1. LUMBAR SPINE

MRI technologies

J Orthop Sports Phys Ther. 2019 Mar 26:1-32. doi: 10.2519/jospt.2019.8793

Are Magnetic Resonance Imaging Technologies Crucial to Our Understanding of Spinal Conditions?

Crawford RJ¹, Fortin M^{2,3}, Weber KA 2nd¹, Smith A⁴, Elliott JM^{5,6}.

The development of persistent spinal (traumatic and non-traumatic) pain is common and contributes to high societal and personal costs, globally.

There is an acknowledged urgency for new and interdisciplinary approaches to the problem, and soft tissues including skeletal muscles, the spinal cord, and brain are rightly receiving increased attention as important biological contributors. In reaction to recent suspicion of and questioned value for imaging-based findings, this paper serves to recognize the promise that the technological evolution of imaging techniques, and particularly magnetic resonance imaging (MRI), is allowing in characterizing previously less visible morphology.

We emphasize the value for quantification and data analysis of several contributors in the biopsychosocial model for understanding spinal pain. Further, we highlight emerging evidence regarding the pathobiology of changes to muscle composition (eg, atrophy, fatty infiltration) as well as advancements in neuro- and musculoskeletal imaging techniques (eg, fat/water imaging, functional MRI, diffusion imaging, magnetization transfer imaging) of these important soft tissues. These non-invasive and objective data sources may complement known prognostic factors of poor recovery, patient self-report, diagnostic tests, and the -omics fields. When combined, advanced 'big-data' analyses may assist in identifying associations previously not considered.

Our clinical commentary is supported by empirical findings that may orient future efforts towards collaborative conversation and hypotheses-generation, interdisciplinary research, translating across a number of health fields.

Our emphasis is that MRI technologies and research are crucial to the advancement of our understanding of the complexities of spinal conditions. J Orthop Sports Phys Ther, Epub 26 Mar 2019. doi:10.2519/jospt.2019.8793.

5. SPINAL SURGERY

Side effects of Lumbar surgery

Spine Open Access

Complications, reoperations, readmissions, and length of hospital stay in 34 639 surgical cases of lumbar disc herniation

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Published Online:31 Mar 2019https://doi.org/10.1302/0301-620X.101B4.BJJ-2018-1184.R1 **Aims**

The aims of this study were to determine the rates of surgical complications, reoperations, and readmissions following herniated lumbar disc surgery, and to investigate the impact of sociodemographic factors and comorbidity on the rate of such unfavourable events.

Patients and Methods

This was a longitudinal observation study. Data from herniated lumbar disc operations were retrieved from a large medical database using a combination of procedure and diagnosis codes from all public hospitals in Norway from 1999 to 2013. The impact of age, gender, geographical affiliation, education, civil status, income, and comorbidity on unfavourable events were analyzed by logistic regression.

Results

Of 34 639 operations, 2.7% (95% confidence interval (CI) 2.6 to 2.9) had a surgical complication, 2.1% (95% CI 2.0 to 2.3) had repeat surgery within 90 days, 2.4% (95% CI 2.2 to 2.5) had a non-surgical readmission within 90 days, and 6.7% (95% CI 6.4 to 6.9) experienced at least one of these unfavourable events. Unfavourable events were found to be associated with advanced age and comorbidity.

Conclusion

The results suggest that surgical complications are less frequent than previously suggested. There are limited associations between sociodemographic patient characteristics and unfavourable events.

Cite this article: *Bone Joint J* 2019:101-B:470–477.

7. PELVIC ORGANS/WOMAN'S HEALTH

Periodontitis and abortion

J Periodontol. 2019 Apr;90(4):381-390. doi: 10.1002/JPER.18-0174. Epub 2018 Nov 14.

Association between periodontitis and spontaneous abortion: A case-control study.

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BACKGROUND:

Spontaneous abortion, or miscarriage, is a complication of pregnancy which can severely affect women both physically and psychologically. We investigated the associations of periodontitis and periodontopathic bacteria with spontaneous abortion.

METHODS:

We conducted a matched case-control study in two tertiary hospitals in Khon Kaen, Thailand. Cases were 85 women with spontaneous abortion at <20 weeks of gestation matched to 85 controls on age, gestational age, and hospital. Full-mouth periodontal examinations were performed. Periodontitis was defined as at least one site with probing depth \geq 5 mm and clinical attachment level \geq 2 mm at the same site. Subgingival plaque samples were collected to determine the levels of Porphyromonas gingivalis, Tannerella forsythia, and Fusobacterium nucleatum using real time polymerase chain reaction.

RESULTS:

The cases were significantly more likely to have periodontitis (50.6%) than the controls (21.2%; P = 0.007). Conditional logistic regression revealed a crude odds ratio (OR) of 4.1 for the association between periodontitis and spontaneous abortion (95% confidence interval [CI] = 1.9-8.9, P = 0.001). The OR decreased, but was still significant, after controlling for previous miscarriage (OR = 3.3, 95% CI = 1.4-7.8, P = 0.006). There was no significant association between the levels of periodontopathic bacteria and spontaneous abortion. Increased levels of P. gingivalis and F. nucleatum were associated with periodontitis in both case and control groups. Association between increased T. forsythia levels and periodontitis was observed only in the case women.

CONCLUSIONS:

Periodontitis was more common in women with spontaneous abortions as compared with matched controls. Levels of periodontopathic bacteria was not associated with spontaneous abortion in this population.

CV risk after pregnancy

Placental Growth Factor as an Indicator of Maternal Cardiovascular Risk After Pregnancy Laura Benschop Eric A.P. Steegers James M. Roberts Robin E. Gandley

2019https://doi.org/10.1161/CIRCULATIONAHA.118.036632Circulation. 2019;139:1698–1709

Background: Angiogenic placental growth factor (PIGF) concentrations rise during pregnancy, peaking at the end of midpregnancy. Low PIGF concentrations during pregnancy are associated with pregnancy complications with recognized later-life cardiovascular risk. We hypothesized that low PIGF concentrations, especially in midpregnancy, identify not only a subset of women at risk for pregnancy complications but also women with greater cardiovascular risk factor burden after pregnancy regardless of pregnancy outcome.

Methods: In a population-based prospective cohort study of 5475 women, we computed gestational age—adjusted multiples of the medians of early pregnancy and midpregnancy PIGF concentrations. Information on pregnancy complications (preeclampsia, small for gestational age, and spontaneous preterm birth) was obtained from hospital registries. Six years after pregnancy, we measured maternal systolic and diastolic blood pressures, cardiac structure (aortic root diameter, left atrial diameter, left ventricular mass, and fractional shortening), carotid-femoral pulse wave velocity, and central retinal arteriolar and venular calibers. Blood pressure was also measured 9 years after pregnancy.

Results: Women were on average 29.8 (SD, 5.2) years of age in pregnancy, were mostly European (55.2%), and 14.8% developed a pregnancy complication. Quartile analysis showed that especially women with midpregnancy PIGF in the lowest quartile (the low-PIGF subset) had a larger aortic root diameter (0.40 mm [95% CI, 0.08–0.73]), left atrial diameter (0.34 mm [95% CI, -0.09 to 0.78]), left ventricular mass (4.6 g [95% CI, 1.1–8.1]), and systolic blood pressure (2.3 mm Hg [95% CI, 0.93–3.6]) 6 years after pregnancy than women with the highest PIGF. Linear regression analysis showed that higher midpregnancy PIGF concentrations were associated with a smaller aortic root diameter (-0.24 mm [95% CI, -0.39 to -0.10]), smaller left atrial diameter (-0.75 mm [95% CI, -0.95 to -0.56]), lower left ventricular mass (-3.9 g [95% CI, -5.5 to -2.3]), and lower systolic blood pressure (-1.1 mm Hg [95% CI, -1.7 to -0.46]). These differences persisted after the exclusion of women with complicated pregnancies.

Conclusions: Women with low PIGF in midpregnancy have a greater aortic root diameter, left atrial diameter, and left ventricular mass and higher systolic blood pressure 6 and 9 years after pregnancy compared to women with higher PIGF, including women with uncomplicated pregnancies. The pathophysiological implications of lower PIGF concentrations in midpregnancy might provide insight into the identification of pathways contributing to greater cardiovascular risk factor burden.

Vit D levels and fetal growth

Association of first trimester maternal vitamin D, ferritin and hemoglobin level with third trimester fetal biometry: result from cohort study on vitamin D status and its impact during pregnancy and childhood in Indonesia

Raden Tina Dewi Judistiani Tita Husnitawati Madjid, Rizky Abdulah Budi Setiabudiawan

BMC Pregnancy and Childbirth2019**19**:112 https://doi.org/10.1186/s12884-019-2263-1

Introduction

The role of vitamin D in placental functions and fetal growth had been addressed in many reports with conflicting results. However, such report is limited for Indonesian population. The aim of this study was to explore the association between maternal vitamin D level in the first trimester and fetal biometry in the later stage of pregnancy with adjusted OR for other determinants like hemoglobin and ferritin level.

Methods

From July 2016 a prospective cohort study of pregnant women had begun in four cities in West Java, Indonesia. Data on maternal vitamin D, ferritin, hemoglobin level, maternal demography and fetal biometry were analyzed with linear regression.

Results

Among 203 recruited women, 195 (96.06%) had hypovitaminosis D. One hundred fifty two (75%) were in deficient state and 43 women (21%) were in insufficient state. Women with insufficient vitamin D had the highest proportion of anemia, while women with normal vitamin D level had the highest proportion of low ferritin level. Maternal serum vitamin D showed significant associations with biparietal diameter ($\beta = 0.141$, p = 0.042) and abdominal circumference ($\beta = 0.819$, p = 0.001) after adjustment with maternal age, pre-pregnancy body mass index, parity, serum ferritin level, and hemoglobin level.

Conclusion

Our study suggested that sufficient maternal vitamin D level was an important factor to improve fetal growth and development.

IVF and mortality

BJOG. 2019 Mar 27. doi: 10.1111/1471-0528.15668.

Risk of severe maternal morbidity associated with in vitro fertilisation: a population-based study.

Le Ray C^{1,2}, Pelage L^{1,3}, Seco A^{1,4}, Bouvier-Colle MH¹, Chantry AA¹, Deneux-Tharaux C¹; Epimoms Study Group.

OBJECTIVE:

To investigate the association between in vitro fertilisation IVF and severe maternal morbidity (SMM) and to explore the role of multiple pregnancy as an intermediate factor.

DESIGN:

Population-based cohort-nested case-control study.

SETTING:

Six French regions in 2012/13.

POPULATION:

Cases were 2540 women with SMM according to the EPIMOMS definition; controls were 3651 randomly selected women who gave birth without SMM.

METHODS:

Analysis of the associations between IVF and SMM with multivariable logistic regression models, differentiating IVF with autologous oocytes (IVF-AO) from IVF with oocyte donation (IVF-OD). The contribution of multiple pregnancy as an intermediate factor was assessed by path analysis.

MAIN OUTCOME MEASURES:

Severe maternal morbidity overall and SMM according to its main underlying causal condition and by severity (near misses).

RESULTS:

The risk of SMM was significantly higher in women with IVF (adjusted OR = 2.5, 95% CI 1.8-3.3). The risk of SMM was significantly higher with IVF-AO, for all-cause SMM (aOR = 2.0, 95% CI 1.5-2.7), for near misses (aOR = 1.9, 95% CI 1.3-2.8), and for intra/postpartum haemorrhages (aOR = 2.3, 95% CI 1.6-3.2). The risk of SMM was significantly higher with IVF-OD, for all-cause SMM (aOR = 18.6, 95% CI 4.4-78.5), for near misses (aOR = 18.1, 95% CI 4.0-82.3), for SMM due to hypertensive disorders (aOR = 16.7, 95% CI 3.3-85.4) and due to intra/postpartum haemorrhages (aOR = 18.0, 95% CI 4.2-77.8). Path-analysis estimated that 21.6% (95% CI 10.1-33.0) of the risk associated with IVF-OD was mediated by multiple pregnancy, and 49.6% (95% CI 24.0-75.1) of the SMM risk associated with IVF-AO.

CONCLUSION:

The risk of SMM is higher in IVF pregnancies after adjustment for confounders. Exploratory results suggest higher risks among women with IVF-OD; however, confidence intervals were wide, so this finding needs to be confirmed. A large part of the association between IVF-AO and SMM appears to be mediated by multiple pregnancy.

TWEETABLE ABSTRACT:

The risk of severe maternal morbidity is higher in IVF-conceived pregnancies than in pregnancies conceived by other means.

8. VISCERA

Allergies relationship to CA

Allergies and the Subsequent Risk of Cancer among Elderly Adults in the United States

Monica D'Arcy, Donna R. Rivera, Andrew Grothen and Eric A. Engels **DOI:** 10.1158/1055-9965.EPI-18-0887

Background: Allergic conditions may prevent some cancers by promoting immune surveillance. We examined associations of allergic rhinitis, asthma, and eczema with cancer risk among elderly Americans.

Methods: We used Surveillance Epidemiology and End Results (SEER)-Medicare linked data to perform a case-control study. Cases were individuals with first cancer diagnosed in SEER registries (1992–2013, ages 66–99; N = 1,744,575). Cancer-free controls (N = 100,000) were randomly selected from Medicare and matched on sex, age, and selection year. Allergic conditions were identified using Medicare claims, and logistic regression was used to estimate adjusted ORs (aOR) with significance gauged with a Bonferroni P cutoff (P < 0.00034). Results: Allergic rhinitis, asthma, and eczema were present in 8.40%, 3.45%, and 0.78% of controls, respectively. For allergic rhinitis, strong inverse associations (aORs, 0.66–0.79) were observed for cancers of the hypopharynx, esophagus (squamous cell), cervix, tonsil/oropharynx, and vagina/vulva. More modest but significant inverse associations were noted for cancers of the esophagus (adenocarcinoma), stomach, colon, rectosigmoid/rectum, liver, gallbladder, lung, uterus, bladder, and miscellaneous sites. Associations were stronger in analyses requiring a dispensed medication to confirm the presence of allergic rhinitis. Asthma was associated with reduced risk of liver cancer [aOR 0.82; 95% confidence interval (CI), 0.75–0.91], whereas eczema was associated with elevated risk of T-cell lymphoma (aOR, 4.12; 95% CI, 3.43–4.95). Conclusions: Inverse associations with allergic rhinitis are present for multiple cancers and require etiologic investigation.

Impact: Understanding of mechanisms by which allergic conditions reduce cancer risk may advance cancer prevention and treatment.

13 D. SLEEP

Periodontist and sleep quality

J Periodontol. 2019 Mar 29. doi: 10.1002/JPER.19-0034.

The Association Between Stage-Grade Of Periodontitis And Sleep Quality And Oral Health-Related Quality Of Life.

Karaaslan F¹, Dikilitas A¹.

BACKGROUND:

Inadequate sleep increases inflammatory and proinflammatory markers among many other influences. Due to its potential to influence inflammation and oxidative stress which are the main pathogenetic mechanisms actually recognized in the periodontal damage, poor sleep quality could be a factor for periodontitis and quality of life. In this context, the aim of this study is to investigate the association of stage-grade of periodontitis with sleep quality. Investigating the effect of periodontitis on the quality of life is an additional aim.

METHODS:

The study consisted of clinical examination and a questionnaire. The questionnaire was based on demographic information, Oral Health Impact Profile-14 (OHIP-14) and Pittsburgh Sleep Quality Index (PSQI). Patients were diagnosed according to the 2017 World Workshop. Clinical examination included probing depth (PD) and clinical attachment loss (AL).

RESULTS:

The mean age of 99 participants was 30.27 ± 5.80 years ranging from 18 to 40 year-old. The mean clinical values of the patients in this study were AL 4.03 ± 2.46 mm and PD 4.27 ± 1.55 mm. The mean of the global OHIP-14 score was 13.43 ± 6.23 and the mean PSQI global score was 6.57 ± 3.53 .

CONCLUSIONS:

Stage-grade of periodontitis was associated with short sleep duration, low sleep quality and low oral health-related quality of life (OHRQoL). This article is protected by copyright. All rights reserved.

16. CONCUSSIONS

Concussion and balance testing

ORIGINAL RESEARCH

POST-CONCUSSIVE CHANGES IN BALANCE AND POSTURAL STABILITY MEASURED WITH CANESENSETM AND THE BALANCE ERROR SCORING SYSTEM (BESS) IN DIVISION I COLLEGIATE FOOTBALL PLAYERS: A CASE SERIES

Luis A. Feigenbaum, PT, DPT1,4 Kyoung J Kim, PhD1,3 Ignacio A. Gaunaurd, PT, PhD1,3 Lee D. Kaplan, MD4 Vincent A. Scavo, ATC, LAT4 Christopher Bennett, PhD2,3 Robert S. Gailey, PT, PhD1,3

ABSTRACT

Introduction: Impairments in postural stability have been identified following sports-related concussion. CaneSenseTM is a recently developed mobile lower limb motion capture system and mobile application for movement assessment which provides an objective measure of postural stability. One of the components within CaneSenseTM is the Post-Concussive Excursion Index (PCEI), a measure of postural stability expressed as a percentage of symmetry between lower limbs.

Purpose: The purpose of this case series is to examine pre- and post-concussion differences using two separate measures, Cane- SenseTM, and a known test, the Balance Error Scoring System (BESS), in Division I collegiate football players.

Methods: A convenience sample of eight football players diagnosed with a concussion, were the subjects in this case series. All subjects underwent baseline testing prior to the start of pre-season camp consisting of the single limb stance (SLS) test with Cane- SenseTM and the BESS test. Twenty-four to 72 hours following their concussion, SLS with CaneSenseTM test and the BESS test, were administered. Segmental excursions for the thigh and shank segments for each lower limb were combined into the Post-Concussion Excursion Profile (PCEP), which represents each segment's maximum excursion in the medial-lateral and anterior-posterior direction. The PCEI is a single metric generated to quantify differences within subjects by comparing the PCEP value between lower limbs during SLS where 100% suggests absolute symmetry.

Results: The PCEI value decreased significantly post-concussion ($41.43 \pm 15.53\%$ vs. $87.41 \pm 6.05\%$, p < 0.001) demonstrating a 52.6% decrease in inter-limb symmetry when compared to baseline values. There was an unanticipated 36.36% improvement in composite BESS performance post-concussion (10.5 ± 4.87 errors vs. 16.5 ± 8.49 errors, p = 0.10).

Conclusions: Differences in inter-limb postural stability were found in subjects post-concussion. By assessing postural stability in both lower limbs individually, using the PCEI, impairments were detected that otherwise would have likely gone undiagnosed using the BESS test alone.

The International Journal of Sports Physical Therapy | Volume 14, Number 2 | April 2019 | Page 296 DOI: 10.26603/ijspt20190296

Cervical spine changes post-concussion

ORIGINAL RESEARCH

CHARACTERIZATION OF CERVICAL SPINE IMPAIRMENTS IN CHILDREN AND ADOLESCENTS POST-CONCUSSION

Devashish Tiwari, PT, PhD1 Allon Goldberg, PT, PhD2 Amy Yorke, PT, PhD2 Gregor

F.archetti, PT, PhD3 Bara Alsalaheen, PT, PhD2

Background: Patients with concussion may present with cervical spine impairments, therefore accurate characterization of cervical post-concussion impairments is needed to develop targeted physical therapy interventions.

Purpose: To characterize the type, frequency and severity of cervical impairments in children and adolescents referred for physical therapy after concussion.

Study design: Retrospective, descriptive study

Methods: A retrospective analysis was conducted for 73 consecutive children and adolescents who received cervical physical therapy following a concussion. Data was classified into six broad categories. The frequency and intensity of cervical impairments within and across the categories was reported.

Results: Ninety percent of patients demonstrated impairments in at least three out of five assessment catego- ries whereas 55% demonstrated impairments in at least four out five assessment categories. Of the five assess- ment categories, posture (99%) and myofascial impairment (98%) demonstrated highest impairment frequency followed by joint mobility (86%) and muscle strength (62%). Cervical joint proprioception was the least com- monly evaluated assessment category.

Conclusion: High prevalence of cervical spine impairments was observed in the subjects included in this study with muscle tension, joint mobility, and muscle strength being most commonly affected. The categories of impairments examined in this cohort were consistent with the recommendations of the most recent clinical practice guidelines for neck pain. This study provides preliminary data to support the framework for a cervical spine evaluation tool in children and adolescents following concussion.

The International Journal of Sports Physical Therapy | Volume 14, Number 2 | April 2019 | Page 282 DOI: 10.26603/ijspt20190282

24. ELBOW

Lateral epiconditis and scapula weakness

Comparison of scapular position and upper extremity muscle strength in patients with and without lateral epicondylalgia: a case-control study

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DOI: https://doi.org/10.1016/j.jse.2018.12.010

Background

The symptoms of lateral epicondylalgia (LE) can be persistent, and recurrence is frequent. Recurrence can be related to proximal segment impairment of the kinetic chain. Knowledge of any relation in the kinetic chain in LE may help treatment. We aimed to investigate scapular position and upper extremity muscle strength in patients with LE and to compare them with controls.

Methods

The study enrolled 51 patients with LE and 51 age-matched controls. We assessed scapular position asymmetry using the lateral scapular slide test and measured the strength of the upper trapezius (UT), middle trapezius (MT), lower trapezius, and serratus anterior muscles in addition to shoulder abduction, external rotation, and internal rotation and grip strength.

Results

The percentage of participants with scapular asymmetry was greater in the patients than in the controls (P = .005). The involved side regarding shoulder external rotation among the patients was significantly weaker than in the controls (P = .016, P = .009). The involved side of the LE patients was significantly weaker than the uninvolved side in terms of shoulder abduction, external rotation, and internal rotation (P = .013, P = .048, P = .013). The UT/MT ratio on the nondominant side of the controls was significantly greater than that on the involved side of the LE patients (P = .016).

Conclusion

Upper extremity muscle strength, grip strength, UT/MT ratio, and scapular position are affected in patients with LE. In addition to the elbow, focusing on the upper segments is essential in the management of LE.

30 A. HIP IMPINGEMENT

Changes in muscles

Arthroscopy. 2019 Mar 26. pii: S0749-8063(18)31137-X. doi: 10.1016/j.arthro.2018.11.053

Patients With Unilateral Femoroacetabular Impingement Syndrome Have Asymmetrical Hip Muscle Cross-Sectional Area and Compensatory Muscle Changes Associated With Preoperative Pain Level.

Malloy P¹, Stone AV¹, Kunze KN¹, Neal WH¹, Beck EC¹, Nho SJ².

PURPOSE:

To compare the symptomatic hip muscle cross-sectional area (CSA) in patients with unilateral femoroacetabular impingement syndrome (FAIS) with the asymptomatic-side hip muscle CSA and to determine whether correlations exist between the hip muscle CSA and preoperative pain level, preoperative symptom duration, and postoperative function.

METHODS:

We performed a retrospective review of magnetic resonance imaging data of patients who underwent hip arthroscopy from January 2012 through June 2015 for the treatment of unilateral FAIS and who had a minimum of 2 years' follow-up after hip arthroscopy for FAIS. A picture archiving and communication system workstation with an embedded region-of-interest tool was used to measure the muscle CSA of both the symptomatic and asymptomatic sides in FAIS patients. One-way repeated-measures analyses of variance were used to determine differences between symptomatic and asymptomatic hip muscle CSAs. Spearman rank correlations were used to determine relations between the symptomatic-side hip muscle CSA and preoperative pain level, preoperative symptom duration, and multiple validated patient-reported outcomes to quantify the level of function.

RESULTS:

A total of 50 patients met the inclusion criteria and were analyzed. The mean age of the patients was 34.22 ± 14.12 years, and 64% were women. Specific muscles of the symptomatic hip displaying significantly decreased CSAs compared with the asymptomatic hip included the gluteus maximus (P = .007), gluteus minimus (P = .022), and rectus femoris (P = .028). The tensor fascia lata (ρ = 0.358; P = .011), pectineus (ρ = 0.369, P = .008), adductor longus (ρ = 0.286, P = .044), and obturator externus (ρ = 0.339, P = .016) showed a moderate positive correlation with preoperative pain level on a visual analog scale in unilateral FAIS patients. No associations were found between the symptomatic-side hip muscle CSA in patients with unilateral FAIS and symptom duration or patient-reported function.

CONCLUSIONS:

Patients with unilateral FAIS have a significantly decreased muscle CSA in the symptomatic hip compared with the asymptomatic hip. The symptomatic-side hip muscle CSA was correlated with the preoperative pain level on a visual analog scale. The association between the muscle CSA and preoperative pain level may represent a compensatory change in muscle function around the hip joint in patients with unilateral FAIS.

97% return to dance after surgery

Arthroscopy. 2019 Mar 8. pii: S0749-8063(18)31005-3. doi: 10.1016/j.arthro.2018.10.121.

Return to Dance and Predictors of Outcome After Hip Arthroscopy for Femoroacetabular Impingement Syndrome.

Ukwuani GC¹, Waterman BR², Nwachukwu BU³, Beck EC¹, Kunze KN¹, Harris JD⁴, Nho SJ⁵. *PURPOSE*:

To investigate the rate of return to dance and factors influencing this primary outcome after hip arthroscopy for the treatment of femoroacetabular impingement syndrome.

METHODS:

A consecutive series of self-identified dancers with femoroacetabular impingement syndrome was included. To assess for the impact of hypermobility on outcomes, patients were classified as having either generalized joint laxity (GJL) or no GJL based on the Beighton-Horan Joint Mobility Index. A return-to-dance survey, the modified Harris Hip Score, and the Hip Outcome Score (HOS)-Activities of Daily Living and HOS-Sports-Specific subscales were collected preoperatively and postoperatively at 6, 12, 24, and 36 months. The preoperative-to-postoperative outcome score change was compared using the minimal clinically important difference and patient acceptable symptomatic state. Return to dance was evaluated regarding (1) return to any dance activity, (2) return to prior level of dance, and (3) number of hours of dance participation after surgery. Clinical and demographic predictors and return to dance were analyzed using univariate or bivariate analysis where appropriate.

RESIJITS:

The study included 64 consecutive dancers (62 female and 2 male patients) (mean age, 22.3 ± 9.4 years; body mass index, 22.8 ± 4.1) with a mean follow-up period of 23.0 months. Postoperatively, 62 patients (97%) returned to dance at an average of 6.9 ± 2.9 months; 40 patients (62.5%) reported that they returned to a better level of participation, whereas 20 dancers (31%) returned to the same level of participation. Statistically significant increases were observed for the HOS-Activities of Daily Living subscale (60.5 ± 19.5 vs 92.4 ± 11.8 , P < .001), HOS-Sports-Specific subscale (40.3 ± 20.3 vs 83.5 ± 19.4 , P < .001), and modified Harris Hip Score (57.0 ± 13.6 vs 86.6 ± 13.9 , P < .001). There was, however, a significant decrease in the number of hours of dance postoperatively: 11.5 ± 8.2 h/wk preoperatively versus 9.0 ± 7.3 h/wk postoperatively (P = .041). All postoperative hip outcome measures showed statistically significant (P < .001) and clinically relevant improvements. Patient-reported outcomes and return time showed no significant differences between the patient groups with GJL and without GJL (P = .1 and P = .489, respectively). For competitive dancers, a correlation was shown with a shorter time to return to dance ($r^2 = 0.45$, P = .001), but there were no significant differences by skill level in patient-reported outcomes or dance hours.

CONCLUSIONS:

After hip arthroscopy, 97% of dancers returned to dance at an average of 6.9 months, with most dancers dancing at a level higher than their preoperative status. Dance experience level was the only significant factor influencing return-to-dance outcomes, with competitive dancers showing a faster return to dancing conclusion LEVEL OF EVIDENCE: Level IV, therapeutic case series.

Risk factors for impingement

Acetabular Retroversion Is a Risk Factor for Less Optimal Outcome After Femoroacetabular Impingement Surgery

Hamed Vahedi, MD Arash Aalirezaie, MD Patrick K. Schlitt avad Parvizi, MD, FRCS*

DOI: https://doi.org/10.1016/j.arth.2019.02.050

Background

Patients with acetabular retroversion are at risk of labral tear and hip pain. It is unknown whether femoroacetabular osteoplasty (FAO) without reverse periacetabular osteotomy can be used in these patients. This study evaluated the outcome of mini-open FAO in patients with acetabular retroversion and compared that to patients without acetabular retroversion.

Methods

Fifty-one patients (29 male, 22 female) with acetabular retroversion who had undergone FAO between 2007 and 2015 were identified. The minimum 2-year clinical and radiological outcome was compared with 550 patients without dysplasia or retroversion who underwent FAO by the same surgeon. The preoperative and postoperative alpha angle, center-edge angle, Tonnis grade, joint space, and presence of labral tear and chondral lesion were determined.

Results

The mean age in the retroversion cohort was 27.4 ± 9.5 years compared to 34.5 ± 11.2 years in the control. The mean follow-up was 4.8 ± 1.5 years for retroversion and 4.1 ± 1.2 years for the control. The mean preoperative Short-Form 36 Health Survey and modified Harris hip score were not different between the cohorts. At the latest follow-up, the mean modified Harris hip score and Short-Form 36 Health Survey were significantly lower in the retroversion group (75.4 and 76.5) compared to the control (83.4 and 85.6). There was a higher percentage of failure among retroversion patients (13.7%) compared to the control (2.5%).

Conclusion

Acetabular retroversion resulting in femoroacetabular impingent may be treated by FAO, but the outcome appears to be less optimal compared to patients with femoroacetabular impingent and no evidence of dysplasia and acetabular retroversion. Hip preservation surgeons should be aware of this anatomic variation and possible inferior treatment results after FAO in these patients.

31. KNEE

Alignment

How coronal alignment affects distal femoral anatomy: an MRI-based comparison of varus and valgus knees

Daniel A Cohen Ali C Gursel and Adrian K Low

Journal of Orthopaedic Surgery and Research201914:92 https://doi.org/10.1186/s13018-019-1133-x

Purpose

In contemporary total knee arthroplasty (TKA), most often, the goal is to align the femoral component to the epicondylar axis (EA). The posterior condylar axis (PCA) is easier to define than the EA, and thus the relationship of PCA to the EA is then used instead to align the femoral component to the EA. However, the relationship of PCA to EA is not constant and has been reported to differ between varus and valgus knees and with increasing deformity. The aim of this large MRI-based study was to evaluate the relationship between PCA and EA with varying coronal deformity especially with increasing valgus deformity.

Methods

EA, PCA, AP (Whiteside's line) and the mechanical axis were obtained from 474 magnetic resonance imaging (MRI) scans used to create patient-specific instrumentation (PSI) for the Biomet Signature (Warsaw, NJ) system.

Results

The relationship of EA relative to the PCA showed considerable heterogeneity in both varus and valgus groups. In the valgus group, there was statistically greater external rotation (P < 0.05) of the EA from the PCA with a mean of 2.52° (range -1.9° to 6°) compared to the varus group with a mean of 2.03° (range -3.9° to 6.9°). This relationship did not significantly change with increasing severity of coronal malalignment.

Externally rotating the femoral cutting guide by 3° from the PCA, 11% (42 of 382) of varus knees would lie outside of \pm 3° from EA. In valgus knees, externally rotating the femoral cutting block by 3° or 5° from the PCA, 6.5% (6 of 92) and 33.7% (31 of 92) of knees, respectively, would lie outside of \pm 3° from EA.

Conclusion

The relationship of PCA to EA is heterogeneous and is not altered significantly with increasing valgus coronal deformity. External rotation beyond 3° from PCA in valgus knees may lead to significant femoral component malrotation in a large proportion cases.

32 A. KNEE/ACL

Copers vs non-copers functional level

J Orthop Sports Phys Ther. 2008 Oct;38(10):586-95.

Individuals with an anterior cruciate ligament-deficient knee classified as noncopers may be candidates for nonsurgical rehabilitation.

Moksnes H¹, Snyder-Mackler L, Risberg MA.

STUDY DESIGN:

Prospective cohort study.

OBJECTIVES:

First, to classify a group of individuals with an anterior cruciate ligament (ACL)-deficient knee as potential copers or potential noncopers, based on an established screening examination. Second, to prospectively follow a cohort of individuals with an ACL injury and characterize the nonoperatively treated subjects as true copers and true noncopers 1 year after injury, and evaluate the outcomes in operatively treated individuals 1 year after ACL reconstruction. Finally, to calculate the predictive value of the screening examination based on a 1-year follow-up of the group of subjects with ACL tears treated nonoperatively.

BACKGROUND:

A screening examination has been developed for early classification of individuals with ACL injuries. Potential copers have successfully been identified as rehabilitation candidates and have shown that they are able to continue preinjury activities without ACL reconstruction (true copers). However, the potential of individuals identified as noncopers to become true copers has not been studied.

METHODS AND MEASURES:

One hundred and twenty-five subjects with ACL injury were evaluated using a screening examination consisting of 4 single-legged hop tests, the Knee Outcome Survey activities of daily living scale, the global rating of knee function, and the numbers of episodes of giving way. Knee laxity measurements, the international knee documentation committee subjective knee form (IKDC2000), and return to sport were included as outcome measurements.

RESULTS:

Thirty-seven percent (n = 46) of the subjects with ACL injury were classified as potential copers at the screening examination. Of the 102 subjects examined at follow-up, 51% (n = 52) had undergone nonoperative treatment. Sixty-five percent (n = 34) of the nonoperated subjects were classified as true copers at the 1 year follow-up. Among the potential copers, 60% were true copers, while 70% of the subjects initially classified as potential noncopers were true copers at the 1 year follow-up. The positive predictive value for correctly classifying true copers at the screening examination was 60% (95% confidence interval: 41%-78%), while the negative predictive value was 30% (95% confidence interval: 16%-49%).

CONCLUSION:

A majority (70%) of subjects classified as potential noncopers were true copers after 1 year of nonoperative treatment. Individuals with nonoperative treatment and ACL reconstruction showed excellent knee function and were highly active at the 1 year follow-up. The prognostic accuracy of this screening examination for correctly classifying true copers was poor.

33. MENISCUS

OA development greater after surgery

Early MRI-based Changes in Patients with Meniscal Tear and Osteoarthritis

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https://doi.org/10.1002/acr.23891

Objective

To evaluate changes in knee MRI findings over the course of 18 months in subjects with osteoarthritic change (OA) and meniscal tear (MT) treated with arthroscopic partial meniscectomy (APM) or non-operatively with physical therapy (PT).

Methods

We used 18-month follow up data from the **Me**niscal **Te**ar in **O**steoarthritis **Research** (MeTeOR) Trial. MRIs were read using the MRI OA Knee Score (MOAKS). We focused on 18-month change in bone marrow lesions (BMLs), cartilage thickness, cartilage surface area, osteophytes size, effusion-synovitis, and Hoffa-synovitis. We used multinomial logistic regression to assess associations between MRI-based changes in each feature and treatment type.

Results

351 subjects were randomized and 225 had both baseline and 18-month MRI. In both treatment groups, patients experienced substantial changes in several MRI-based markers. In 60% of the APM group, vs. 33% of the PT group, cartilage surface area damage advanced in ≥2 subregions (adjusted odds ratio (OR) 4.2 (95% CI 2.0, 9.0). Patients who underwent APM also had greater advancement in scores for osteophytes and effusion-synovitis. We did not find significant associations between treatment type and change in cartilage thickness, BMLs, or Hoffa-synovitis.

Conclusion

This cohort with meniscal tear and OA had marked advancement in MRI-based features over 18 months. Those treated with APM had more advancement in some features compared to those treated non-operatively. The clinical relevance of these early findings is unknown and requires further study.

37. OSTEOARTHRITIS/KNEE

Predicting knee OA

Arthritis Care Res (Hoboken). 2019 Apr;71(4):558-562. doi: 10.1002/acr.23685.

A Prediction Model for the 40-Year Risk of Knee Osteoarthritis in Adolescent Men.

Magnusson K¹, Turkiewicz A², Timpka S³, Englund M⁴.

OBJECTIVE:

To simplify the previously published Nottingham 12-year risk prediction model for knee osteoarthritis (OA) and examine whether it can be used to predict the 40-year risk of knee OA in young men.

METHODS:

Our cohort included 40,118 men who were 18 years of age and had undergone military conscription in Sweden from 1969 to 1970. Diagnostic OA codes were obtained from the Swedish National Patient Register for persons registered from 1987 to 2010. The original Nottingham model included as predictors age, sex, body mass index (BMI), knee injury, occupational risk, and family history of OA, with a receiver operating characteristic area under the curve (AUC) of 0.70 (95% confidence interval [95% CI] 0.61-0.79) in the model development sample, and AUC 0.60 (95% CI 0.58-0.63) in an external validation sample. In our sample, we used predictors that were available only in adolescence (age, BMI, and knee injury) and evaluated the discrimination of the simplified model using AUC.

RESULTS:

The AUC statistic of the modified knee OA model to predict 40-year risk was 0.60 (95% CI 0.59-0.61). Hence, using the reduced model, an 18-year-old man with a BMI of 30 and a knee injury would have 3 times the risk of developing knee OA within 40 years when compared to a man of similar age having a BMI of 25 and no knee injury (predicted risks 22% and 7%, respectively).

CONCLUSION:

The 40-year risk of knee OA on individual and population levels can be predicted in 18-year-olds from a few easily measured covariates with moderate discrimination. The discrimination of this simplified model based on data available in adolescents was comparable to that of the full Nottingham model in middle-aged individuals.

42. PLANTAR SURFACE

Plantar heel pain

J Orthop Sports Phys Ther. 2019 Mar 26:1-26. doi: 10.2519/jospt.2019.8813.

Topographical Pressure Pain Sensitivity Maps of the Feet Reveal Bilateral Pain Sensitivity in Patients With Unilateral Plantar Heel Pain.

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BACKGROUND:

Plantar heel pain is one of the most common foot pain conditions treated by healthcare providers.

OBJECTIVE:

To investigate differences in topographical pressure pain sensitivity maps of the feet between patients with unilateral plantar heel pain and healthy subjects and to determine the relationship between topographical pressure maps, pain intensity, disability and fascia thickness.

METHODS:

Thirty-five patients with unilateral plantar heel pain and 35 matched healthy controls participated. Pressure pain thresholds (PPT) were assessed over 7 plantar locations on each foot. Topographical pressure pain sensitivity maps of the plantar region were generated using the averaged PPT of each assessed point. Pain and related-disability were assessed with a numerical pain rate scale (0-10) and the Foot and Ankle Ability Measure (FAAM), respectively. Plantar fascia thickness was measured via ultrasound. All outcomes were obtained by an assessor blinded to the subjects' condition.

RESULTS:

Topographical pressure sensitivity maps revealed lower bilateral PPTs in patients with plantar heel pain as compared to healthy controls, and higher PPT on the calcaneus bone (P<0.01). Females showed lower PPTs than men in all areas (P<0.001). Individuals with plantar heel pain also exhibited an increase of fascia thickness, but only on the affected side, compared to healthy controls. Higher pressure pain sensitivity in the foot was associated with higher pain intensity at first step in the morning and a higher fascia thickness at the calcaneus bone.

CONCLUSIONS:

Topographical pressure sensitivity maps revealed that individuals with unilateral plantar heel pain exhibited generalized bilateral pressure pain sensitivity in the plantar region. Higher pain intensity and fascia thickness were associated with higher pressure pain sensitivity in individuals with plantar heel pain. Our findings can be used for improving ergonomic interventions, e.g., foot orthoses, in individuals with plantar heel pain.

LEVEL OF EVIDENCE: Case-control study, Level 4. J Orthop Sports Phys Ther, Epub 26 Mar 2019. doi:10.2519/jospt.2019.8801.

44. RHUMATOID ARTHRITIS

Physical activity reduces risk of RA

Long-term physical activity and subsequent risk for rheumatoid arthritis among women: A prospective cohort study

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https://doi.org/10.1002/art.40899

Objective

To evaluate long-term physical activity and subsequent risk for rheumatoid arthritis (RA).

Methods

We investigated physical activity and RA risk in the Nurses' Health Study II (1989-2015). Physical activity exposures and covariates were prospectively obtained using biennial questionnaires. Women who self-reported RA on biennial questionnaires and screened positive on a supplemental survey had medical records reviewed by two independent rheumatologists. All incident RA cases met 1987 ACR or 2010 ACR/EULAR classification criteria. The primary analysis investigated long-term cumulative average recreational physical activity 2-8 years prior to RA diagnosis to reduce potential for reverse causation bias since early RA affects physical activity prior to diagnosis. Cox regression estimated hazard ratios (HRs) and 95% confidence intervals (CIs) for RA serologic phenotypes (all, seropositive, seronegative) by physical activity categories. We adjusted for body mass index (BMI) at age 18 and time-varying potential confounders and quantified the mediating effect of updated BMI between physical activity and RA risk.

Results

Among 113,366 women, we identified 506 incident RA cases (67.0% seropositive) during 2,428,573 person-years of follow-up. Adjusted for confounders including smoking, dietary quality, and BMI at age 18, increasing cumulative average total hours of recreational physical activity was associated with reduced RA risk; HRs(95%CIs) were: 1.00(reference) for <1hr/wk, 1.00(0.78,1.29) for 1-<2hrs/wk, 0.92(0.72,1.17) for 2-<4hrs/wk, 0.84(0.63,1.12) for 4-<7hrs/wk, and 0.67(0.47,0.98) for \geq 7hrs/wk (p trend=0.02). The proportion of the effect between physical activity and RA mediated by updated BMI was 14.0% (p=0.002) for all RA and 20.0% (p=0.001) for seropositive RA.

Conclusion

Higher levels of physical activity were associated with reduced RA risk. These results add to the literature implicating metabolic factors in RA pathogenesis.

48 A. STM

Psoas Tendon

Evaluation of Endoscopic Iliopsoas Tenotomy for Treatment of Iliopsoas Impingement after Total Hip Arthroplasty

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https://doi.org/10.1016/j.arth.2019.03.030Get rights and content

Background

Iliopsoas impingement after total hip arthroplasty (THA) occurs in up to 4.3% of patients resulting in functional groin pain. Operative treatment historically has included open iliopsoas tenotomy or acetabulum revision. We present a large single surgeon series of patients treated with endoscopic iliopsoas tenotomy for iliopsoas impingement after THA to evaluate the effectiveness and risks.

Methods

A consecutive series of 60 patients with iliopsoas impingement after THA treated with endoscopic iliopsoas tenotomy was retrospectively evaluated. Outcomes assessed were resolution of pain, change in Hip Outcome Score (HOS), and complications. Radiographs were reviewed by a musculoskeletal radiologist to evaluate component positioning and compare to a control cohort.

Results

At last follow-up (mean, 5.5 months), 93.3% of patients had resolution of pain. The HOS activities of daily living (ADL) subscale mean was 57.5 (range, 10.9-89.3; SD 18.8) preoperatively and 71.6 (range, 14.1-100; SD 26.1) postoperatively (p=0.005). The HOS sports subscale mean was 37.3 (range, 0-83.3; SD 24.0) preoperatively and 58.1 (range, 0-100; SD 33.2) postoperatively (p=0.002). One complication was reported, a postoperative hematoma managed conservatively. Body mass index and increased offset were associated with iliopsoas symptoms after THA in this series.

Conclusion

Endoscopic iliopsoas tenotomy after THA had a 93.3% resolution of pain, clinically important improvements in HOS, and low rate of complications. Endoscopic tenotomy should be considered as a treatment option in patients with iliopsoas impingement after total hip arthroplasty.

59. PAIN

Genetic basis of neuropathic pain

Genetics and postsurgical neuropathic pain An ancillary study of a multicentre survey

Blanc, Pierre; Génin, Emmanuelle; Jesson, Béline; Dubray, Claude; Dualé, Christian the EDONIS-gene Investigating group

European Journal of Anaesthesiology (EJA): May 2019 - Volume 36 - Issue 5 - p 342–350 doi: 10.1097/EJA.00000000000086

Article Metrics

BACKGROUND Neuropathic pain following surgery could be a useful model for the study of the genetic mechanisms of peripheral neuropathic pain.

OBJECTIVE The aim of this study was to identify genetic predictors of persistent postsurgical neuropathic pain.

DESIGN An ancillary study from a prospective cohort.

SETTING Eighteen French university hospitals.

PATIENTS Five hundred and sixty-one patients at risk of persistent postoperative pain who underwent scheduled surgery were classified as 159 cases and 402 controls.

INTERVENTION Pre-operative blood sampling for DNA analysis and questionnaires sent at the third and sixth month after surgery.

MAIN OUTCOME MEASURES The phenotype was the report of pain at the site of surgery with a positive response in the DN4 questionnaire within 6 months after surgery. Out of a list of 126 candidate genes involved in the initial processes of peripheral neuropathic pain, a set of 4599 single nucleotide polymorphisms was tested on an Illumina chip. We carried out the association tests, based on an additive model, on 4422 single nucleotide polymorphisms.

RESULTS After correcting for type-I error inflation, only one suggestive association was reached for one single nucleotide polymorphism, the rs2286614, which we had selected to tag KCNK4. This gene encodes for TRAAK, a two-pore domain background K+ channel involved in the modulation of the primary thermoreceptors of the transient receptor potential channels family. CONCLUSION This is the first genetic association study specifically investigating the occurrence of persistent postsurgical neuropathic pain. Its results help target future research to better understand the mechanisms of peripheral neuropathic pain.

Biopsychosocial model

The impact of multisite pain on functional outcomes in older adults: biopsychosocial considerations

Authors Butera KA, Roff SR, Buford TW, Cruz-Almeida Y **Published** 29 March 2019 Volume 2019:12 Pages 1115—1125 **DOI** https://doi.org/10.2147/JPR.S192755

Abstract: Multisite pain, or pain that occurs simultaneously at >1 anatomical site, is more prevalent than single-site pain.

While multisite pain affects over half of older adults, it remains an understudied pain entity that may have important functional implications in an aging population. Greater understanding of this complex pain entity from a biopsychosocial perspective is critical for optimizing clinical and functional outcomes in older adults with pain. Therefore, the primary purpose of this review is to summarize the relationship between multisite pain and functional outcomes in older adults to further elucidate the impact of multisite pain as a distinct entity within this population.

A comprehensive literature search revealed 17 peer-reviewed articles. Multisite pain in older individuals is associated with reductions in several physical function domains: 1) lower-extremity mobility; 2) upper-extremity impairments; 3) balance and increased fall risk; and 4) general disability and poor physical function. Further, multisite pain in older individuals is associated with psychological dysfunction (eg, anxiety and depressive symptoms) and social factors (eg, income and education).

Overall, this review highlights the scant literature investigating the functional implications of multisite pain in an aging population. Further, while multisite pain appears to have functional consequences, the neurobiological mechanisms contributing to this relationship are unknown. Thus, how this pain characteristic may contribute to the variability in pain-related functional outcomes among older adults is not clear. Future investigations are strongly warranted to advance the understanding of multisite pain and its broad impact on physical and psychosocial function in older adults.

62 A. NUTRITION/VITAMINS

Obesity surgery and mortality

Effects of Obesity Surgery on Overall and Disease-specific Mortality in a 5-Country, Population-based Study

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DOI: https://doi.org/10.1053/j.gastro.2019.03.048

Background & Aims

Bariatric surgery might reduce overall mortality from obesity. We investigated whether survival times of patients who have undergone bariatric surgery are similar to those of the general population levels and are longer than in obese individuals who did not receive surgery.

Methods

We performed a population-based cohort study of persons with a diagnosis of obesity listed in nationwide registries from Nordic countries, from 1980 through 2012. Bariatric surgery was analyzed in relation to all-cause mortality and the obesity-related morbidities cardiovascular disease, diabetes, cancer, and suicide. Poisson models provided standardized mortality ratios (SMRs) with 95% CIs. Multivariable Cox regression provided hazard ratios (HRs) for mortality in operated and non-operated participants.

Results

Among 505,258 participants, 49,977 underwent bariatric surgery. Overall all-cause SMR was increased after surgery (1.94; 95% CI, 1.83–2.05) and increased with longer follow up, to 2.28 (95% CI, 2.07–2.51) \geq 15 years post-surgery. SMRs were increased for cardiovascular disease (2.39; 95% CI, 2.17–2.63), diabetes (3.67; 95% CI, 2.85–4.72), and suicide (2.39; 95% CI, 1.96–2.92), but not for cancer (1.05; 95% CI, 0.95–1.17); SMRs increased with time. In non-operated obese participants, all-cause SMR was 2.15 (95% CI, 2.11–2.20), which remained stable during follow up. Compared to non-operated obese participants, patients who underwent bariatric surgery had decreased overall mortality from all causes (HR, 0.63; 95% CI, 0.60–0.66), cardiovascular disease (HR, 0.57; 95% CI, 0.52–0.63), and diabetes (HR, 0.38; 95% CI, 0.29–0.49), but increased mortality from suicide (HR, 1.68; 95% CI, 1.32–2.14). Cancer mortality was decreased overall (HR, 0.84; 95% CI, 0.76–0.93), but increased \geq 15 years of follow up (HR, 1.20; 95% CI, 1.02–1.42).

Conclusions

In a study of persons with a diagnosis of obesity listed in nationwide registries of Nordic countries, we found that obese patients who undergo bariatric surgery have longer survival times than non-operated obese individuals, but their mortality is higher than that of the general population and increases with time. Obesity-related morbidities could account for these findings.

63. PHARMACOLOGY

Generics a good as originals

PLoS Med. 2019 Mar 13;16(3):e1002763. doi: 10.1371/journal.pmed.1002763. eCollection 2019 Mar.

Comparative effectiveness of generic and brand-name medication use: A database study of US health insurance claims.

Desai RJ¹, Sarpatwari A¹, Dejene S¹, Khan NF¹, Lii J¹, Rogers JR¹, Dutcher SK², Raofi S³, Bohn J⁴, Connolly JG⁴, Fischer MA¹, Kesselheim AS¹, Gagne JJ¹.

BACKGROUND: To the extent that outcomes are mediated through negative perceptions of generics (the nocebo effect), observational studies comparing brand-name and generic drugs are susceptible to bias favoring the brand-name drugs. We used authorized generic (AG) products, which are identical in composition and appearance to brand-name products but are marketed as generics, as a control group to address this bias in an evaluation aiming to compare the effectiveness of generic versus brand medications.

METHODS AND FINDINGS: For commercial health insurance enrollees from the US, administrative claims data were derived from 2 databases: (1) Optum Clinformatics Data Mart (years: 2004-2013) and (2) Truven MarketScan (years: 2003-2015). For a total of 8 drug products, the following groups were compared using a cohort study design: (1) patients switching from brand-name products to AGs versus generics, and patients initiating treatment with AGs versus generics, where AG use proxied brand-name use, addressing negative perception bias, and (2) patients initiating generic versus brand-name products (bias-prone direct comparison) and patients initiating AG versus brand-name products (negative control). Using Cox proportional hazards regression after 1:1 propensity-score matching, we compared a composite cardiovascular endpoint (for amlodipine, amlodipine-benazepril, and quinapril), non-vertebral fracture (for alendronate and calcitonin), psychiatric hospitalization rate (for sertraline and escitalopram), and insulin initiation (for glipizide) between the groups. Inverse variance meta-analytic methods were used to pool adjusted hazard ratios (HRs) for each comparison between the 2 databases. Across 8 products, 2,264,774 matched pairs of patients were included in the comparisons of AGs versus generics. A majority (12 out of 16) of the clinical endpoint estimates showed similar outcomes between AGs and generics. Among the other 4 estimates that did have significantly different outcomes, 3 suggested improved outcomes with generics and 1 favored AGs (patients switching from amlodipine brand-name: HR [95% CI] 0.92 [0.88-0.97]). The comparison between generic and brand-name initiators involved 1,313,161 matched pairs, and no differences in outcomes were noted for alendronate, calcitonin, glipizide, or quinapril. We observed a lower risk of the composite cardiovascular endpoint with generics versus brand-name products for amlodipine and amlodipine-benazepril (HR [95% CI]: 0.91 [0.84-0.99] and 0.84 [0.76-0.94], respectively). For escitalopram and sertraline, we observed higher rates of psychiatric hospitalizations with generics (HR [95% CI]: 1.05 [1.01-1.10] and 1.07 [1.01-1.14], respectively). The negative control comparisons also indicated potentially higher rates of similar magnitude with AG compared to brand-name initiation for escitalopram and sertraline (HR [95% CI]: 1.06 [0.98-1.13] and 1.11 [1.05-1.18], respectively), suggesting that the differences observed between brand and generic users in these outcomes are likely explained by either residual confounding or generic perception bias. Limitations of this study include potential residual confounding due to the unavailability of certain clinical parameters in administrative claims data and the inability to evaluate surrogate outcomes, such as immediate changes in blood pressure, upon switching from brand products to generics.

CONCLUSIONS: In this study, we observed that use of generics was associated with comparable clinical outcomes to use of brand-name products. These results could help in promoting educational interventions aimed at increasing patient and provider confidence in the ability of generic medicines to manage chronic diseases.