Original Clinical Article

JOURNAL OF CHILDREN'S ORTHOPAEDICS

Preoperative mental health status is a significant predictor of postoperative outcomes in adolescents treated with hip preservation surgery

Heather M. Richard
Shelby P. Cerza
Adriana De La Rocha
David A. Podeszwa

Abstract

Purpose This study was designed to evaluate predictive factors that influence pain, mental health symptoms and postoperative outcomes at six-months post-hip preservation surgery (HPS) in adolescent surgical candidates.

Methods In total, 58 HPS candidates (39 female, 19 male; mean age 15.53 years (10 to 19)) were evaluated. Diagnoses included: acetabular dysplasia (34); idiopathic femoroacetabular impingement (15); Perthes disease (six); avascular necrosis (six); and slipped capital femoral epiphysis (six). All patients underwent periacetabular osteotomy (36), surgical hip dislocation (17) or arthroscopy (five). Patients completed the following: Numerical Pain Rating Scale (NPRS); Child Health Questionnaire-87 (CHQ-87); Pediatric Symptom Checklist-Youth (PSC-Y), preoperatively and six months postoperatively. A single psychologist assessed patients in clinics and one to two additional appointments.

Results In all, 78% of patients reported one to three years of pain prior to HPS (modified Harris hip score). All pain scores (NPRS) significantly decreased at six months postoperatively. Preoperative mental health scores (CHQ-87) significantly predicted postoperative pain scores ($F(1, 57) = 4.07$; $p < 0.048$; $R^2 = 0.068$). Mental health symptoms (PSC-Y) decreased significantly ($p < 0.001$). Patients who were seen by a psychologist two or more times reported better six-month postoperative outcomes than those seen once: usual pain (NPRS; $p = 0.012$); patient-reported physical function (CHQ-87; $p = 0.029$); and mental health (PSC-Y; $p = 0.019$). HPS patients seen ≥ 60 days prior to surgery showed marked improvements at six months compared with patients seen < 60 days prior to surgery.

Conclusion HPS candidates evaluated preoperatively by psychology, as part of an integrated treatment approach, demonstrated statistically significant improvements in pain, health-related quality of life and mental health symptoms. Two+ visits, more than 60 days prior to surgery appears to be impactful. Preoperative pain and mental health symptoms were predictive of postoperative pain.

Level of Evidence: II

Cite this article: Richard HM, Cerza SP, De La Rocha A, Podeszwa DA. Preoperative mental health status is a significant predictor of postoperative outcomes in adolescents treated with hip preservation surgery. *J Child Orthop* 2020;14:259-265. DOI: 10.1302/1863-2548.14.200013

Keywords: paediatric orthopaedics; hip preservation surgery; surgical outcomes; adolescent; mental health

Introduction

Premorbid psychological functioning in paediatric patients undergoing surgery has been shown to be predictive of postoperative outcomes.[1,2] Multiple factors, including pain, depression, anxiety, premorbid physical functioning, adherence and family functioning can significantly influence outcomes.[1-4] Mitigating these factors prior to surgical intervention has improved patient outcomes postoperatively in specific paediatric medical populations.[1,2,5] Previous studies have demonstrated that 33% of adolescent candidates for hip preservation surgery (HPS) reported maladaptive behaviours that significantly influenced postoperative outcomes.[3] However, the selected, broad measures were not sensitive enough to detect specific symptoms and change over a relatively short period of time, thus potentially under-representing HPS patient struggles. The study did highlight that preoperative mental health factors play an influential role in overall surgical outcomes. In addition, common 'red flags' were identified, which, when present, significantly raised suspicion of underlying psychological factors of patients' presentations, increasing potential negative outcomes following surgical intervention.[3]

To improve patient care and proactively identify and prepare adolescents with chronic hip pain requiring HPS, an interdisciplinary intervention was implemented.

Texas Scottish Rite Hospital for Children, Dallas, Texas, USA

Correspondence should be sent to Heather M. Richard, Texas Scottish Rite Hospital for Children 2222 Welborn St Dallas Texas 75219-0567 USA.
E-mail: Heather.Richard@tsrh.org

Richard et al[6] proposed an interdisciplinary, preoperative care model, including psychological intervention, physical therapy and nursing education to outline postoperative expectations and goals. Patient mental health, resiliency and physical activity were assessed pre- and postoperatively. Patients reported decreased emotional symptomology and social stress, improved self-concept, resilience and physical function six-months postoperatively.[6]

Although factors have been identified and preoperative psychological intervention has demonstrated utility with adolescent candidates for HPS, further research to specify salient and predictive indicators has yet to be studied. How the psychologist participates, when the psychologist intervenes and the key elements the psychologist addresses with patients and families have not been established in this paediatric medical population.

The purpose of this study was to outline how to address the potential predictive factors in a timely, cost-efficient manner before scheduling surgery. The authors purport that patients who are evaluated by a psychologist preoperatively, as part of an interdisciplinary team, will demonstrate significant, positive postoperative outcomes.

Materials and methods

This institutional review board-approved study prospectively assessed adolescent participants identified as candidates for HPS at a single institution. Consented, enrolled patients in this study were given a series of self-report measures preoperatively and six-months postoperatively: Numerical Pain Rating Scale (NPRS);[7] Child Health Questionnaire-87 (CHQ-87);[8] Pediatric Symptom Checklist-Youth (PSC-Y).[9] Table 1 describes the measures administered. Patients were seen by a staff paediatric psychologist at medical appointment and an average of one to two additional outpatient appointments.

Patients who were not deemed appropriate for surgery (i.e. radiographically or psychologically) were not included. A control group was also not identified, as practice has demonstrated the benefit of surgery preparation and withholding beneficial intervention questioned ethical patient care.

Preoperative psychological evaluation

All patients in this cohort were seen by one paediatric psychologist with specific experience with preoperative evaluation and preparation in paediatric orthopaedics. Psychology has been an integral discipline in the hip preservation specialty clinics at our institution for approximately ten years. After a series of postoperative, inpatient consultations with the psychologist for acute challenges, i.e. difficulty mobilizing, pain management challenges and prolonged hospital stays, a proactive, preoperative practice was adopted.

The paediatric psychologist works side-by-side with the physician for simultaneous and holistic evaluation of a patient's presenting complaints. Nurses and physical therapists are also concurrently evaluating the patient. The psychologist then follows up with more specific evaluation of contributing factors to pain and changes of function (i.e. mental health symptoms, psychosocial struggles), in the context of the medical diagnosis. This begins in the medical appointment and includes follow-up at a separate psychology appointment.

It is difficult to delineate the impact each member of the clinical team has on patient readiness. The authors are not attempting to isolate the impact of the psychologist's involvement in HPS patient preoperative planning. While this paper specifically refers to psychological assessment, all patients in this cohort have been treated by an interdisciplinary team (Table 2).[12-23]

A total of 58 HPS candidates (39 female, 19 male; mean age 15.53 years (10 to 19)); Caucasian (41); Hispanic (ten); Black (five); Asian/Pacific Islander (two) were evaluated. Diagnoses included: acetabular dysplasia (34); idiopathic femoroacetabular impingement (15); Perthes disease (six); avascular necrosis (two); and slipped capital femoral epiphysis (six). All patients underwent preoperative physical therapy, psychological evaluation (with intervention and counselling as indicated) and subsequent periacetabular osteotomy (36), surgical hip dislocation (17) or hip arthroscopy (five). When looking at insurance coverage: 81% (n = 41) were privately insured; 12.1% (n = 5) used Medicaid; 3.4% (n = 2) had both private insurance and Medicaid; and 3.4% (n = 2) did not have insurance

Table 1 Patient reported outcome measures

Measure	Description of measure (including score range)
Numerical Pain Rating Scale	This measure assesses current, usual, best and worst pain levels.[7] These subscale scores range from 1 to 10; with lower scores indicating less pain. A total pain score is also assessed; these scores range from 10 to 40; with lower scores indicating less pain.
Child Health Questionnaire-87	This measure assesses health-related quality of life related to pain, physical functioning and psychosocial functioning.[8] There are 11 sub-scales that are scored independently.
Pediatric Symptom Checklist-Youth	This is a self-reported paediatric mental health screener designed to identify cognitive, emotional and behavioural problems.[9] Scores range from 0 to 70; with lower scores indicating fewer problems.
Modified Harris Hip Score	This measure assesses hip function. Scores range from 0 to 28.[10] Higher scores indicate more limited hip function.
University of California Los Angeles Activity Score	This measure assesses patient activity levels.[11] Scores range from 0 to 10, with higher scores indicating higher levels of activity participation.

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Table 2 Specific preoperative factors to assess prior to surgical intervention[12-23]

Factor	Assessment
Preoperative education	Assess patient and family understanding of procedure and anticipated postoperative rehabilitation. Provide repeat and consistent education from preparation of treatment through healing/rehabilitation phase.
Current function	Assess school performance and activities (prosocial behaviours). Evaluate sleep quality and sleep habits. Account for and intervene with deviant behaviours; i.e. substance use/abuse; poor self-care.
Psychiatric symptoms (caregiver and patient)	Rule out mental health conditions. Stabilize mental health symptoms. Refer for appropriate psychiatric and/or psychological intervention, as indicated. Schedule surgery only after symptoms have improved.
Pain	Evaluate current level of pain in context of medical condition and activity level. Understand how patient communicates pain and caregivers' responses. Implement pain management and coping strategies.
Goals of treatment	Assure patient and family's goals of postoperative outcomes, i.e. pain level, function, are aligned with medical team's expected goals.
Postoperative expectations	Provide education regarding acute postoperative protocol of time out of bed; physical therapy; expected discharge. Expectations of rehabilitation course, physical therapy, weight-bearing status and return to sport or activity evaluated for consistency with surgical intervention and physician's plan of care.
Adherence	Actively assess patient and family's ability to follow medical advice prior to scheduling surgery by prescribing preoperative home exercise programme and family scheduling follow-up appointment with psychologist when they are ready to further discuss surgery. Preoperative adherence is predictive of postoperative adherence.
Planning	Evaluate potential barriers to positive outcomes and minimize interference; i.e. school testing schedule; prom; graduation. This gives patients control and can enhance commitment to treatment.

coverage. Socioeconomic status was assessed by patient zip code and average household income for the area; 3.6% (n = 2) live in an area with an average household income of $20 000 to $49 999; 83.9% (n = 47) live in an area with an average household income of $45 000 to $139 999; 1.8% (n = 1) live in an area with an average household income of $140 000 to $149 999; and 10.7% live in an area with a household income of $150 000 to $199 999. Two patients were excluded from the socioeconomic assessment because their primary residence is not in the United States.

Statistical analyses included measure of central tendency, *t*-tests, between group comparisons and regression analyses. A p-value of 0.05 was used to determine statistical significance.

A cohort comparison was conducted between patients treated with the interdisciplinary treatment model and those who received surgery prior to the implementation of this model. The cohort that was treated prior to the implementation of the interdisciplinary treatment model did not receive the same measures. The two groups were compared in terms of age, sex, diagnoses, surgical approach, estimated blood loss, time of surgery and length of stay (LOS) (Table 2).

Results

Patients attended one to two scheduled sessions of required, preoperative psychological evaluation and intervention, in addition to the collaborative medical appointments. Total visits with a psychologist, in clinic and/or in the psychology department, mean 2.52 (1 to 9). Length of time from initial contact with psychologist to surgery had a mean of 72.02 days (1 to 415). The mean acute, postoperative inpatient hospitalization LOS was 2.84 days (1 to 5).

Table 3 Demographic and treatment information

Variable	Integrated treatment cohort (n = 58)	Non-integrated treatment cohort (n = 310)
Mean age, yrs (range)	15.53 (10 to 19)	15.29 (9 to 19)
Female sex (%)	39 (*67.2*)	201 (*64.8*)
Caucasian race (%)	41 (*70.7*)	212 (*68.4*)
Hip dysplasia diagnosis (%)	34 (*58.6*)	158 (*51.5*)
Periacetabular osteotomy surgery (%)	36 (*62.1*)	189 (*61*)
Mean length of stay	2.84 days (2-4)	3.83 days (2-5)

In total, 60.5% of patients reported having active to highly active lifestyles prior to surgical intervention (University of California Los Angeles Activity Scale).[11] In all, 29.% of patients had a family history of mental health diagnoses, with approximately 16% of patients having an identified mental health diagnosis. Differences in diagnosis, surgical approach and sex were not significant pre- or postoperatively.

When assessing differences between the cohort that received the interdisciplinary treatment and the cohort that did not, there were no differences noted in age, sex, diagnosis or surgical approach (Table 3). The interdisciplinary cohort had significantly reduced LOS (26%) compared with the cohort that did not have psychological intervention (2.84 days to 3.83 days; $p < 0.001$).

Pain and mental health

A total of 78% of patients reported one to three years of pain prior to HPS (modified Harris hip score).[10] All pain scores (NPRS) significantly decreased from pre- to six months postoperatively: current pain (4.09 to 0.69; $p < 0.001$); usual pain (4.57 to 1.26; $p < 0.001$); best pain (2.9 to 0.57; $p < 0.001$); worst pain (6.66 to 2.45; $p < 0.001$); and total pain scores (18.14 to 5; $p < 0.001$). Preoperative pain scores were found to be predictive of six-month postoperative pain scores (NPRS) ($F(1, 56) = 8.49$; $p = 0.005$;

$R^2 = 0.132$). Patients who reported high pain levels preoperatively continued to report elevated pain at six months postoperatively compared with those reporting lower pain scores preoperatively.

Preoperative mental health scores on the health-related quality of life (HRQOL) measure (CHQ-87) significantly predicted postoperative pain scores ($F(1, 57) = 4.07$; $p < 0.048$; $R^2 = 0.068$). Using a multiple linear regression analysis, preoperative PSC-Y mental health scores ($p < 0.001$) and preoperative CHQ-87 patient-reported mental health scores ($p < 0.011$) predicted six-month postoperative pain scores (NPRS) ($F(2,57) = 5.68$; $p < 0.006$; $R^2 = 0.171$). The more mental health symptoms reported preoperatively the higher the predicted pain scores at six months post-HPS. In another multiple linear regression, preoperative self-esteem (CHQ-87) was found to be a significant predictor of six-month postoperative PSC-Y scores ($F(1, 57) = 8.07$; $p = 0.006$; $R^2 = 0.126$).

Patient-reported mental health symptoms (PSC-Y) decreased significantly (14.71 to 7.83; $p < 0.001$), postoperatively. Improvements were noted in attention problems (4.38 to 2.47; $p < 0.001$), internalizing problems (i.e. depression, anxiety) (7.09 to 3.84; $p < 0.001$) and externalizing problems (i.e. fighting, impulsive behaviours) (2.84 to 1.4; $p < 0.001$).

HRQOL

Pre- and postoperative improvements on the patient-reported HRQOL (CHQ-87) were statistically significant in: general health (72.07 to 79.22; $p < 0.005$); physical functioning (63.9 to 85.79; $p < 0.001$); role functioning – behavioural (93.9 to 99.05; $p = 0.007$); role functioning – physical (79.98 to 95.05; $p < 0.001$); bodily pain (36.03 to 85.28; $p < 0.001$); behaviour (85.17 to 91.4; $p < 0.001$); mental health (79.62 to 85.67; $p < 0.001$); self-esteem (81.1 to 85.97; $p < 0.002$); change in health (3.05 to 4; $p < 0.001$); family activities (81.95 to 91.14; $p < 0.001$); and family cohesion (81.9 to 85.6; $p < 0.04$). All other subscales of the CHQ-87 did not yield statistically significant changes.

Preoperative preparation factors

All patients were seen by a staff paediatric psychologist knowledgeable in paediatric orthopaedic conditions, as part of the integrated care team in medical clinics and at scheduled, outpatient appointments. On average, patients were seen 2.52 times by the psychologist. Specifically, the majority of HPS candidates (n = 50) were only seen for one additional psychology appointment outside of regularly scheduled medical appointments.

Between-group comparisons were conducted to assess the efficacy of preoperative preparation. The first comparison evaluated differences in the number of times patients were seen by the psychologist, in clinic and at scheduled psychology appointments combined. More specifically, comparisons were conducted between patients who were seen by the psychology department once prior to surgery *versus* patients who were seen twice or more (2 to 9) times prior to surgery. Patients who were seen by a psychologist two or more times reported better six-month postoperative outcomes than those seen once: usual pain (NPRS; 1.04 *versus* 2.3; $p = 0.012$); physical function (CHQ-87; 87.31 *versus* 78.5; $p = 0.029$); and mental health (PSC-Y; 6.88 *versus* 12.4; $p = 0.019$) (Table 4).

Patients who were seen three or more times preoperatively noted significant improvements six months postoperatively in worst pain (NPRS;1.76 *versus* 2.89; $p = 0.025$) and overall pain (NPRS; 3.43 *versus* 5.89; $p = 0.014$) when

Table 4 Psychology appointments and outcomes

Variable – six-month outcomes	Less than two appointments prior to surgery	Two or more appointments prior to surgery	p-value (between group T-test)
NPRS usual pain	2.3	1.04	0.012
CHQ-87 physical function	78.5	87.31	0.029
CHQ-87 role functioning – behaviour	94.5	100	< 0.001
CHQ-87 role functioning – physical	90.1	96.08	0.033
CHQ-87 family activities	81.7	93.1	0.008
PSC-Y attention difficulties	401	2.32	0.028
PSC-Y internalizing symptom	5.7	3.46	0.049
PSC-Y total	12.4	6.88	0.019

NPRS, Numerical Pain Rating Scale; CHQ-87, Child Health Questionnaire-87; PSC-Y, Pediatric Symptom Checklist-Youth

Table 5 Days seen by psychologist prior to surgery and outcomes

Variable – six-month outcoes	< 60 days prior to surgery	≥ 60 days prior to surgery	p-value (between group T-test)
NPRS current pain	1.03	0.3	0.038
NPRS usual pain	1.71	0.74	0.022
NPRS total pain	6.42	3.37	0.049
CHQ-87 physical functioning	81.9	90.26	0.035

NPRS, Numerical Pain Rating Scale; CHQ-87, Child Health Questionnaire-87

compared with patients seen less than three times prior to surgery.

HPS patients seen initially ≥ 60 days prior to surgery showed marked improvements at six months compared with patients seen < 60 days prior to surgery in: total pain (NPRS; 3.37 *versus* 6.42; p = 0.049); and patient reported physical functioning (CHQ-87; 90.26 *versus* 81.9; p = 0.035) (Table 5). There was a positive trend of improvement the longer the time from initial psychological assessment to surgical intervention.

Discussion

Predictive factors for postoperative outcomes have been demonstrated in the literature with specific paediatric medical populations. Specifically, anxiety, depression, perception of pain and pre-morbid functioning are described as key risk factors to medical treatment adherence, participation, rehabilitation and surgical outcomes.

Previous studies with adolescents undergoing HPS have concluded that there are as many as 33% of patients reporting maladaptive behaviours that negatively impact surgical outcomes. Additionally, an integrated, multi-disciplinary approach has demonstrated benefits in this population.[3,6]

The purpose of this study was to more specifically identify factors that may be predictive of postoperative outcomes in adolescents undergoing HPS and outline a recommended preparation timeline. The data also demonstrates that psychological evaluation and intervention does not need to add significant burden to families and may actually reduce burden with improved overall functioning postoperatively. Pain, mental health and HRQOL were evaluated preoperatively and six months postoperatively. Predictive factors were also identified.

Postoperative pain following paediatric orthopaedic surgery can precipitate ongoing problems in everyday functioning.[7,8] Chidambaran et al[1] found preoperative pain and anxiety scores were predictive of persistent postoperative pain in adolescent idiopathic scoliosis (AIS) patients. Similarly, Sieberg et al[2] reported preoperative pain, depression and HRQOL in AIS patients were predictive of postoperative pain.

Of the 58 participants, nearly 16% had reported a mental health diagnosis. Patient-reported mental health symptoms (PSC-Y) significantly reduced postoperatively, specifically with regard to attention, internalizing and externalizing problems. The incidence of mental health symptoms in this study is consistent with incidence in the general population and in adolescents who report chronic pain.[24-26] While it cannot be determined from this study the specific cause of improved mental health symptoms postoperatively, it is likely that the team-based approach, surgical intervention and rehabilitation, improved pain and return to reasonable functioning all contributed to improvements. The worry and distress of upcoming surgery may also have contributed to reported pre-surgical symptoms.[27]

Preoperative pain levels (NPRS) significantly reduced at six-month follow-up. HRQOL (CHQ-87), including physical functioning, bodily pain, behaviour, mental health, self-esteem, health and family activities, significantly improved postoperatively. Preoperative pain scores were predictive of six-month postoperative pain scores. Those who reported higher levels of pain preoperatively, continued to have higher pain levels than those who reported lower pain scores initially. Additionally, preoperative mental health symptoms on two measures (CHQ-87 and PSC-Y) were predictive of pain scores six months postoperatively, in a positive direction. Those who endorsed more preoperative mental health symptoms were more likely to have higher postoperative pain scores. Studies have shown that patients who report higher levels of pain prior to medical intervention, continue to have high levels of pain, regardless of medical intervention.[2,28] Pain may improve, but reports of pain may not reduce to the same level as those who begin treatment with lower levels of pain.[29] The interplay between chronic pain and mental health symptoms has also been identified.[30] Managing pain, in the context of medical diagnosis and mental health symptoms to lower pre-treatment/preoperative pain and associated mental health symptoms improves patient-reported outcomes.

When evaluating the enrolled cohort who participated in preoperative, interdisciplinary treatment to a similar patient cohort that had no preoperative preparation, HPS patients who had received psychological intervention had a 26% reduction in hospital LOS compared with those who did not experience psychological intervention. Other factors related to surgery were analyzed and not found to be significantly correlated with reduced LOS. While there are several factors that contribute to desired postoperative outcomes and improved patient care, the implementation of an interdisciplinary, pre-habilitation model including psychological consultation, intervention and home exercise programme (beyond the scope of this study) cannot be ignored.

This study elucidates the role of mental health symptoms and pain preoperatively, as they impact postoperative pain scores following HPS. Despite an orthopaedic hip condition, psychological evaluation, intervention and surgery preparation/planning, prior to scheduling surgery positively impacts patient outcomes.

Oftentimes, there are concerns of adding burden or delaying surgical intervention when other medical preoperative assessments and clearances are recommended/required. In actuality, pre-habilitating patients and reducing or removing known risk factors prior to surgery may reduce the time of rehabilitation and recovery

Table 6. Treatment recommendations

Recommended preoperative preparation	Specific information
Number of times seen by psychologist	≥ 2 appointments (combination of medical and outpatient psychology appointments)
Number of days seen prior to surgery	Initially, ≥ 60 days
Preoperative pain	Assess pain, and factors contributing to pain, as they are predictive of postoperative pain
Preoperative mental health status	Evaluate mental health symptoms and diagnoses, as they are as predictive of postoperative pain

postoperatively. It may also lead to less prescribed pain medications, fewer unscheduled visits and increased patient satisfaction. When the surgery and return to function meet the medical team and patient's expectations, as individually defined, there is improved satisfaction for all.

While there is no exact script for psychological evaluation and intervention, results from this study indicate that integrated psychological consultation in the medical clinic, and one to two scheduled appointments with the team psychologist more than two months before surgery may be a general, minimum, criteria for improved outcomes of painful, adolescent hip conditions treated with HPS (Table 6). Specific factors such as: education about treatment; mental health symptoms; pain; goals of treatment; patient and family expectations; adherence; and general planning (Table 2) are important to assess and address appropriately before scheduling surgical intervention. While each patient requires varying levels of intervention, all patients were assessed by a psychologist on these various factors. The more time and psychological intervention, the higher likelihood of positive patient-reported, postoperative outcomes. Following the assessment of these factors, a preoperative treatment and preparation plan was created to ensure that the patient was adequately prepared for surgical intervention and the postoperative course.

While this study supports a proactive, preparation approach, some limitations should be noted. First, we do not have a control group against which to compare. Only surgical hip preservation patients were evaluated as standard of care and enrolled in the current study. We did not include patients who were not surgical candidates, for any number of reasons. Patients who had difficulty with preoperative preparation or those who did not move forward with surgery were not included. In order to make this a homogenous study population, the authors chose to exclude patients who had a second or repeat surgery (n = 9). This was to reduce any natural changes to scores due to patients having: 1) completed the surveys before; 2) experience with treatment and postoperative protocol. Another limitation was the variability of the length of time the patient was seen by a psychologist prior to surgery, with a range one to 415 days before surgery. There was one outlier who was seen by psychology 1186 days prior to surgery. This patient presented with significant, preoperative risk factors that required in-depth, long-term intervention prior to HPS. Finally, the patient sample was unequal in surgery groups, sex and race; as they were mostly Caucasian females. However, we feel this sample is an accurate representation of this specialty medical population.

Conclusions

Based on this study's results, integrated psychological consultation, assessment and intervention to assist with patient readiness as part of the medical treatment plan yields benefits to patient-reported outcomes after HPS. Required psychological evaluation only required one to three appointments, which is minimal when considering the implications of unmanaged mental health symptoms or poor readiness after surgery. One way to approach the continued improvement is by creating a screening measure that could be administered in clinic to better inform the orthopaedic team of specific factors or red flags that might interfere with positive patient outcomes with HPS candidates. Patients with elevated preoperative pain and mental health scores are likely to benefit from appropriate preoperative intervention and surgical preparation from the integrated care team of psychologists, orthopaedists, nurses, physical therapists and other ancillary team members. Identifying a small battery of questions that assess the most salient and predictive indicators of postoperative outcome, would help guide physicians that do not have the luxury of a psychology team in clinic or even in their institution. Lastly, future research could be improved by conducting longer follow-up with these patients to assess long-term outcomes.

Received 22 January 2020; accepted after revision 15 June 2020.

COMPLIANCE WITH ETHICAL STANDARDS

FUNDING STATEMENT

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

OA LICENCE TEXT

ETHICAL STATEMENT

Ethical approval: Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

Informed consent: Informed consent for participation in the study was obtained.

ICMJE CONFLICT OF INTEREST STATEMENT

None declared.

AUTHOR CONTRIBUTIONS

HMR: Study design, Data validation, Statistical planning, Manuscript preparation.
SPC: Patient enrollment, Data collection, Data validation, Statistical analyses and planning, Manuscript preparation.
ADLR: Study design, Manuscript preparation.
DAP: Study design, Manuscript preparation.

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