Factors influencing pain response following GLA:D® patient education and supervised exercise in males and females with hip osteoarthritis

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Running Head: Pain outcome post education/exercise for hip OA by sex

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Conflict of interest
Dr. Roos is deputy editor of Osteoarthritis and Cartilage, developer of the Knee injury and Osteoarthritis Outcome Score (KOOS) and several other freely available patient-reported outcome measures, and co-founder of Good Life with Osteoarthritis in Denmark (GLA:D®), a not-for-profit initiative hosted at University of Southern Denmark aimed at implementing clinical guidelines for OA in clinical practice. Dr. Skou is associate editor of Journal of Orthopaedic & Sports Physical Therapy, has received grants from The Lundbeck Foundation, and personal fees from Munksgaard, all of which are outside the submitted work. He is co-founder of GLA:D®.
Dr. Davis is a member of the board of the Osteoarthritis Research Society International, Associate Editor, Osteoarthritis & Cartilage, and member of the Editorial Board of Arthritis Care & Research.

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ABSTRACT

Objective: Understand factors associated with pain intensity responder status following non-surgical hip OA intervention, according to sex.

Methods: Data were from individuals with hip OA participating in the Danish GLA:D® 8-week education and exercise program. Factors captured at program entry: age, education, mental well-being, comorbidities, body mass index, symptoms in hip, knee and low back, and program-specific factors: education sessions, former participant lecture, supervised exercise sessions. Pain intensity was captured at baseline and 3-months (post-program) on a 0-100 visual analogue scale. Response was defined as pain intensity improvement ≥30% from baseline to post-program. Logistic regression was used and conducted separately in males and females.

Results: The sample included 791 males and 2,253 females. Females had a mean baseline pain of 47.2/100 (95% CL: 46.4, 48.1) and males 41.7 (95% CL: 40.3, 43.1). By post-program, the proportion of pain responders was 50.4% among females and 45.8% among males (difference p=0.025). Among females, program-specific factors (attending former participant lecture and more supervised exercise sessions) were positively associated with pain response, as were better mental well-being and fewer comorbidities, while symptoms in other joints/site were associated with a decreased likelihood of response. Among males, program-specific factors were not associated with response, while better mental well-being and fewer comorbidities were associated with being a responder.

Conclusions: Findings suggest that the influence of some factors on pain response differ for males and females, and point to a potential need for targeted approaches for males and females who may require different key messages/approaches from healthcare providers.

Keywords: hip osteoarthritis; education; exercise; GLA:D; pain intensity
Significance and Innovations

- There has been minimal work examining outcomes following education and exercise interventions for individuals with hip osteoarthritis.
- In addition, there is a gap in understanding as to whether the same set of factors influence outcomes in males and females.
- While better mental well-being and fewer comorbidities were associated with a positive pain response in females and males, intervention program-specific factors were associated with positive pain response only in females.
- There may be a need for targeted approaches for males and females who may require different key messages/approaches from healthcare providers.
Clinical guidelines support education and exercise as effective first line care for reducing symptoms and improving function and health-related quality of life in people with symptomatic hip and knee osteoarthritis (OA).[1-3] While much research has focused on people with knee OA, less has addressed the outcomes for people with hip OA. Following a meta-analysis of randomized control trials, Fransen et al. reported that exercise was efficacious in reducing pain and improving function in people with symptomatic hip OA.[4] There is a paucity of outcome reporting specifically for people with symptomatic hip OA and, consequently, there is minimal data evaluating the results of these interventions when implemented in real-world, clinical settings, and the uptake of education, exercise, and weight loss as first line treatment in clinical OA practice is suboptimal.[5]

Recognizing the significant health and economic societal burden of hip and knee OA, national initiatives (e.g. in Canada, U.S., Denmark, Australia and Sweden) are therefore promoting self-management practices and introducing programs focused on implementing clinical guidelines for OA into clinical care.[6-10] However, reported data most often combine the results of those reporting the hip and knee as their predominant symptomatic joint. For example, Eyles et al. evaluated who responded [11] or deteriorated [12] after participating in the Australian OA management program. The sample was predominately comprised of individuals with symptomatic knee OA as their primary complaint (85% of the sample), and results were reported for hip and knee combined. These authors did conclude, however, that there was a trend toward those with knee OA being less likely to report deterioration than those with hip OA.[12] Work by Pisters and Snijders similarly had a small number of hip OA participants and did not report findings for those with hip and knee complaints separately.[13, 14] In other studies, descriptive data were presented, but a multivariable assessment of how participant and program factors influenced outcomes was not undertaken.[9, 15] Identifying factors that influence outcomes within real-world settings may reveal potential avenues to refine or further personalize approaches in order to optimize program effectiveness.[5]
In addition to the paucity of outcome data for those with hip OA generally, there is a gap in understanding as to whether the same set of factors influence outcomes in men and women. Research in those with knee OA supports that there are biological differences and experiential differences between men and women that may impact outcome.[16-19] Identifying factors influencing outcome, by sex, may help further refine programmatic approaches to improve outcomes.

To understand non-surgical treatment outcomes and their influencing factors for males and females, we studied a group of individuals with symptomatic hip OA in Denmark who participated in an 8-week education and exercise program for their OA – Good Life with Osteoarthritis in Denmark (GLA:D®). Considering pain intensity scores, we sought to identify factors associated with responder status at the post-program (3 months) time point, according to sex.

Methods

Source of data and participants

We used data from the ongoing nationwide GLA:D® initiative in Denmark, which comprises a 2-day course for physiotherapists and other clinicians, an 8-week patient program consisting of two educational sessions (there is an optional third education session from a former patient of the program) and 12 supervised neuromuscular exercise therapy group sessions delivered by a trained clinician in clinical practice, and individual consultations at the beginning and end of the program. Patient and clinician-reported data are recorded in the GLA:D® registry. Participant data were collected at baseline and following the program. The data set includes participants’ demographics, clinical and participant-reported health measures, and outcomes evaluating changes during the GLA:D® program. Detailed descriptions of the education, neuromuscular exercise program and GLA:D® registry have been published.[9]

Patients with OA had to provide baseline data to be included in the study, and the current work
includes those individuals that stated their hip as the joint of primary complaint. As pain outcomes for those undergoing surgery are likely to significantly differ from those not having surgical intervention, this study focused specifically on those who had not undergone joint replacement during the 3-month period of the program (thus, n=81 individuals were excluded). To maintain clinical and research relevance, additions have been made to the measures since the program’s inception. To minimize participant burden, some measures consequently were dropped. Given our specific interest, participants that provided baseline data from July 2014 to April 2018 along with 3-month follow-up data were included in the current study.

According to the Danish Data Protection Act, the data subjects consent was not required as personal data was processed exclusively for research and statistical purposes. The Danish Data Protection Agency approved the GLA:D® registry (SDU; 10.084) and according to the ethics committee of the North Denmark Region, ethics approval for GLA:D® was not needed. This report conforms to the Strengthening the Reporting of Observational Studies in Epidemiology statement (STROBE).

**Outcomes**

At program initiation and post-program, pain intensity in the previous month in the most affected hip was evaluated on a 100 mm visual analogue scale (VAS) with terminal descriptors of ‘no pain’ (0 mm) and ‘maximum pain’ (100 mm). Percent change in pain intensity score was calculated by taking the difference between the baseline and post-program pain intensity scores, dividing the difference by the baseline score, and multiplying by 100. ‘Responder’ was defined as a ≥30% improvement in pain intensity score.[20, 21]

Several factors viewed as potentially influencing change in hip pain were considered.[22, 23] These included personal factors: age and level of education (≤high school vs. greater); general health factors: mental well-being (SF-12 mental component score (MCS)), comorbidity count, and body mass index (BMI; kg/m²) (normal (18.5-24.9), overweight (25-29.9), obese (30+); 22 underweight individuals were
excluded); and, musculoskeletal factors: other hip, knee or low back symptoms (index hip + other vs. index hip alone). GLA:D® program-specific factors included number of patient education sessions attended (2 vs. <2), attendance at lecture given by former GLA:D® participant (yes/no), and number of supervised exercise sessions completed (10+ vs. <10;[24]).

**Statistical Analysis**

Baseline characteristics for participants with complete and missing data (missing follow-up or missing a baseline variable(s)), and those who withdrew from the study, were reported and examined for important differences. For the analytical sample (complete-case analysis), characteristics are reported for females and males by responder status. Logistic regression was used to identify factors associated with responder status, using SAS 9.4 (SAS Institute Inc., NC, USA) and considering p-values<0.05 as statistically significant. All analyses were conducted separately in males and females.

**Sensitivity Analysis**

All baseline variables and an additional four auxiliary variables [25] (baseline generic health status (EQ5D); quality-of-life (HOOS/KOOS); 40-meter walk test; 30 sec. chair stand test) were used in a multiple imputation model in order to impute missing values (data from patients that withdrew from the study were not included). Logistic regression was used by fully conditional specification methods for binary variables, which performs best for missing-at-random patterns and a missing proportion of less than 50%.[26]. Thirty-nine imputed datasets were generated so that the number of imputations was at least equal to the percent of data missing on one or more variables, and Rubin’s rules were used in combining the estimates across the imputed datasets.[27]

**Results**

The baseline characteristics for the samples with complete (n=3067) and missing data (missing follow-up, n=917; missing a baseline variable(s), n=1057), and for those that withdrew from the study (n=636), are presented in Table S1 (Supplementary file). While some statistically significant differences
were found between those with complete and missing data, none were deemed to be clinically meaningful.

The characteristics of the 2,253 females and 791 males comprising the analytical study sample are presented in Table 1 by responder status. A statistically significant (p=0.024) difference in proportion of pain responders was found between females and males. Among females, pain intensity responder rate was 50.4% (95% CL: 48.3, 52.5). Compared to female responders, female non-responders were on average 1 year older, had more comorbidities (2+: 13% vs. 18%), fewer attended a lecture by a former GLA:D® participant, fewer completed 10 or more supervised exercise sessions, and their mean baseline pain intensity scores were higher. Among males, pain intensity responder rate was 45.8% (95% CL: 42.3, 48.2). Only the mean baseline pain intensity score differed between male responders and non-responders, 45.9 and 38.1, respectively.

Results from the sex-stratified logistic regression analyses are presented in Table 2. Among females, increasing age was associated with decreased odds of being a responder, as was an increasing comorbidity count. Females with symptoms in their hip, knees, or lower back, beyond the index hip, had a 17% decreased odds of being a pain responder (Odds ratio (OR): 0.83 (95% CL 0.69, 0.99)). Worse baseline pain intensity score (OR: 1.21 (per 10 units) (95% CL 1.16, 1.27)) and higher (better) mental component score (OR: 1.13 (per 10 units) (95% CL 1.02, 1.24)) were associated with increased odds of being a responder. Of the program-specific factors, females who attended a lecture by a previous GLA:D participant had 23% greater odds of being a responder (OR: 1.23 (95% CL 1.01, 1.51), and those who completed 10 or more supervised exercise sessions had a 31% increased odds of being a responder (OR: 1.31 (95% CL 1.04, 1.66)).

Among males, higher (worse) baseline pain intensity score (OR: 1.26 (per 10 units) (95% CL 1.17, 1.36)) and higher (better) mental component scores (OR: 1.20 (per 10 units) (95% CL 1.01, 1.44)) were associated with increased odds of being a responder. Increasing comorbidity count was associated with
decreased odds of being a responder (OR: 0.85 (95% CL 0.73, 1.00). None of the program-specific factors were associated with responder status in males.

Table S2 presents the means (sd) or proportions for each study variable from the complete-case and imputed datasets. No systematic differences were found. Table S3 presents the results from the pooled logistic regression analyses using the imputed datasets. No meaningful differences were found between these estimates and those derived from the main analysis.

Discussion

This study, based on a large sample of individuals with symptomatic hip OA in Denmark who participated in an education and exercise program for their hip OA symptoms, identified significant relationships between pain intensity responder status and better mental well-being and fewer comorbidities, while program-specific factors were significant in females, but not in males. This may have implications for first line care initiatives aimed at reducing symptoms in people with symptomatic hip OA, suggesting a potential need for targeted and different approaches for males and females.

The interest in the 3-month time point in the study stemmed from findings that minimal to no further changes occur after this time point (i.e. scores are stable from 3 through to 12 months).[9, 15, 28] Not unlike descriptive reports from symptomatic hip, and knee, OA participants undergoing similar education and exercise programs,[7, 15] overall improvement in pain intensity was observed during the period of program participation in the current sample. Importantly within the context of a real-world, clinical setting, we found that among females GLA:D® program-specific factors influenced outcomes. Specifically, attending a lecture by a prior GLA:D® participant and completing a greater number of supervised exercise sessions was associated with a 23% and 31% increased likelihood of being a pain responder, respectively. The influence of these program factors, while positive, did not reach statistical significance among males, however. While we do not have data that could provide insights into what
may explain these sex differences, the findings suggest a potential need for targeted strategies for males who may require different key messages or approaches than females from health care providers. This has been previously highlighted in regards to chronic disease self-management programs generally.[29-31] This also highlights the potential importance of considering sex in the design, evaluation and targets of education and exercise programs, and the need, therefore, for additional research to understand not only what differs between sexes generally but also to understand how and why the same factors may differentially affect outcomes for males and females. While much work has been done to promote critical thinking about the influence of sex, and gender, on health outcomes, most health research in OA continues to overlook this.[32, 33] Our findings confirm evidence of the need to consider that factors associated with outcomes from education and exercise interventions for hip OA may differ for males and females.

The presence of other symptomatic joints/site (hip/knees/low back), beyond the index hip, was generally more prevalent among females than males, 66% and 59%, respectively. The presence of these symptoms was associated with a 17% decreased odds of being a hip-pain responder among females; a relationship was not found among males. As has been consistently reported in community and clinical OA samples, a greater number of symptomatic joints in OA generally is associated with greater disability and reduced quality of life, and, similar to the current findings, multiple symptomatic joints are more frequently reported by females than males.[34-37] The implications within the current context is that physical activity and exercise programs targeted to improving symptoms in specific joints in OA need to consider the reality of multiple symptomatic joints being highly prevalent in OA. Findings support a likely need for some level of individualized and supervised exercise instruction by trained healthcare professionals to perhaps tailor approaches depending on the presence of multiple other symptomatic joints.

Biological differences between males and females may also contribute to differences in response to
interventions. In knee OA studies, for example, some systemic inflammatory markers have been shown to be associated with, among other things, pain and disability levels but differently in males and females,[19, 38, 39] and consequently may be further associated with differences in response to analgesic and anti-inflammatory drugs for males and females, for example.[40, 41] Such factors and their association with study outcomes were not considered in the present study. While body mass index could also conceivably play a role—a greater proportion of males in the sample were overweight and obese compared to females—we did not find any differences in responder rate between those with normal and unhealthy BMI (≥25) in females or males.

The experience of pain is multi-factorial, influenced by psychological, emotional, and social factors.[42, 43] Differences in pain experiences can be shaped by gender differences in pain appraisal, pain behaviours and or by different social roles of men and women. From a systematic review and meta-analysis, Alabas et al. reported that gender stereotypes specific to pain scales showed stronger associations with sex differences in pain sensitivity response than personality-based scales, for example.[44] In the current sample, females had higher pain scores at program entry. Feminine gender norms are more often regarded as allowing for more pain expression, whereas masculine gender norms are often associated with increased pain tolerance, meaning men may be less likely to express pain relative to women.[45, 46] An additional consideration is sex and gender effects as they relate to participation in programs like GLA:D®, and indeed self-management and chronic disease management programs more generally. In an insightful scoping review of qualitative and quantitative studies exploring the individual-level and program-specific factors that affect male participation rates in chronic disease prevention and management programs, Gavarkovs et al. identify program-specific factors that attract men to participate in interventions, including the setting, group components with like-minded men, use of humor in information delivery, and the inclusion of nutrition and physical activity components.[47] In examining men’s barriers to arthritis self-management programs, Gibbs et al.
reported that many men would only consider self-management programs if their condition progressed to the point that they could no longer work, but also discussed that work demands were reported as barriers to engagement in chronic disease prevention and management programs, and that this influence was strongest in midlife when work commitments are greatest.[48, 49] A number of studies also explored the effects of masculinity on men’s perceptions of weight loss programs and health promotion programs in general, and authors reported that many men felt that these programs were inherently feminine.[47] Men accounted for only 26% of participants in the current sample, comparable to proportions in similar programs, yet much lower proportionally than would be suggested by the male:female ratio of hip OA in general and surgical populations. Further work to understand gender effects and to understand facilitators and barriers to inform the design or redesign of programs in OA that will improve the engagement and participation of men is warranted.[47]

The number of participants with missing data at follow-up is a limitation of the study, and though loss to follow-up typically is greater with observational registry-based studies in real-world settings compared to trial conditions, this nevertheless has the potential to introduce bias. While there was minimal to no difference in baseline status between participants with complete versus missing data, and minimal to no difference in regression results between the complete-case and imputed-case analyses, we do not know if participants with missing data had better or worse 3-month outcome, and it is difficult to speculate what the impact of this would be. It is possible that participants who improved early in the program may have discontinued further participation believing that attending further exercise sessions would not provide additional benefit. Alternatively, for some, worsening of symptoms, pain flares or lack of early positive results might have discouraged further participation. This may in part be the case for some of those that proceeded to have joint replacement surgery during their time in the program (<1.5% of the sample). While 3-month response rates were available, and higher compared to the overall sample, for the 80 individuals (data not shown), attribution of pain intensity response (i.e. to the
program, to surgery, or both) would not have been possible. Finally, while this is the first study to examine relationships in males and females separately within the context of hip OA and participation in an education and exercise program, the focus was only on pain intensity. Additional work will be necessary to determine whether similar sex-specific findings can be identified for other important outcomes as well, such as function, which may differ because of strength differences and or physical demands, and overall quality of life.

Conclusion

Our results suggest that within a real-world, clinical setting, a key to understanding, possibly optimizing, the effectiveness of education and exercise programs necessitates consideration of participant sex. There appears to be some rationale for considering tailored intervention content for females and males. While this work provides some foundational understanding, the direct application of these results to immediate clinical changes will be dependent on quantitative and qualitative research work to better understand sex and gender effects in OA care programs.
References


Table 1. Description of study sample by sex and responder status†.

<table>
<thead>
<tr>
<th>Factors</th>
<th>Females (n=2253)</th>
<th>Males (n=791)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-responder</td>
<td>Pain Responder</td>
</tr>
<tr>
<td></td>
<td>(48.9%)</td>
<td>(50.4%)</td>
</tr>
<tr>
<td>Personal factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Mean (range)</td>
<td>65.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>64.8 *</td>
</tr>
<tr>
<td>Education</td>
<td>≤High-school</td>
<td>26.8%</td>
</tr>
<tr>
<td>General health factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-12 MCS**</td>
<td>Mean (range)</td>
<td>52.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>52.5</td>
</tr>
<tr>
<td>Comorbidity count</td>
<td>Median (IQR)</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(0-1)</td>
</tr>
<tr>
<td>Body mass index</td>
<td>normal</td>
<td>43.2%</td>
</tr>
<tr>
<td></td>
<td>overweight</td>
<td>37.2%</td>
</tr>
<tr>
<td></td>
<td>Obese</td>
<td>19.5%</td>
</tr>
<tr>
<td>Musculoskeletal/OA health factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other joint sites</td>
<td>Index hip only</td>
<td>32.5%</td>
</tr>
<tr>
<td></td>
<td>Index+knee/low back/other hip</td>
<td>67.5%</td>
</tr>
<tr>
<td>GLA:D® program factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education sessions</td>
<td>&lt;2</td>
<td>17.6%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>82.4%</td>
</tr>
<tr>
<td>Prior GLA:D participant lecture</td>
<td>yes</td>
<td>20.3%</td>
</tr>
<tr>
<td>Supervised exercise sessions</td>
<td>&lt;10</td>
<td>17.8%</td>
</tr>
<tr>
<td></td>
<td>10+</td>
<td>82.2%</td>
</tr>
<tr>
<td>Pain intensity, baseline (/100)</td>
<td>Mean (range)</td>
<td>43.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50.6 *</td>
</tr>
</tbody>
</table>

†Responder: improvement of ≥30% in pain intensity score from baseline to post-program.

*p<0.05 based on t-test, Wilcoxon-Mann-Whitney test or chi-square test, as appropriate, between responder and non-responders, by sex.

**SF-12 mental component score (MCS): higher is better.
Table 2. Results from logistic regression assessing factors associated with pain intensity response†, by sex.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Females</th>
<th></th>
<th>Males</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio</td>
<td>(95% CL)</td>
<td>p-value</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>Baseline pain intensity score (per 10-unit)</td>
<td>1.21</td>
<td>(1.16, 1.27)</td>
<td>&lt;0.01</td>
<td>1.26</td>
</tr>
<tr>
<td>Age (per 5 years)</td>
<td>0.95</td>
<td>(0.91, 0.99)</td>
<td>0.041</td>
<td>1.03</td>
</tr>
<tr>
<td>≤Highschool vs. greater</td>
<td>0.83</td>
<td>(0.68, 1.01)</td>
<td>0.062</td>
<td>0.98</td>
</tr>
<tr>
<td>SF-12 MCS (per 10-units)</td>
<td>1.13</td>
<td>(1.02, 1.24)</td>
<td>0.015</td>
<td>1.20</td>
</tr>
<tr>
<td>Comorbidity count (per unit)</td>
<td>0.85</td>
<td>(0.77, 0.94)</td>
<td>0.002</td>
<td>0.85</td>
</tr>
<tr>
<td>BMI overweight vs. normal</td>
<td>1.04</td>
<td>(0.85, 1.25)</td>
<td>0.728</td>
<td>0.93</td>
</tr>
<tr>
<td>BMI obese vs. normal</td>
<td>1.01</td>
<td>(0.80, 1.29)</td>
<td>0.932</td>
<td>0.92</td>
</tr>
<tr>
<td>Index + other joint/site vs. index only</td>
<td>0.83</td>
<td>(0.69, 0.99)</td>
<td>0.047</td>
<td>0.93</td>
</tr>
<tr>
<td>Education sessions (2 vs. &lt;2)</td>
<td>0.98</td>
<td>(0.78, 1.24)</td>
<td>0.886</td>
<td>0.89</td>
</tr>
<tr>
<td>prior GLA:D® participant lecture (yes/no)</td>
<td>1.23</td>
<td>(1.00, 1.51)</td>
<td>0.043</td>
<td>1.14</td>
</tr>
<tr>
<td>Supervised exercise sessions (10+ vs. &lt;10)</td>
<td>1.31</td>
<td>(1.04, 1.66)</td>
<td>0.023</td>
<td>1.09</td>
</tr>
</tbody>
</table>

†Responder: improvement of ≥30% in pain intensity score from baseline to post-program.