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COMBINED EMAIL AND IN OFFICE TECHNOLOGY IMPROVES PATIENT REPORTED OUTCOMES COLLECTION IN STANDARD ORTHOPAEDIC CARE

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Purpose: Patient reported outcomes (PRO) provide an important measure of clinical condition from the patient's perspective. Recently, there has been increasing interest in the use of PRO scores during routine clinical practice, as the focus on quality and value-based healthcare continues to grow. However, the routine collection of PRO data without disrupting clinical workflow remains a challenge. This study evaluates the capture rates of PRO data as part of standard orthopaedic care, collected electronically via either e-mail or in the office setting.
Methods: An electronic PRO collection system was developed at a large, tertiary, academic medical center in 2012, designed to routinely collect PRO data as part of standard care. An e-mail distribution function was built to send a secure HIPPA compliant e-mail to patients three days before their visit. A PRO questionnaire link is embedded in the e-mail allowing completion at home prior to the visit. Patients who do not complete via e-mail receive a touchscreen in the office to complete the PRO questionnaire prior to their clinical exam. PRO scores are calculated in real-time, integrated into the patient's EMR, and made available to the evaluating physician for clinical decision-making.
Results: Between May, 1st, 2012 and April 30, 2013, PRO questionnaires were completed for 19218 of 26548 total patient visits to 21 adult reconstruction or sports medicine practices. Overall, completion rates were 79% and 68%. Office staff collected email addresses for 48% of total patient visits, and consequently, 64% (12306 of 19218) of the completed PRO questionnaires were done in the office versus 36% (6912 of 19218) via email. The completion rate via email was 41% in adult reconstruction and 32% in sports medicine. When the email completion rate is calculated based on patients for whom office staff obtained email addresses, completion rates via email at home are 55% in adult reconstruction and 53% in sports medicine. Elderly patients ($\geq$65 years) had a higher e-mail completion rate (57%) than younger ($<$40 years) patients (52%), $p < 0.001$.
Conclusion: Electronic collection of PRO scores as part of standard orthopaedic care is feasible, especially when both email and office-based collection methods are used. Older patients were more compliant with email than younger patients. Email is a useful tool for PRO collection in the orthopaedic outpatient setting, and office staff should work to obtain email addresses even from older patients, who are more compliant with home email completion of surveys than younger patients. Patients should be encouraged to complete PRO questionnaires via email to minimize disruption to office clinical workflow.

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CORRELATION BETWEEN ROUTINE ASSESSMENT OF PATIENT INDEX DATA 3 (RAPID3) AND WOMAC IN ROUTINE CARE IN PATIENTS WITH KNEE OSTEOARTHRITIS

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Objective: To compare Routine Assessment of Patient Index Data 3 (RAPID3) on a Multidimensional Health Assessment Questionnaire (MDHAQ) with the Western Ontario and Mc-Master Universities Osteoarthritis Index (WOMAC) in patients with knee osteoarthritis and to evaluate its reliability.
Methods: Consecutive patients with symptomatic knee osteoarthritis (VAS $>$50 mm) based on ACR Classification criteria were enrolled. A radiological Kellgren-Lawrence index 1–2 was required. Correlation between indices was estimated with Spearman's Rho. A General Linear Model (GLM) was used to estimate the effect size between indices. Reliability analysis was assessed finally using coefficients of IntraClass Correlation.
Results: 221 patients were enrolled and completed WOMAC and MDHAQ-RAPID3 questionnaires during the period 2009–2013. RAPID 3 mean value was 5.7 $\pm$ 1.3 in patients with knee OA. Kurtosis -0.287 ± 0.211, skewness -0.61 ± 0.12. The ceiling/floor effect, % of responses that are coded at the maximum/minimum value, ranged $<$10%. WOMAC total score was 57.2 $\pm$ 13.4. Spearman's rho index was 0.84. Using a General Linear Model (GLM) to estimate the proportion of variation of WOMAC explained by RAPID 3 we found an effect size of 0.82 ($p < 0.01$). Coefficients of IntraClass Correlation between mean values of WOMAC and RAPID3 was 0.812, F test with $P = 0.001$.
Conclusion: RAPID3 scores provide similar quantitative information to WOMAC in patients with knee osteoarthritis.

Clinical Trials

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COST-UTILITY OF EXERCISE THERAPY ADDED TO GENERAL PRACTITIONERS' CARE VERSUS GENERAL PRACTITIONERS' CARE ALONE IN PATIENTS WITH HIP OSTEOARTHRITIS

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Purpose: To determine the cost-effectiveness over a period of 12 months of exercise therapy added to general practitioners' care compared to general practitioners' care alone in patients with a new episode of hip OA in general practice.
Methods: A cost-utility study was performed in conjunction with a multi-center randomized controlled trial with a parallel group design. Patients participated if they were 45 years or older, comply with the clinical American College of Rheumatology criteria for hip OA, and visited their general practitioner (GP) for a new episode of complaints due to hip osteoarthritis. Patients were excluded if they: 1) were already treated with exercise therapy in the present episode of hip OA, 2) had a hip pain score of $<$2 on the 11-point numeric rating scale (0 to 10), 3) had a high level of physical function, a score of $<$2 on the walking ability and the physical function sections of the Algofunctional index, 4) had undergone hip surgery or on the waiting list, 5) had severe disabling co-morbidity and 6) had insufficient comprehension of the Dutch language and/or were mentally incapable of participation.
The patients were allocated at random in two treatment groups: one group received exercise therapy supervised by a physiotherapist (up to 15 sessions in the first 3 months and 3 follow-up sessions in month 5, 7 and 9) added to GP care and the control group received GP care only. The cost-utility study was primarily conducted from a societal perspective, but the healthcare perspective was also applied. Data on direct medical costs, productivity costs and quality of life was collected at baseline and at 6, 13, 26, 39 and 52 weeks follow-up. Annual costs were determined by adding up the costs per period. The costs for the time between the measurement periods (week 6–7) were established through linear interpolation. All costs were based on Euro 2011 cost data. The quality of life score per patient during the 52 weeks follow up was estimated by combining the EQ-5D scores at all measurement moments. Differences between the intervention and control group were assessed by means of the independent sample T test (for variables showing a normal distribution), the Mann Whitney U test (for variables not normally distributed) or Pearson Chi-square test (for variable fractions). Using nonparametric bootstrapping (drawing 2,500 observations at random), the degree of uncertainty for costs and health effects and the cost-utility ratio was examined on the so-called CE-plane. In addition, an acceptability curve was generated to indicate the probability that the intervention has lower incremental costs per quality adjusted life year (QALY) gained than various thresholds for the maximum willingness to pay for an extra QALY.
Results: The study took place in the period 2009–2012 and finally 203 patients were included. The annual direct medical costs per patient were significantly lower for the exercise group (€ 1,233) compared to the control group (€ 1,331) despite additional physiotherapy visits. The average annual societal costs per patient were lower in the exercise group (€ 2,634 versus € 3,241; P = 0,002). Productivity costs were higher than direct medical costs. Patients in the exercise group experienced a slightly, but not significantly, higher quality of life (0.776 versus 0.770). We found a societal average cost effectiveness (CE)-ratio of – € 107,505 per quality adjusted life year (exercise cost effective). When only direct medical

costs were included, the average cost per quality adjusted life year amounted to € −17,441, but the uncertainty around both CE-ratios was substantial.
Conclusions: Over a period of 52 weeks, with a CE-ratio of – € 107,505 per QALY from the societal perspective and a CE-ratio of € −17,441 per QALY from the healthcare perspective, our study revealed a considerable probability that exercise therapy added to GP care is cost saving or cost effective as compared to GP care alone.

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RESULTS FROM A SINGLE CENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY OF THE EFFICACY AND SAFETY OF INTRA-ARTICULAR ONABOTULINUMTOXINA FOR OSTEOARTHRITIS KNEE PAIN

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Purpose: The peripheral release of inflammatory mediators may sensitize nociceptors, provoke central sensitization, and facilitate clinical pain. Inhibition of the peripheral manifestations in knee osteoarthritis (OA) by onabotulinumtoxinA (onabotA) may reduce the drive, central consequences, and eventually clinical pain. Study objectives were to determine the safety and efficacy of a single intra-articular (IA) onabotA injection in patients (pts) with painful knee OA.
Methods: Pts 40–75 y with knee OA (American College of Rheumatology modified clinical classification criteria; Kellgren-Lawrence grade I-III) were enrolled in this 16-wk, single-center, double-blind, randomized, placebo-controlled, parallel-group phase 1b study. Pts were stratified by baseline 14-day average daily worst pain score (ADWP; 4.0–9.0 [0–10 numeric rating scale]), and randomized (1:1) to ultrasound-guided injection of either onabotA (200 U) or placebo (saline). Pts recorded worst daily pain for 2 wks before and 12 wks after injection (study visits: 1, 4, 8, 12 wks).
The planned primary efficacy assessment was 14-day ADWP score change from baseline, jointly analyzed for wks 4, 8, and 12 by repeated measures analysis of covariance (RMANCOVA); secondary planned efficacy outcomes included Western Ontario McMaster (WOMAC) OA Index (total, pain, and physical function scores) and pt global impression of change (GIC). Other planned outcomes included the Pain*DETECT* questionnaire (PD-Q), assessed at baseline and each visit. 3 pain subtypes have been defined by total PD-Q score: nociceptive (PD-Q score ≤12), neuropathic (≥19), and uncertain (≥13 and ≤18). Unplanned post-hoc analyses of primary and secondary outcomes by baseline PD-Q pain subtype were performed. Safety data were collected, including muscle strength around the knee (knee extension/flexion, ankle dorsiflexion/plantarflexion) for the study side and the contralateral side.
The primary efficacy assessment (intent-to-treat population) was analyzed using RMANCOVA for between-group comparisons, adjusted for baseline ADWP score. Secondary efficacy variables were analyzed with a Wilcoxon rank-sum test; WOMAC analyses did not use a baseline covariate. The safety population included all pts who received drug. All randomized pts received the assigned drug.
Results: Of 170 screened pts, 121 were randomized to onabotA (n = 61) or placebo (n = 60). Mean age was 62.3 y, all Caucasian, and comparable male (n = 59) and female (n = 62) participation. No clinically relevant between-group differences were observed at baseline.
The primary efficacy analysis yielded no significant difference between onabotA and placebo for the change from baseline in ADWP score to the 3 prospectively defined time points ($P = 0.70$). Between-group differences were also not significant for ADWP score change from baseline to each individual time point (each of wks 2–12), WOMAC (total index, pain, or physical function scores at wks 1, 4, 8, 12), or GIC (wks 1, 4, 8, 12). Post-hoc analyses by PD-Q pain subtype found numerically greater improvement for all efficacy outcomes among pts with nociceptive pain (PD-Q≤12) who received onabotA (n = 36) versus placebo (n = 32) across all time points (Figure); significant differences were seen at wk 8 and/or 12 for all WOMAC outcomes and GIC.
Adverse events (AEs) were reported for 24 pts (39.3%) receiving onabotA and 27 pts (45.0%) receiving placebo. Treatment-related AEs were reported for both onabotA (arthralgia, n = 1 [1.6%]; burning sensation, n = 1 [1.6%]) and placebo (n = 1 [1.7%] each: arthralgia, arthropathy, hypoaesthesia, joint stiffness, joint warmth, muscular weakness); all were mild. Muscle strength evaluations found no decrease from baseline in any knee or ankle extension/flexion measure in either group at any visit.
Conclusion: This exploratory study found no significant between-group differences in primary or secondary efficacy endpoints; improvement from baseline was observed for both treatment groups. Post-hoc analyses found numerically greater improvement for all efficacy endpoints among the PD-Q nociceptive pain subtype that received onabotA versus placebo, suggesting the PD-Q may be useful in identifying onabotA-responsive pts with knee OA pain. Locally administered onabotA (200 U IA) had an acceptable safety profile and did not decrease muscle strength around the knee. Further evaluation of onabotA efficacy among pts with nociceptive knee OA pain is needed to confirm these post-hoc findings.
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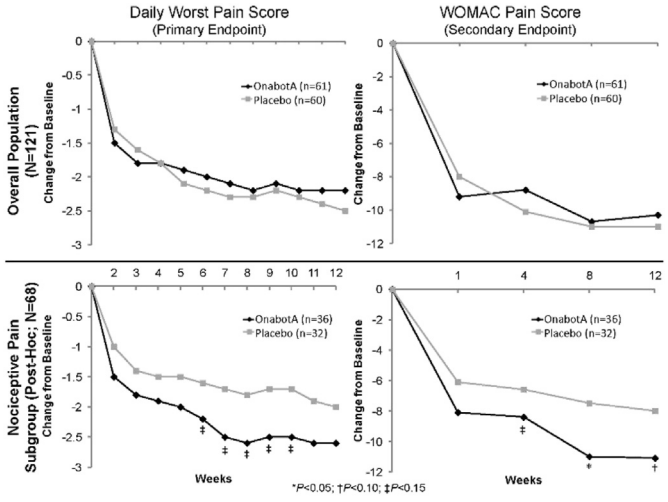

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PHYSIOTHERAPIST-DELIVERED EXERCISE AND PAIN COPING SKILLS TRAINING IS MORE EFFECTIVE THAN EITHER INTERVENTION ALONE IN KNEE OSTEOARTHRITIS

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Purpose: Pain is often the primary symptom of knee osteoarthritis (OA) and results from a complex interaction between structural changes, physical impairments and psychological factors. Much evidence supports the benefits of strengthening exercise in this patient population. There is also limited research supporting psychologist-delivered pain coping skills training (PCST), a form of cognitive behavioural therapy, in knee OA. Though typically provided separately, there are potential symptom-, resource- and personnel-advantages of exercise and PCST being delivered together by a single healthcare professional. Physiotherapists are a logical choice to be trained to deliver a PCST intervention as they already have expertise in administering exercise and are cognisant of the need for a biopsychosocial approach to management. This study aimed to investigate whether an integrated 12-week exercise and PCST treatment program delivered by physiotherapists is more efficacious than either program alone in treating pain and physical function in individuals with knee OA.
Methods: The study utilized a 3-arm randomized controlled trial design with measurements taken by a blinded assessor at baseline, 12, 32 and 52 weeks following randomization. Twelve weeks was the primary time