, including concerns about future breast events and death of DCIS.

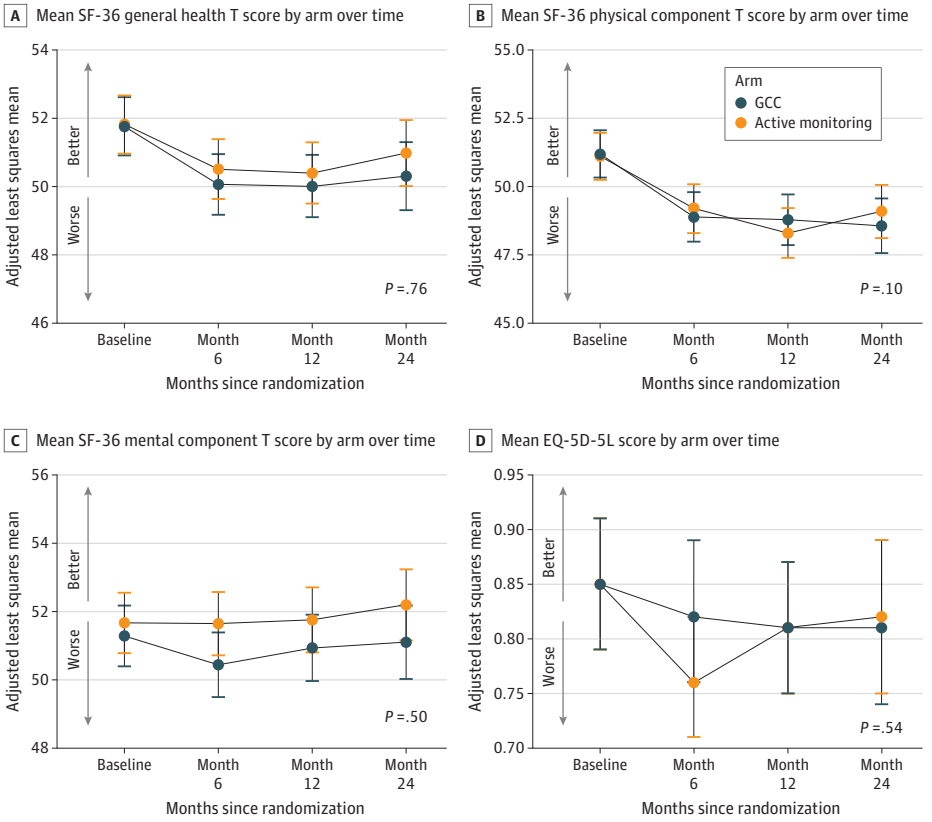
The third domain was breast cancer treatment-related symptoms, including breast pain. A modified 19-item version of the Breast Cancer Prevention Trial symptom checklist[27] was used to evaluate commonly reported symptoms (0 = not at all, 4 = extremely). There are 8 symptom clusters, including hot flashes, nausea, bladder control, vaginal problems, musculoskeletal pain, cognitive problems, weight problems, and arm problems. The Breast Cancer Pain Questionnaire (BCPQ)[9,28,29] was used to assess neurosensory effects, and the Brief Pain Inventory[29] was used to measure general pain, disability and interference, for which a score of 3 or greater is considered clinically significant.[9]

Statistical Analysis

All outcomes were analyzed as continuous scores; we also analyzed the CES-D-10 by its clinical threshold of 10 for depression screening. Distributions of scores were assessed for symmetry, and we used a square root transformation before analysis as needed. Several scores had negative values that precluded transformation, and robust mixed models were fit as part of a planned sensitivity analyses. We fit linear mixed-effects models to assess change in score domains over time. Models included fixed effects for time and study arm, as well as the interaction of time and study arm, with random effects for individuals, controlling for participant age, with a first-order autoregressive variance structure. The primary intent-to-treat analysis was performed using all participants as randomized. We also performed a per-protocol sensitivity analysis that included only participants who adhered to their protocol assignment. The primary comparison of interest reported was based on the type 3 effect of GCC vs AM over time, which was based on the interaction term of the mixed models.

This analysis compared PROs among COMET participants at baseline, 6 months, 1 year, and 2 years after randomization. We used marginal 2-part models to accommodate the overabundance of 0s and the highly skewed distribution of non-0 values in pain scores (BCPQ), which allows inferences to be made about the combined population of participants.[30-33] The marginal 2-part 0-inflation portion of the model for sensory disturbances was adjusted for age and study arm, while the fixed effects portion included age, study arm, time, and the interaction of time and study arm. The 0-inflation model

Figure 2. Quality of Life (QOL) Outcomes for the Medical Outcomes Study Short-Form (SF)–36 General Health, Physical Component, and Mental Component Scores as well as EuroQol 5-Dimensions 5-Levels (EQ-5D-5L)



Higher scores indicate better QOL. GCC indicates guideline-concordant care.

was completed using PRO GENMOD, while the remaining models were completed using PROC MIXED, both in SAS, version 9.4 (SAS Institute). R, version 4.1.2 (R Foundation) was used to create plots. Statistical significance was presumed as $P < .05$.

Results

Response Rates and Patient Characteristics

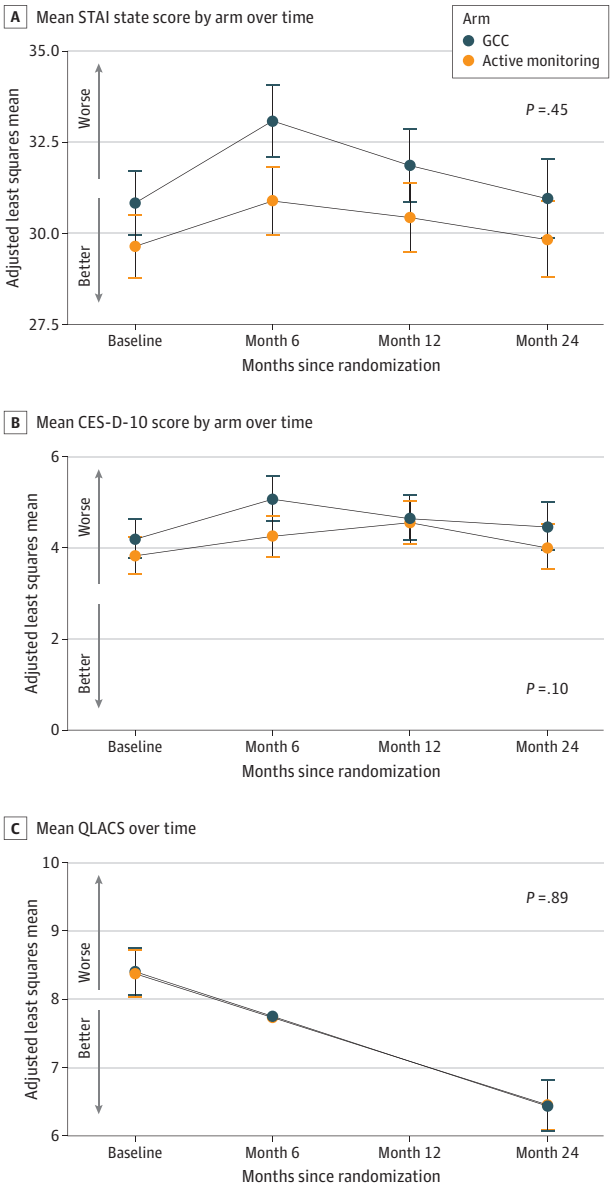
Of the 957 participants enrolled and included in the intention-to-treat analysis in COMET, 953 of 957 (99.5%) completed any questionnaire, and the response rates during follow-up were higher than 83% for most points (**Figure 1**). A total of 70 women (7%) only completed the baseline questionnaire; some did not complete all questionnaires at every point. Overall, response to the 2-year survey did not vary by study group (284 [87%] in the GCC group vs 303 [84%] in AM; $P = .43$); however, older participants (age >65 years), Black participants, and those with a higher tumor grade were less likely to complete the baseline and 2-year surveys. Specific outcomes are presented with scores and items demonstrated in **Figure 2**, **Figure 3**, and **Figure 4** (details of all PROs are provided in the eAppendix in Supplement 1).

Sociodemographic characteristics of participants who responded to the baseline survey were well balanced between the groups. Of the 953 participants, 225 (24%) were younger than 55 years at enrollment, 325 (34%) were aged 55 to 65 years, and 403 (42%) were older than 65 years; 46 participants (5%) were Asian, 149 (16%) Black, 51 (5%) Hispanic, 716 (75%) White, and 42 (4%) with unknown/other race (**Table**). A total of 251 participants (26%) had nuclear grade 1 DCIS, 702 (74%) had grade 2, and 771 (81%) were postmenopausal at diagnosis, with the remaining being premenopausal/perimenopausal. Among the 953 participants in the PRO intention-to-treat population, 292 (32%) underwent lumpectomy (including reexcision) and 43 (5%) mastectomy overall. This included 253 (56%) in the GCC group who underwent lumpectomy or mastectomy and 82 (17%) in the AM group who underwent lumpectomy or mastectomy. Overall, 162 (17%) underwent radiotherapy, including 126 (27%) in the GCC group and 36 (7%) in the AM group. A total of 20 participants (69%) received any endocrine therapy, including 310 (66%) in the GCC group and 343 (71%) in the AM group (eTable E1 in Supplement 1).

Health-Related QOL

Comparison of overall QOL as measured by the SF-36 and EQ-5D-5L revealed no substantial differences between the groups over time (Figure 2). Mean SF-36 scores were stable from baseline to 24 months in both groups and similar to population norms, with a nonclinically significant decrease in mean SF-36 general health scores during the 24-month follow-up period, ranging from 52 to 50 in the GCC group and 52 to 51 in the AM

Figure 3. Emotional/Psychological Outcomes for Anxiety, Depression, and Quality of Life in Adult Cancer Survivors (QLACS)



Higher scores indicate greater symptom burden or worry. CES-D-10 indicates Center for Epidemiologic Studies Depression scale; GCC, guideline-concordant care; STAI, State Trait Anxiety Inventory.

group (pooled SD, 9.2; Figure 2A).[34] There were modest changes in physical functioning over time, as demonstrated by PCS mean scores decreasing from 51 to 49 in both groups (pooled SD, 9.4; Figure 2B). Physical functioning was the only specific SF-36 domain (contributing to the PCS overall) for which fluctuations differed significantly by group over time, with mean scores ranging from 50 (baseline) to 48 (6, 12, and 24 months) in the GCC group and 50 (baseline) to 47 (12 months) and 48 (6 and 24 months) in the AM group (pooled SD, 9.9; $P = .01$) (eFigure E1F in Supplement 1). Mental component summary mean scores were stable during the same period, ranging from 51 to 50 to 51 in the GCC group and stable at 52 over time in the AM group, with no differences between groups over time (pooled SD, 9.6; Figure 2C). Mean EQ-5D-5L scores ranged from 0.89 (baseline) to 0.87 (12 and 24 months) in the GCC group and 0.90 (baseline) to 0.87 (12 months) in the AM group (pooled SD, 0.06; Figure 2D) (see eFigure E1 in Supplement 1 for all SF-36 domains).

Emotional and Psychological Outcomes

Mean scores on the State Trait Anxiety Inventory ranged from 31 to 33 in the GCC group and 30 to 31 in the AM group, indicating low levels of anxiety on average, with no significant differences in scores by group over time (Figure 3A). Mean anxiety was highest in the GCC group at 6 months and returned to baseline levels at 24 months. Depressive symptoms as measured by the CES-D-10 revealed borderline significant mean depression score changes by group over time, with the GCC group reporting the highest average depression scores at 6 months (Figure 3B). When categorized at a clinically significant threshold of 10, the probability of depression over time was greater numerically in GCC participants at each point and over time (GCC probability was 0.18, 0.23, 0.22, and 0.25 at baseline, 6 months, 12 months, 24 months, respectively, vs an AM probability of 0.15, 0.18, 0.21, and 0.16, respectively; $P = .08$). Frequency (1 = never; 7 = always) of worries about DCIS, as measured by the adapted QLACS items to evaluate concerns about future breast events and death of DCIS, were higher at baseline than 24 months in the overall cohort and did not differ by group at baseline or over 2-year follow-up (Figure 3C).

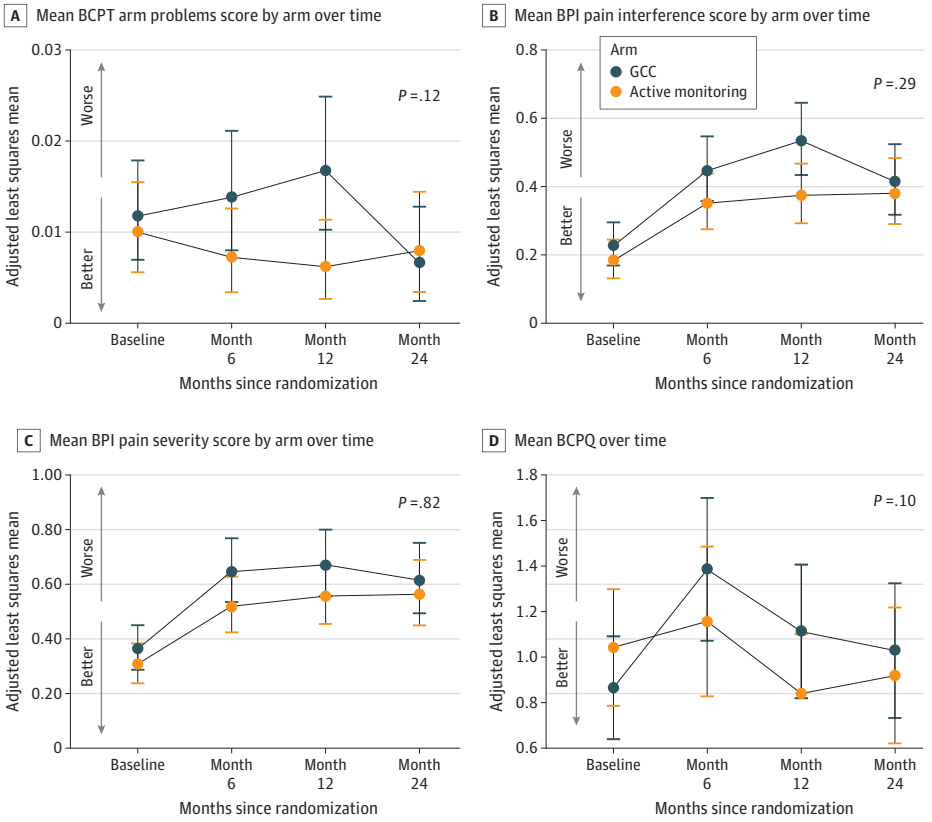
Physical Symptoms, Including Pain

Changes in specific symptoms as assessed by the Breast Cancer Prevention Trial, as well as measures of overall pain (Brief Pain Inventory) and breast pain (BCPQ), did not differ between groups over time (eFigures E3A-K in Supplement 1). Overall, participants reported relatively low mean levels of menopausal and body image symptoms, including arm problems, as well as pain (Figure 4). Mean BCPQ sensory disturbance scores were higher at baseline in the AM group (1.04) compared with GCC (0.86), while at 24 months, scores were higher in the GCC group (1.03) compared with AM (0.92). However, group differences over time were not statistically significant (Figure 4C).

Sensitivity Analyses

In a sensitivity analysis that included only those participants who adhered to their assigned protocol schedule, changes in the trajectory of overall mean physical health (PCS scores) as well as physical functioning and role physical domains differed by group over time. Mean arm problems were transiently worse at 6 and 12 months in the GCC group compared with the AM group with subsequent resolution. Breast pain differed by group over time, with mean BCPQ sensory disturbance scores lower at baseline and then worsening over time in the GCC group compared with the AM group, for whom scores were higher at baseline and improved over time (eTables E1 and E2 in Supplement 1). Additional analysis comparing PROs controlling for race, age, and grade, as well as use of en-

Figure 4. Breast Cancer–Related Symptoms, Including Pain Outcomes for Breast Cancer Prevention Trial (BCPT) Arm Symptoms, Brief Pain Inventory (BPI), and Breast Cancer Pain Questionnaire (BCPQ)



Higher scores indicate greater symptom burden. GCC indicates guideline-concordant care.

docrine therapy given that 2-year survey response rates varied by these factors (eTables E3 and E4 in Supplement 1), did not reveal GCC vs AM group differences over time.

Discussion

The COMET study demonstrated that AM was noninferior to GCC for managing low-risk DCIS during the first 2 years after diagnosis based on the clinical end point of invasive breast cancer.[5] In the present analysis comparing PROs among participants in COMET, overall QOL, anxiety, depression and symptom trajectories were comparable between groups without clear evidence of substantial negative effect of 1 approach vs the other during 2 years of follow-up.

This analysis potentially advances our understanding of the effect of AM and GCC on the management of DCIS by showing that neither approach results in a demonstrably different effect on PROs. Despite concerns that monitoring DCIS might be associated with heightened anxiety compared with surgical management, this was not the case for women who enrolled in COMET. Levels of anxiety measured in both groups over time were on average not clinically significant, with scores falling within a low to normal range. Findings from prior research examining the psychosocial health of women with a history of DCIS have been more mixed, with some studies reporting high levels of anxiety among women with DCIS.[6,7,35,36] Depression and worries about DCIS in particular were also fairly modest in the study population, which may reflect better physician-patient communication and patient education in this trial population.[37] The low levels of depression were consistent with prior studies of women with DCIS, most of which were conducted among women who underwent GCC.[6,38,39] Concerns about DCIS in particular among COMET participants as measured by the distress about recurrence domain on the QLACS were lower on average than previously reported among women with invasive cancer. Prior evidence showed that such concerns may be similar among women with either invasive breast cancer or DCIS, although these prior studies included women with DCIS of any risk level.[26,35] While we were unable to collect PROs on women with low-risk DCIS who were eligible for but did not participate in COMET, it is possible that they would report different levels of psychosocial distress and symptoms related to breast cancer treatment. The findings support previous studies that suggested that women with a diagnosis of DCIS face uncertainties about treatments and outcomes and that most women include QOL considerations when prioritizing treatment choices.[40-43]

The spectrum of symptoms reported among COMET study participants was typical of women who are receiving endocrine therapy and at risk for or with a history of DCIS, which is not surprising given that most participants in both groups elected to receive endocrine therapy.[44,45] However, the overall symp-

Table. Baseline Characteristics of COMET Patient-Reported Outcome Participants by Intention-to-Treat Group

Characteristic	No. (%)		
	Total (N = 953)	GCC (n = 471)	Active monitoring (n = 482)
Age, y			
<55	225 (24)	113 (24)	112 (23)
55-65	325 (34)	163 (35)	162 (34)
>65	403 (42)	195 (41)	208 (43)
Race			
Asian	46 (5)	23 (5)	23 (5)
Black	149 (16)	70 (15)	79 (16)
White	716 (75)	358 (76)	358 (74)
Unknown/other[a]	42 (4)	20 (4)	22 (5)
Ethnicity			
Hispanic	51 (5)	17 (4)	34 (7)
Non-Hispanic	875 (92)	439 (93)	436 (90)
Unknown	27 (3)	15 (3)	12 (2)
Menopause			
Premenopausal/perimenopausal	182 (19)	92 (20)	90 (19)
Postmenopausal	771 (81)	379 (80)	392 (81)
Comorbidity			
Yes	539 (57)	256 (54)	283 (59)
No	321 (34)	173 (37)	148 (31)
Unknown	93 (10)	42 (9)	51 (11)
ER status			
Positive	936 (98)	465 (99)	471 (98)
Unknown	17 (2)	6 (1)	11 (2)
PR status			
Positive	720 (76)	358 (76)	362 (75)
Negative	92 (10)	51 (11)	41 (9)
Unknown	141 (15)	62 (13)	79 (16)
ERBB2 (formerly *HER2*)			
0	4 (0.42)	3 (0.64)	1 (0.21)
≥1	8 (0.84)	5 (1)	3 (0.62)
Not performed	812 (85)	405 (86)	407 (84)
Unknown	129 (14)	58 (12)	71 (15)
DCIS grade			
1	251 (26)	126 (27)	125 (24)
2	702 (74)	345 (73)	357 (74)

Abbreviations: DCIS, ductal carcinoma in situ; ER, estrogen receptor; GCC, guideline-concordant care; PR, progesterone receptor.

[a] Other race included Alaska Native, American Indian, Central American, Ethiopian, Hispanic, multiracial, Hispanic, and Puerto Rican.

tom burden was relatively low for the COMET population, which may be due in part to participation bias. It may also be somewhat attributable to the high proportion of women in the GCC arm who opted to decline surgical management.[5] This was further supported by the per-protocol analysis findings of a greater effect of GCC on participants' physical and physical role functioning, as well as arm problems and breast pain (at least transiently) during follow-up, as expected from prior studies.[44]

Limitations

The findings of this analysis of PROs from the COMET study, a large, multicenter randomized clinical trial with high participant response rates to serially administered validated measures, should be interpreted in the context of its limitations. While COMET was open at 100 sites that are part of a national clinical trials group, women of racial and ethnic minority groups were underrepresented, and women younger than 40 years were not eligible for participation, limiting the generalizability of findings to these populations. Further, longer-term follow-up, including assessment of QOL, symptoms, and concerns of those participants in the AM group who ultimately experience disease progression, a population likely to increase over time, is needed to fully capture the experience of individuals treated with AM for low-risk DCIS. Participants in the COMET study continue to complete scheduled longitudinal surveys as part of long-term follow-up. Finally, while findings from the per-protocol sensitivity analysis done to address participant nonadherence to randomization allocation did not reveal substantial differences in findings, contamination bias may have affected the results. The proportion of participants undergoing surgery during 2-year follow-up in the AM group (23%) was lower than the proportion not undergoing surgery in the GCC arm (43%), suggesting that women who enrolled in the trial may have been particularly interested in the AM management strategy for their care. However, the surgery rates in the AM group exceeded the documented rates of disease progression during the first 2 years, suggesting that some women and clinicians were uncomfortable with a nonsurgical management strategy at baseline or over time. It will be important to follow these trends over time in this population.

Conclusions

The findings in this prespecified secondary analysis of PROs from a randomized clinical trial comparing GCC with AM among women with low-risk DCIS demonstrated that the overall lived experience of women who are treated for low-risk DCIS with AM was comparable with that of those who undergo up-front surgical management (GCC) during the 2 years following randomization. For women considering AM or GCC for managing low-risk DCIS, the COMET study provides critical data suggesting that in short-term follow-up, both strategies have only limited effects on average health-related QOL, psychosocial outcomes, and breast cancer treatment-related symptoms.

ARTICLE INFORMATION

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